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LABORATORIO DEI DIRITTI FONDAMENTALI

Allocation of resources and constitutional protection of the right to health

European Health Systems and the Italian Case

by
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List of Acronyms

ABF	Activity-Based Financing
Age.Na.S.	*Agenzia nazionale per i servizi sanitari regionali* (National Agency for Regional Health Services – Italy)
AGS	Annual Growth Survey
AIFA	*Agenzia italiana del farmaco* (Italian Medicines Agency)
AME	*Aide Médicale d'État* (France)
AO	Hospital or Hospital Trust (Italy)
AOU	University Hospital or Hospital Trust (Italy)
ARS	*Agences régionales de santé* (France)
ARS Toscana	*Agenzia regionale di sanità per la Toscana* (Regional health authority for Tuscany – Italy)
ASL	*Azienda sanitaria locale* (Local health authority – Italy)
AWSMG	All Wales Strategy Medicines Group (Wales)
CAM	Combined Approach Matrix
CBA	Cost-Benefit Analysis
CCG	Clinical Commissioning Group (England)
CEA	Cost-Effectiveness Analysis
CEPS	*Commission Économique des Produits de Santé* (France)
CFPP	*Commission Fédérale des Prestations et des Principes de l'Assurance-Maladie* (Switzerland)
CJEU	Court of Justice of the European Union
CHF	Swiss franc
CIMHS	Intercantonal Convention on highly specialised medicine (Switzerland)
CIPE	Interministerial Committee for Economic Planning
CMU	*Couverture maladie universelle* (France)
CNB	*Comitato nazionale per la bioetica* (National Bioethics Committee – Italy)
COG	*Convention d'objéctifs et de gestion* (France)
CORIPE	Consortium for Research and Continuing Education in Economics
COVID-19	Coronavirus disease
CRSA	*Conférence Régionale de Solidarité et d'Autonomie* (France)
CSI Piemonte	*Consorzio per il sistema informativo* (Regional Consortium for Information Systems – Piedmont, Italy)

CSP	*Code de la santé publique* (France)
CSS	*Consiglio superiore di sanità* (National Health Council - Italy) *Code de sécurité sociale* (France)
CUA	Cost-Utility Analysis
CUD	*Commissione unica dispositivi medici* (Single Medical Devices Committee – Italy)
DALY	Disability-Adjusted Life Year
DEA	*Dipartimenti di emergenza-urgenza accettazione* (Emergency Departments – Italy)
DEF	*Documento di economia e finanza* (Economic and financial planning document – Italy)
DGFDM	*Direzione generale dei dispositivi medici e del servizio farmaceutico del Ministero* (General Directorate for Medical Devices and Pharmaceutical Service of the Ministry of Health – Italy)
DGR	*Delibera di Giunta Regionale* (Regional Council Decision – Italy)
DHB	District Health Boards (New Zealand)
DRG	Diagnosis Related Group
EBM	Evidence Based Medicine
ECB	European Central Bank
ECHR	European Convention for the Protection of Human Rights and Fundamental Freedoms
ECtHR	European Court of Human Rights
EMA	European Medicines Agency
ERDF	European Regional Development Fund
ESM	European Stability Mechanism
ESTAR	*Enti di sostegno tecnico amministrativo regionale Toscana* (Regional technical administrative support agencies – Tuscany, Italy)
ESTAV	*Ente per i servizi tecnico-amministrativi di Area Vasta Toscana* (Body for technical-administrative services of wide areas – Tuscany, Italy)
EU	European Union
EUnetHTA	European network for HTA
FSN	*Fondo sanitario nazionale* (National Health Fund – Italy)
GB-A	*Gemeinsamer Bundesausschuss* (Single Federal Committee, Germany)
GDP	Gross domestic product
GG	*Grundgesetz* (Basic Law, Germany)
GKV	*Gesetzliche Krankenversicherung* (Public Insurance

	System, Germany)
GP	General Practitioners
HAS	*Haute Autorité de Santé* (France)
HB	Health Board (Scotland)
HEN	Health Evidence Network
HIS	Health Improvement Scotland (Scotland)
HTA	Health Technology Assessment
HTAi	Health Technology Assessment International
HYE	Healthy-Years Equivalent
ICER	Incremental Cost-Effectiveness Ratio
INAHTA	International Network of Agencies for Health Technology Assessment
IQWIG	*Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen* (Institute for Quality and Efficiency in Health Care, Germany)
IRCCS	*Istituti di ricovero e cura a carattere scientifico* (Scientific Research and Care Institutes – Italy)
IRES Piemonte	*Istituto di ricerche economico-sociali del Piemonte* (Regional Institute of Economic and Social Research – Piedmont, Italy)
IRPEF	*Imposta sul reddito delle persone fisiche* (Personal Income Tax, Italy)
ISS	*Istituto superiore di sanità* (National Health Institute, Italy)
ISTAT	*Istituto nazionale di statistica* (National Statistical Institute, Italy)
LAMal	*Loi fédérale sur l'assurance-maladie* (Switzerland)
LEA	*Livelli essenziali di assistenza* (Essential levels of care, Italy)
LEP	*Livelli essenziali delle prestazioni* (Essential service levels, Italy)
LHB	Local Health Board (Wales)
MCDA	Multi-Criteria Decision Analysis
MMG	*Medico di Medicina Generale* (General Practitioner, Italy)
NHS	National Health Service (England)
NIC	National Insurance Contribution (England)
NICE	National Institute for Health and Care Excellence (England)
NICU	Neonatal Intensive Care Unit
NIS	National Insurance Scheme (Norway)
NSIS	*Nuovo sistema informativo sanitario* (New Health Information System, Italy)

OAMal	*Ordonnance sur l'assurance-maladie* (Switzerland)
OECD	Organisation for Economic Co-operation and Development
OFSP	*Office Fédéral de Santé Publique* (Switzerland)
OHSC	Oregon Health Services Commission
OLNF	Ordinance limiting the number of service providers authorised to practise at the expense of compulsory health care insurance (Switzerland)
OMT	Outright Monetary Transactions Programme
OP	Operational Programmes
OPAS	*Ordonnance sur les prestations dans l'assurance obligatoire des soins en cas de maladie* (Switzerland)
PBMA	Programme Budgeting Marginal Analysis
PAL	*Piani attuativi locali* (Local Implementation Plans, Italy)
PAT	*Programma delle attività territoriali* (Programme of Territorial Activities, Italy)
PCT	Primary Care Trust (England)
PDR	*Piani di rientro dal disavanzo sanitario* (Health Deficit Recovery Plans, Italy)
PGE	*Presupuestos Generales del Estado* (Spain)
PKV	*Private Krankenversicherung* (private insurance sector, Germany)
PS	*Pronto soccorso* (Emergency room, Italy)
PSN	*Piano sanitario nazionale* (National Health Plan, Italy)
PSR	*Piano sanitario regionale* (Regional Health Plan, Italy)
PUMA	*Protection universelle maladie* (France)
PWH	Public Health Wales Trust (Wales)
QALY	Quality-Adjusted-Life-Year
OH	Ordinary Hospitalisations
SALAR	*Sveriges Kommuneroch Landsting* (Association of Municipalities and Counties, Sweden)
SARS-COV-2	Severe Acute Respiratory Syndrome - Coronavirus – 2
SBU	*Statens Beredning för Medicinskoch Social Utvärdering* (Agency for the Evaluation of Medical Technology and Social Services, Sweden)
SDS	*Società della salute - Toscana* (Health Society, Tuscany - Italy)
SEPI	*Servizio di epidemiologia del Piemonte* (Regional epidemiology service, Piedmont – Italy)
SERMIG	*Servizio missionario giovani* (Youth Missionary Service, Italy)
SET	*Servizio di emergenza territoriale* (Territorial

	emergency service, Italy)
SGB	*Sozialgesetzbuch* (Federal Code of Social Legislation, Germany)
SGP	Stability and Growth Pact
SHTG	Scottish Health Technologies Group (Scotland)
SIAARTI	*Società italiana di anestesia, analgesia, rianimazione e terapia intensiva* (Italian Society of Anaesthesia, Analgesia, Resuscitation and Intensive Care)
SMC	Scottish Medicines Consortium (Scotland)
SMEs	Small and medium-sized enterprises
SPA	*Specialistica ambulatoriale* (Outpatient specialist, Italy)
SSN	*Servizio Sanitario Nazionale* (National Health Service, Italy)
SSR	*Servizio sanitario regionale* (Regional Health Service, Italy)
STEM	*Struttura tecnica di monitoraggio* (Technical monitoring structure, Italy)
SWISSMEDIC	*Institut Fédéral des Produits Thérapeutiques* (Switzerland)
TFEU	Treaty on the Functioning of the European Union
VHI	Voluntary Health Insurance (Denmark)
WHO	World Health Organization
WHO-CHOICE	CHOosing Interventions that are Cost-Effective
ZEKO	*Zentrale Ethikkommission bei der Bundesärztekammer* (Central Ethics Committee at the German Medical Association, Germany)

Preface

The study *Resource allocation and constitutional protection of the right to health*. *European health systems and the Italian case*, conducted by the authors of the report presented here, was conceived to investigate the ways and places in which the allocation of public resources for health care is defined in various national systems in Europe. The main focus was on Italy and specific attention was paid to two regions, Tuscany and Piedmont, for which the authors were able to obtain data on the trend of health services for the period 2011-2016. This phase was characterised by a decrease of available funds, particularly for Piedmont as a result of the Region's efforts to balance the regional budget. Italy has seen a gradual decrease in the public economic resources allocated to healthcare for many years. The recent 2020 Report of the Italian Court of Auditors on the coordination of public finances acknowledged the gradual reduction of public expenditure on health and the increasing burden on the citizen's expenditure. The Court also pointed to the nationwide reduction of hospitalisation facilities, which was not accompanied by an adequate development of regional care. The consequences have become particularly evident recently, during the dramatic spread of COVID-19; the pandemic, however, was not the object of this research, which predates the outbreak of the global pandemic. The Court of Auditors also noted both the decrease in the number of doctors and nurses, due to reductions in permanent staff, and the slowdown of investments, which were sacrificed in the name of other, more urgent needs.

In order to ensure the fundamental right to health as laid out in Article 32 of the Italian Constitution, the quantification of the resources allocated for health in the framework of the general national budget is crucial, as are the criteria followed in the allocation process in order to meet the various needs. Depending on the level at which the choices are made, it is reasonable to expect the adoption of different decision-making criteria: political criteria if the decision-maker is a politician, managerial criteria if the decision-maker is an administrator, and criteria based on medical considerations and ethics if the decision-maker is a medical professional. Another issue concerns the transparency of allocation decisions in terms of accountability, from the central to the regional government level, right down to the assessments that individual doctors make when performing health interventions on individual patients. For each of these aspects, the survey identified the various systems in place and analysed them analytically.

The reduction of funding for the Italian national health service (SSN) has been accompanied by the communication, at political level, of the need to eliminate inefficiencies in the management of hospitals and to exercise greater attention regarding the appropriateness of diagnostic examinations, medicines and treatments prescribed. For the purpose of this study, the request for and evaluation of data related to some services provided by the public health service in Piedmont and Tuscany was intended to determine the impact of the decrease of economic resources on the public's satisfaction with the implementation of the right to health. However, the data and graphs presented in this report do not point to a clear answer, because the effect of trends concerning waiting lists and certain reductions in the availability of health services remains unknown, e.g., with regard to the individual's decision to seek a medical examination or to resort to private medical facilities. While the latter decision does not, in itself, affect the individual's right to health, it does carry an obvious political significance with respect to the establishment of a universalistic public health service. The results this research presents for discussion pertain to crucial aspects of the public duty to provide a concrete and effective response to the individual's right to health and the corresponding interest of the community (Article 32 of the Italian Constitution).

The research benefited greatly from the open collaboration of and discussion with the staff and the researchers of the Regional Health Authority of Tuscany, the Health Department and the Suprazonal Epidemiology Service of the Piedmont Region, CORIPE and Turin's "Città della Salute" University Hospital. The LDF, alongside Caterina Di Costanzo and Alessandra Cerruti, wishes to express its sincerest gratitude to all of them.

VLADIMIRO ZAGREBELSKY

This book is the result of a joint effort and discussion between the authors on all the aspects that emerged as relevant or problematic during the research. However, the authorship of individual chapters and paragraphs is as follows:
Introduction: Alessandra Cerruti and Caterina Di Costanzo.
Chapter 1: edited by Caterina Di Costanzo.
Chapter 2: sections 1, 2, 3, 6, 7.1, 7.4, 9 by Alessandra Cerruti; sections 4, 5, 7.2, 7.3, 8 by Caterina Di Costanzo.
Chapter 3: sections 3, 4, 5 by Alessandra Cerruti; sections 1, 2, 6, 7, 8 by Caterina Di Costanzo.
Chapter 4: edited by Caterina Di Costanzo.
Appendix: edited by Alessandra Cerruti.

Introduction

by Alessandra Cerruti and Caterina Di Costanzo

1. *Allocation decisions in healthcare and constitutional protection of the right to health*

This research deals with the relationship between allocation decisions in the field of health and the constitutional protection of the right to health in the context of the economic crisis that hit Italy in 2011. It investigates, in particular, the impact of the shortage of public funds on the effective protection of the right to health. The analysis, however, is not limited to the Italian case. The right to health, regarded as the individual right to access a health service, represents one of the most expensive social rights, the financing of which has a significant impact on the national budget in both insurance-based and universalist systems[1]. Therefore, all national governments, regardless of how they finance and organise their health systems, use specific decision-making mechanisms to distribute resources as efficiently, fairly and transparently as possible.

However, it was not in Italy that the issue of the allocation of healthcare resources first began to draw broader attention to issues such as the sustainability of healthcare systems, the democratic legitimacy of decision-making methods and allocation criteria, and the quality and effectiveness of care. The first strand of studies on this subject, including the seminal studies by Daniel Callahan[2] and by Norman Daniels and James Sabin[3], emerged in North America in the 1970s[4] , while in Europe

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[1] An estimated three-quarters of health expenditures are made from public resources; see OECD, *Focus on Health Spending*. *OECD Health Statistics*, June 2018, p. 3.

[2] D. Callahan, *Setting limits: Medical goals in an aging society*, New York, Touchstone Book, 1978; D. Callahan, *False hopes. Why America's quest for perfect health is a recipe for failure*, New York, Simon & Schuster, 1998.

[3] N. Daniels and J.E. Sabin, *Limits to health care: Fair procedures, democratic deliberation, and the legitimacy problem for insurers*, in Philosophy and Public Affairs, 1997, no. 4, pp. 303-350; Id., *Setting limits fairly*. *Can we learn to share medical resources?* Oxford, Oxford University Press, 2002.

[4] See V.R. Fuchs, *Who shall live? Health, economics and social choice*, New York, BasicBooks,

the public, scientific and political debate on the scarcity of health resources dates back to the late 1980s, when it primarily concerned the Scandinavian countries and Great Britain[5].

To date, the existing literature has presented a partial spectrum of analysis because, on the one hand, it has focused only on either a few European countries[6] or a few non-European countries[7] and, on the other, it has dealt with individual aspects of health decision-making processes, such as ethical and bioethical issues[8], as well as their technical and

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1974; G. Calabresi and P. Bobbit, *Tragic choices: The conflicts society confronts in the allocation of tragically scarce resources*, New York, W.W. Norton & Co., 1978. The term 'tragic choices', as clarified by American jurists Guido Calabresi and Philip Bobbit, refers not only to questions of life and death, but also to situations in which 'society must choose between different values that are absolutely affirmed, i.e., that do not allow for compromise'.

[5] J. Calltorp, *Priority-setting in health policy in Sweden and a comparison with Norway*, in Health Policy, 1999, No 50, pp. 1-22; C. Newdick, *Who should we treat?* Oxford, Clarendon Press, 1995; K. Syrett, *Law, legitimacy and the rationing of healthcare. A contextual and comparative perspective*, New York, Cambridge University Press, 2007.

[6] The references for the Scandinavian countries are: L. Bernfort, *Decisions on inclusion in the Swedish basic health care package – roles of cost-effectiveness and need*, in Health Care Analysis, 2003, no. 4, pp. 301-308; J. Calltorp, *Priority-setting in health policy in Sweden and a comparison with Norway*, op cit. For the British context see K. Syrett, *Mixing private and public treatment in the UK's National Health Service*: *A challenge to core constitutional principles?* in European Journal of Health Law, 2010, no. 3, pp. 235-255; Id., *The right to health in the United Kingdom*, in Bioethica Forum, 2015, no. 3; C. Newdick, *Who should we treat?*, cit.; Id., *Rebalancing the rationing debate: Tackling the tensions between individual and community rights*, in *Rationing health care: Hard choices and unavoidable tradeoffs*, edited by A. Den Exter and M. Buijsen, Antwerpen, Maklu, 2012; Id., *Promoting access and equity in health*: *Assessing the National Health Service in England*, in *The right to health at the public/private divide. A global comparative study*, edited by C.M. Flood and A. Gross, New York, Cambridge University Press, 2014.

[7] On the Canadian, American and New Zealand allocation systems see K. Syrett, *Law, legitimacy and the rationing of healthcare. A contextual and comparative perspective*, cit.; N. Kenny and C. Joffres, *An ethical analysis of international health priority-setting*, in Health Care Analysis, 2008, no. 2, pp. 145-160; J. Coast, *The Oregon Plan*: *Technical priority setting in the USA*, in *Priority setting: The health care debate*, edited by J. Coast, J. Donovan and S. Frankel, Chichester, Wiley, 1996, pp. 113-139; J. Cumming, *Defining core services*: *New Zealand experiences*, in Journal of Health Services Research & Policy, 1997, no. 1, pp. 31-37; D. Hadorn, *The Oregon priority-setting exercise: Cost-effectiveness and the rule of rescue, revisited*, in Medical Decision Making, 1996, no. 2, pp. 117-119; F. Honigsbaum, J. Calltorp, C. Ham and S. Holmstrom, *Priority setting processes for health care in Oregon, USA, New Zealand, the Netherlands, Sweden, and the United Kingdom*, New York, Taylor & Francis, 1995.

[8] E.H. Kluge and K. Tomasson, *Health care resource allocation: Complicating ethical factors at the macro-allocation level*, in 'Health Care Analysis', 2002, no. 2, pp. 209-220; M. Danis, C. Clancy and L.R. Churchill, *Ethical dimensions of health policy*, New York, Oxford University Press, 2002; R.D. Ellis, *Why there is no 'Incommensurable Pluralism' of value systems*, in Id., *Just results*: *Ethical foundations for policy analysis*, Washington DC, Georgetown University Press, 1998, pp. 33-56; M. Hayry, *European values in bioethics*: *Why, what, and how to be*

scientific implications, which fall within the remit of *health technology assessment* (*HTA*)[9]. In Italy, in particular, reflections on the subject are mostly presented in non-scientific fora and suffer from the inconstancy that has characterised public attention to the financing of healthcare and the spending cuts that have affected it.

Therefore, there seems to be a need for a dedicated study, which would provide a theoretical framework and review the experiences gained in other national contexts, before addressing the specific declinations of the constitutional protection of the right to health and the allocation of health resources in the Italian context (and, in particular, in the two regional contexts of Tuscany and Piedmont).

2. *Resource allocation, prioritisation and rationing. Preliminary attempts at a definition*

All health systems have, at various moments, addressed the issue of the tension between the demand for care and the supply of care. Economic resources are, by nature, limited, but health expenditure tends to increase in most countries, both developed and developing, albeit due to different factors. In developed countries, the aspects at play are epidemiological (such as the increase in chronic diseases), demographic (such as the ageing of the population), technological (such as the development of more sophisticated and more expensive technologies), and anthropological and cultural (such as the increase in the public's expectations concerning health care services). By contrast, in developing countries health resources are inadequate to meet people's basic needs, health institutions and delivery organisations responsible for implementing services are weak, and significant social inequality is often a factor.

Resource allocation, prioritisation, rationing: a variety of terms are used in the literature and in the public debate on the subject, sometimes synonymously even where they are not entirely interchangeable. However, it should be noted that while *resource allocation* is a descriptive term that refers to the process of distribution of funds carried out by means of decision-making procedures that involve institutional actors at

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used? in Theoretical Medicine, 2003, No 24, pp. 199-214; N.P. Kenny and M. Giacomini, *Wanted*: *A new ethics field for health policy analysis*, in Health Care Analysis, 2005, no. 4, pp. 247-260.

[9] *Health technology assessment and health policy today: A multifaceted view of their unstable crossroads*, edited by J.E. del Llano-Señarís and C. Campillo-Artero, London, Springer, 2015; A.J. Rivera López-Tello, J.L. García López and J.E. del Llano Señarís, *HTA in five European countries: learning from one another*, Madrid, Fundación Gaspar Casal, 2013.

different decision-making levels, the concept of *priority setting* is prescriptive. It refers to the distribution of funds among different areas of care and different categories of patients – *horizontal* and *vertical* priority-setting – which can occur in situations characterised by a significant imbalance between existing resources and healthcare demand. Lastly, the term *rationing* refers to a decision-making process that has a one-dimensional impact on the containment of healthcare costs, referring to processes in which linear cuts are made in healthcare spending without a strategy or priority planning. Therefore, from a socio-political perspective, the term has a negative connotation, whereas the use of the term *priority setting* is often perceived as decidedly positive.

Conceptually, the three terms refer to completely different areas. The allocation of resources in the healthcare sector often appears as a projection of the organisational dimension of the healthcare system itself and, more generally, of the political and institutional system of the country. Allocation decision-making processes ultimately paint a picture of the political and legal organisation of a given country and, consequently, of a given health system. Allocation procedures follow a certain organisational and institutional pattern that is determined and conditioned by the organisation of the decision-making entities, the distribution of the institutional actors, and the stratification in regulatory levels of a certain system. For example, countries that are organised on a regional basis (e.g., Italy and Spain) will follow different allocation procedures than countries with a more centralised organisation (e.g., Sweden and Norway).

The concept of prioritisation, on the other hand, presupposes a value judgement of a clinical, ethical or social nature, in which procedural values (such as transparency, accountability and participation) or substantive values (such as clinical effectiveness, economic effectiveness, justice/equity, solidarity and autonomy) are prioritised.

As will be seen, the analysis of the various national and international experiences shows that the allocation of resources is a pre-existing factor in all healthcare systems, whereas the ascribability of individual allocation processes to a model defined by priorities or rationing depends on how explicit the processes themselves are, as well as on how one-dimensional the allocation criteria of reference are. To give just a few examples, in England decision-making methods mainly followed a priority-setting approach until the reform of 2012, whereas in recent years linear measures and rationing have become more common. In Italy, the scientific and political debate on the subject has never gone beyond the issue of the sustainability of the health system, and public opinion has preferred to focus on the *rationalisation* of health expenditure rather than its rationing, in order to reduce the inevitable tensions connected with

cost containment.

3. *Research phases and methodologies used*

The present research covered a period of about three years and went through three main phases.

The analysis began with the framing of the constitutional right to health, understood here as the right of access to health care, and the definition of the fundamental dimensions relevant to resource allocation, priority setting and resource rationing.

Next, a number of European countries were selected (Great Britain, Sweden, Norway, Denmark, France, Germany, Switzerland, Spain and Italy) and the aspects to be investigated were identified in order to draw up analysis sheets to register each country's methods of constitutional protection of the right to health and the system of allocation of health resources, to allow a comparison of the various systems. The analysis indexes used identify the constitutional profiles of health protection, the principles of the health system, their respective organisational and financing methods, and the characteristics of resource allocation and priority-setting processes. The methodology employed consisted of a review of literature, international and national documents, and various reports on the subject. The researchers also did a research stay at the Institute of Health Law at the University of Neuchâtel in Switzerland [10].

Lastly, the research focused on a specific geographical context (the Italian health system, with particular emphasis on the regions of Piedmont and Tuscany[11]) and temporal framework (the years of the recent economic crisis and the following contraction of the resources allocated to health care, namely 2011-2016), in order to investigate in this specific context the concrete articulation of the allocation and management choices that can be linked to the various levels of government and the criteria that have guided them. This phase of the research was characterised by a field analysis aimed at processing data concerning the volumes of health services provided in public and private accredited structures (that is, excluding primary care and community medicine) within the two selected regions, as well as the purely private sector. The objective of this analysis was to assess the trend in turnover

[10] The *Institut de droit de la santé* (IDS), founded by Prof. Olivier Guillod and Dominique Sprumont, is a centre of excellence at the University of Neuchâtel (https://www.unine.ch/ids/).

[11] The choice of these two regions is mainly due to criteria of territorial proximity and the resulting potential for contacts with health authorities (e.g., Regional Health Authority - ARS Tuscany) and other bodies (e.g., CSI Piemonte) involved in the management of information and data flows concerning regional health services.

volumes and to verify the possibility of establishing a link between these volumes and the allocation choices and legislative measures concerning health expenditure. The analysis of the trend looked at various service flows such as that of the emergency room, out-patient, hospitalisation, outpatient specialist services (both at regional level and at the level of some health authorities such as that of Turin) and the former Florence health authority. Additionally, within the outpatient specialist sector, the study drilled down on a selection of services divided into the categories of high, medium and low risk of low appropriateness. In order to improve readability, the data identified above have been reworked into graphs, which are presented in chapter 4 and attached in a specific appendix to this report.

The methodology for this field analysis was refined through a series of periodic discussions that the researchers had with the research group of the Consortium for Research and Continuing Education in Economics (CORIPE) coordinated by Prof. Nerina Dirindin, the members of the Osservatorio per la qualità e l'equità dell'Agenzia regionale di sanità (Observatory for Quality and Equity of the Regional Health Authority (ARS) Toscana) and Prof. Giuseppe Costa's research group at the Servizio di epidemiologia del Piemonte (Piedmont Epidemiology Service - SEPI). Other informal interviews were conducted with the staff of the Health Department of the Piedmont Region, with professionals and members of the management of the University Hospital of Careggi, the University Hospital Città della Salute e della Scienza di Torino, the Local Health Authority of the City of Turin, and with representatives of private bodies carrying out activities in the social and health sectors in the capitals of Piedmont and Tuscany. The authors' gratitude goes to all those with whom they had the opportunity to engage in discussions, in particular: Prof. Nerina Dirindin and Dr. Chiara Rivoiro of CORIPE, for the discussion on how to approach this research and its comparative component, as well as for the data relating to high-cost innovative drugs, which they developed more extensively in separate research; Dr. Andrea Vannucci (then director of ARS Toscana); Dr. Alessandro Sergi (then scientific advisor of ARS Toscana); Dr. Silvia Forni (head of the Quality Assessment Systems for ARS Toscana); Dr. Giacomo Galletti (Quality Assessment Systems for ARS Toscana); Dr. Manuele Falcone (Quality and Equity Observatory of ARS Toscana) for the interpretation and collection of data for Tuscany; Prof. Giuseppe Costa (Director of SEPI) and Dr. Luisa Mondo and Teresa Spadea (SEPI) for the interpretation and collection of data for Piedmont; Dr. Valerio Alberti (then Director General of the Local Health Authority of the City of Turin); Dr. Giulio Fornero (Director of Quality and Risk Management of the University Hospital Città della Salute e della Scienza di Torino) and Dr. Giovanni Battaglia (Director of Quality and Risk

Management at the University Hospital Città della Salute e della Scienza di Torino) for the interpretation and collection of data for Piedmont; Valerio Alberti (then Director General of the Local Health Authority of the City of Turin); Dr. Giulio Fornero (Director of Quality and Risk Management of the University Hospital Città della Salute e della Scienza di Torino) and Dr. Renata Gili for the interpretation and collection of data for Piedmont and data collection on waiting times in the Piedmont Region and at the relevant AOU.

Lastly, the researchers undertook an extensive review of health reports on the right to health and the economic crisis, the findings of which were taken into account throughout the discussion[12].

[12] Health reports on this subject are numerous and varied. The reports considered for the purposes of this research are the following: OECD Health Database for international indicators, on the basis of which the OECD publishes the *Health at a glance* report every two years; reports on the monitoring of health expenditure by the Ragioneria Generale dello Stato (State General Accounting Office); reports of the Corte dei Conti (National Court of Auditors) on the coordination of public finance; CREA Sanità Reports; OASI Reports drawn up by SDA and CERGAS at Bocconi University in Milan; Osservasalute Reports; *PIT salute* reports by Cittadinanza attiva; Noi Italia Reports by ISTAT; GIMBE Foundation Reports on the sustainability of the Italian national health service.

Chapter One

Right to health, resource allocation and priority-setting

by Caterina Di Costanzo

1. *The structural multidimension of the right to health*

The protection of human health encompasses a plurality of issues and problems, ranging from the guarantee of fundamental rights, substantive equality and human dignity to the rational and optimal allocation of health resources aimed at making these rights enforceable. The protection of health is a multidimensional issue both subjectively (in respect to all who are called upon to participate in making this an effective right) and objectively (because it can affect all areas of a person's life).

In this chapter, we will briefly analyse a series of themes that recur throughout the discussion: from the study of the specific modalities of the protection of health, to the identification of the specific content of the right to health in jurisprudence, to addressing the issue of the distribution of resources as a problem emerging at global, supranational and national levels.

The right to health is referred to in numerous documents at various levels. However, it must be noted that these standards frame health as a politically relevant objective, and do so in relation to various contexts. These include Art. 25 of the Universal Declaration of Human Rights; Art. 12 of the UN International Covenant on Economic, Social and Cultural Rights of 1966; Art. 11 of the Council of Europe's European Social Charter of 1961, revised in 1996; Art. 25 of the UN Convention on the Rights of Persons with Disabilities of 2006; and Art. 35 of the Charter of Fundamental Rights of the European Union (EU). The definition contained in the preamble to the Constitution of the World Health Organisation (WHO), signed in New York on 22 July 1946, which defines health as not merely the absence of disease but a state of complete physical, mental and social well-being, marks a shift from a static concept of health to a dynamic one, from a negative to a positive content of health understood as full psycho-physical and social

well-being[1].

In contemporary Western constitutions, the protection of the right to health has both a positive and a negative dimension[2]: the former concerns the profiling of the right to demand a health service, while the latter concerns the protection from external interferences in the subjective sphere of the person. They mark the classic distinction between the social right and the right to freedom that structures the multidimensional content of the right to health.

Therefore, the identification of a programmatic component and a preceptive component of the right to health affects the ability of the right to manifest itself as a *fundamental right*, even if financially conditioned, or as a *policy objective*, even if made effective, from time to time, through connections with other fundamental rights or jurisprudential guidelines.

2. *The right to health at the global and supranational levels*

At global and supranational levels, health protection is of central importance. This protection lends itself to the test of overcoming the categorial distinction between a fundamental right and a politically relevant objective, this in part by virtue of the rules laid down at these levels of regulation. The WHO and the EU take a very broad approach to the concept of health, which appears to be a common good in which to invest, both in terms of the benefits it brings to individual and collective health

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[1] On the evolution of the notion of health, see L.S. Larson, *The conceptualization of health*, in Medical Care Research and Review, 1999, no. 56, pp. 123-136; M. Huber, A. Knottnerus, L. Green, H. Van Der Horst, A.R Jadad, D. Kromhout, B. Leonard, K. Lorig, M.I. Loureiro, J.W.M. Van Der Meer, P. Schnabel, R. Smith, C. Van Weel and H. Smid, *How should we define health?* in British Medical Journal, 2011, no. 343; Lancet Editorial, *What is health? The ability to adapt*, 2009; A.R. Jadad and L. O'Grady, *How should health be defined*, in British Medical Journal, 2008. As regards Italian doctrine, see D. Morana, *La salute come diritto costituzionale*, Torino, Giappichelli, 2015, pp. 79 ff.; A. Pioggia, *Diritto sanitario e servizi sociali*, Torino, Giappichelli, 2015, passim. Pioggia, *Diritto sanitario e dei servizi sociali*, Turin, Giappichelli, 2014, passim. The preamble to the 1946 WHO Constitution states: "Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity". The Ottawa Charter of 1986 states that ''Health promotion is the process of enabling people to increase control over, and to improve, their health."

[2] On the constitutional framework of the right to health in the main European countries, see Chapter 2 of this volume. In liberal constitutions, health is linked to the pursuit of a minimum level of hygiene and health in the population and is therefore considered a collective interest linked to the guarantee of public order. In contemporary constitutions, there is a qualitative leap broadening the content of the right to health considerably from being a public interest to a fundamental right with multiple dimensions. On this subject, see L. Busatta, *La salute sostenibile. La complessa determinazione del diritto ad accedere alle prestazioni sanitarie*, Turin, Giappichelli, 2018, pp. 3 ff.; R. Ferrara, *L'ordinamento della sanità*, Turin, Giappichelli, 2007, pp. 41 ff.

and in terms of prevention, with a view to ensuring the financial stability and sustainability of health systems, and also economically. At this level of analysis, health reveals its expansive potential to affect almost all public sectors[3]. From this perspective the importance of the "social determinants" of health becomes apparent, i.e., all those factors in the local, behavioural, educational, living and working environments that affect the health of the individual or a population group. Acting on social determinants, as understood in the documents adopted at global and supranational levels, aims to generate a preventive impact on people's health before the disease occurs. The consequences include saving public resources and ensuring the sustainability of health systems, and potentially reducing differences in access to health services between people in different states of fragility and belonging to different strata of the population[4].

EU policies take up the challenge proposed by other institutions, first and foremost the WHO, to promote public policies aimed at influencing the determinants of health. In this sense, the European strategy called "Health in All Policies" has been adopted as the primary objective of the third Programme for the Union's action in the field of health (2014-2020)[5], the most relevant aspect of which is the identification of commitments and standards to which Member States declare that they will adhere at global and supranational levels. The balance is struck by the links between the protection of health as a politically relevant objective and the creation of obligations on the part of the public authorities to guarantee access to the services that constitute the content of the right.

Regarding the intersection between politically relevant objectives and specific constraints on states, a decisive contribution on guaranteeing the

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[3] The 1978 Alma-Ata Declaration, which focuses on the need to ensure an effective primary care system in countries, states that "Primary health care... 2. addresses the main health problems in the community, providing promotive, preventive, curative and rehabilitative services accordingly; 3. includes at least: education concerning prevailing health problems and the methods of preventing and controlling them; promotion of food supply and proper nutrition; an adequate supply of safe water and basic sanitation; maternal and child health care, including family planning; immunization against the major infectious diseases; prevention and control of locally endemic diseases; appropriate treatment of common diseases and injuries; and provision of essential drugs; 4. involves, in addition to the health sector, all related sectors and aspects of national and community development, in particular agriculture, animal husbandry, food, industry, education, housing, public works, communications and other sectors; and demands the coordinated efforts of all those sectors…." See also the 1986 Ottawa Charter for Health Promotion and the Helsinki Statement on Health in All Policies of 2013.

[4] World Health Organization (WHO), Rio Political Declaration on Social Determinants of Health, Rio de Janeiro, 21 October 2011.

[5] See Regulation (EU) No 282/2014 of the European Parliament and of the Council of 11 March 2014 on the establishment of a third Programme for the Union's action in the field of health (2014-2020) and repealing Decision No 1350/2007/EC.

individual right of access to healthcare services comes from both the case law of the European Court of Human Rights (ECtHR) and the case law of the Court of Justice of the European Union (CJEU).

The case law of the European Court of Human Rights (ECtHR) highlights the specific relevance of health protection by virtue of the use of the conceptual category of 'positive obligations', which States undertake towards persons in any of the countries party to the European Convention for the Protection of Human Rights and Fundamental Freedoms (ECHR).

The Court states that the allocation of health care resources is a highly political matter and therefore falls within the ECtHR's margin of appreciation, a margin which is actuality quite wide. The ECtHR recognises in its case law that it would be optimal for States to guarantee access to a very wide range of treatments, but they are unable to provide access free of charge, particularly where long-term and particularly expensive treatment is concerned[6].

On the basis of this general approach, States are deemed to have fulfilled their contractual obligations if they have put in place safeguards corresponding to the degree of protection that the individual State is able to provide. Cases on this point concern the provision of both medicines[7] and medical devices[8].

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[6] In the 2005 case of *Pentiacova and Others v. Moldova,* the applicants, suffering from chronic renal failure, needed access to haemodialysis treatment. The appeal was based on the fact that the State, while covering a large part of the costs, did not guarantee completely free access to treatment. The Court addresses the problem of insufficient public funding to fully cover the medical treatment of haemodialysis, employing the "Osman test" (European Court of Human Rights, Grand Chamber, *Osman v. the United Kingdom*, decision of 28 October 1998), and stating that in relation to questions concerning the choice of priorities with respect to the management of economic and human resources, the margin of appreciation of the national authorities is particularly wide. See European Court of Human Rights, 4th section, *Pentiacova and Others v. Moldova*, decision of 4 January 2005.

[7] In *Nitecki v. Poland* (2002)*,* the applicant, who suffered from amyotrophic lateral sclerosis, complained that certain life-saving medicines were only reimbursed up to 70% of their total cost. The applicant contested the responsibility of the State for not having guaranteed effective access to the treatment necessary for his survival. Instead, the European Court held that a reimbursement of 70% of medical expenses was a sufficient measure to comply with the obligations of Article 2 ECHR. See ECtHR, 1st section, *Nitecki v. Poland*, decision of 21 March 2002.

[8] In the 2003 case *Sentges v. the Netherlands,* the applicant suffered from muscular dystrophy and, in order to lead an independent life, applied for a robotic arm that would improve his quality of life by making him more independent. The State provided the applicant with a wheelchair adapted to his specific characteristics. Considering the need to balance the interests of both the community and the individual - in this case, the scarcity of available funds and the need to ensure access to facilities that would improve people's quality of life by prioritising choices, the Court held that there was no violation of Article 8 ECHR. The Court's argument rests on the fact that the State had fulfilled its positive obligations through the provision of a wheelchair and the guarantee of benefits and

Other rulings of the European Court of Human Rights have highlighted the lack of procedural guarantees to ensure the effectiveness of the right of access to health care and the specious nature of the reference to the scarcity of economic resources proposed by some health authorities in order not to comply with a national court order[9].

Another area in which ECtHR case law intervenes is the assessment of the legitimacy of deportation orders when the object of the order suffers from health problems and his or her country of origin may not have sufficient means to ensure adequate care.

There is a consistent line of case law in this area. A deportation by a Member State of the Convention may raise issues relating to violation of Article 3 ECHR if there are reasonable grounds to believe that there are real risks that the person, once returned, may be subjected to treatment in the country of origin in violation of the prohibition in Article 3. The judges of the ECtHR confirm the positive dimension of Article 3 of the ECHR, which in specific circumstances requires the fulfilment of positive obligations on the part of the Member States of the Convention in order to prevent that any omissions in the guarantee of certain performance rights can lead to a loss of health security and result in inhumane and degrading treatment.

If, from a substantive point of view, jurisprudential scrutiny cannot go so far as to assess the legitimacy of a deportation measure on the basis of the differences between the various health care systems concerning the availability of funds and medical equipment[10], from the perspective of procedural requirements the ECtHR can verify compliance with the obligations of States to put in place a series of measures aimed at assessing the existence of concrete risks for the person once he or she has been

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assistance offered to the general population. See European Court of Human Rights, 2nd Section, *Sentges c. Netherlands*, decision of 8 July 2003.

[9] In the 2012 case of *Panaitescu v. Romania,* the Court ruled that State authorities are obliged to fulfil positive obligations related to the guarantee of fundamental rights under the ECHR. In this case, the plaintiff was a terminally ill cancer patient who had been granted the right to receive, without cost, a very expensive and very effective drug for his condition. In spite of a court order, the health authority had denied the possibility of obtaining the drug free of charge. The ECtHR stated that the Romanian health administration's conduct constituted a violation of the right to life enshrined in Article 2 ECHR, since during the trial the applicant's condition deteriorated and he died. See European Court of Human Rights, 3rd Section, *Panaitescu v. Romania*, decision of 10 July 2012.

[10] In the case of *N. v. United Kingdom*, a Ugandan citizen, seriously ill with AIDS, appealed to the Strasbourg Court against the United Kingdom's decision to expel her from the country, arguing that she would not have access to the necessary medical care in Uganda, in view of her state of health, and that this would result in the United Kingdom breaching Articles 3 and 8 ECHR. The judges of the ECtHR clearly stated that health reasons cannot automatically constitute exceptions to the validity and effectiveness of a deportation order. See ECtHR, Grand Chamber, *N. v. United Kingdom*, decision of 27 May 2008.

deported to the country of origin[11]. For its part, the case law of the CJEU has consistently reiterated that competence for the organisation and management of health systems lies with the individual Member State[12]. Consequently, each Member State is competent to determine the content of the service in which the effectiveness of the individual's right to health is enshrined, the conditions of access to the services and the methods of providing them, while the EU is responsible for the remaining actions of coordination and support of the Member States' national health policies[13].

The Court recognised that the objective of maintaining a medical and hospital service accessible to all may allow for the application of derogations on public health grounds according to Article 46 of the Treaty on the Functioning of the European Union (TFEU), where such an objective is aimed at achieving a high level of health protection. It also made clear that Article 46 TFEU allows Member States to restrict the free provision of medical and hospital services, since the maintenance of a health system in the national territory is an essential factor for public health, and even for the survival of the population[14].

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[11] In the case of *Paposhvili v. Belgium,* the ECtHR declared that Belgium had violated Articles 3 and 8 of the ECHR. Mr Paposhvili, a Georgian citizen living in Belgium, had tried several times to regularise his status. His requests were refused because of his criminal record. While detained in a Belgian prison and awaiting a deportation order, he was diagnosed with severe leukaemia, and he began receiving a range of highly specialised treatments in Belgium. In the light of his deteriorating state of health, he twice more applied for regularisation 'on medical grounds' as permitted by the *Loi du 15 décembre 1980 sur l'accès au territoire, le séjour, l'établissement et l'éloignement des étrangers*. The applications were rejected, despite the fact that Mr Paposhvili had argued that, if returned to Georgia, he would not be able to receive such effective and substantial treatment and would therefore be at risk of death within a few months. Pending a new deportation order, he appealed to the European Court of Human Rights. The appeal was assessed negatively by one chamber of the Court, but the appellant requested a review by the Grand Chamber. While awaiting the final verdict, however, Mr Paposhvili died. The Grand Chamber concluded that there is a positive obligation on the State respondent to verify the risks that exist in practice for the person once he or she has been expelled to the State of origin. See ECtHR, Grand Chamber, *Paposhvili v. Belgium*, decision of 13 December 2016.

[12] See Art. 168, para. 7, of the Treaty on the Functioning of the European Union (TFEU) and Art. 35 of the EU Charter of Fundamental Rights.

[13] On this see the case law of the CJEU and, in particular, C-372/04, *Yvonne Watts v Bedford Primary Care Trust and Secretary of State for Health*, 16 May 2006, paragraph 92; C-444/05, *Aikaterini Stamatelaki v NPDD Organismos Asfaliseos Eleutheron Epagelmation*, 19 April 2007, paragraph 23; C-211/08, *European Commission v Kingdom of Spain*, 15 June 2010; C-173/09, *Georgi Ivanov Elchinov v. Natsionalna zdravnoosigurtelna kasa*, 5 October 2010, paragraph 53.

[14] In this sense, see CJEU, C-158/96, *Raymond Kohll v Union des caisses de maladie*, 28 April 1998, paragraphs 41, 50 and 51; C-157/99, *Geraets-Smits and H.T.M. Peerbooms v. Stichting Ziekenfonds VGZ*, 12 July 2001, paragraphs 72-74; C-385/99, *V.G. Müller-Fauré and E.E.M. van Riet v. Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen UA*, judgment of 13

In the wake of these arguments, the Court specified that the quantity and size of hospital infrastructures, their geographical and territorial distribution, their organisation and their technical equipment must be the subject of public planning by the Member State. On the one hand, such planning must pursue the objective of ensuring adequate access to a range of high-quality hospital and/or medical care on the territory of the Member State concerned. On the other hand, it must be an expression of the desire to ensure cost control and to avoid, as far as possible, any waste of financial, technical and human resources[15].

In some cases, the CJEU proposes some relevant criteria for identifying the content of health care services[16]. The resulting indication maintains that States are called upon to deliberate their allocative decisions in the field of health not only on the basis of economic, political, legal and scientific criteria but also on the basis of the criteria for determining scientific evidence that emerge at international level. It is within the competence of the Member State concerned to draw up a list of benefits with precise reference to treatments or methods of treatment, allowing some and excluding others, and indicating the principles on the basis of which the benefits that may be provided are identified or, more generally, the types of treatment or methods of treatment[17].

May 2003, paragraphs 67 and 73, and the *Watts* judgment, cited above, paragraphs. 103-105.

[15] See CJEU, *Smits and Peerbooms*, cited above, paragraphs. 76-79, and *Watts*, cited above, paragraphs 108 and 109.

[16] In the *Smits and Peerbooms* case, the issue revolved around the interpretation of the criterion of 'usual care' which is used in the Dutch and Belgian legal systems to assess applications for authorisation to receive health care abroad. The criterion used by the Court of Justice is the demonstration of scientific evidence of the effectiveness of the treatment as proven by international medical science. See CJEU, *Smits and Peerbooms* judgment, cited above, paragraph 97.

[17] In the *Elchinov* case the Court of Justice was called to rule on the content of the list of guaranteed health services. Mr Elchinov, who suffered from a serious illness, applied to the National Health Insurance Fund (NZOK) for authorisation to undergo medical treatment in Berlin which was not available in Bulgaria. The National Health Insurance Fund refused authorisation, pursuant to Article 22 of Regulation No 1408 of 1971, on the ground that the treatment requested was not among those covered by the Bulgarian system. Indeed, the ophthalmological treatment prescribed by the doctor was not among the treatments for which the Bulgarian system provides reimbursement. After an initial ruling against the appellant, the Bulgarian Supreme Administrative Court annulled the judgment at first instance, stressing the need to ascertain in concrete terms whether the necessary treatment could be provided by a Bulgarian healthcare facility or not, and referred to the Court of Justice a number of preliminary questions related to interpretation. The Court of Justice affirmed that authorization cannot be denied when the services covered by the national system are included in a list which does not expressly and precisely mention the method of treatment applied, but rather defines certain types of treatment that are reimbursed by the competent institution if it is ascertained – according to traditional

In the event of proven structural and organisational shortcomings in the healthcare system of a Member State due to limited financial resources and planning deficiencies, the citizen may be entitled to apply for an authorisation for healthcare mobility in order to guarantee his/her right of access to appropriate and effective healthcare. With a view to protecting patients' rights, the CJEU in fact affirms that the impossibility of receiving a healthcare service must be assessed with reference to both the time frame within which the treatment can be obtained[18] and the structural and organisational adequacy of all the healthcare institutions existing in the country of residence of the plaintiff[19].

3. *The distribution of health resources as a global, European and national issue*

3.1. *Initiatives at global level*

The issue of the optimal allocation of scarce resources in the health sector emerged globally in the 1990s[20].

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hermeneutic principles and following an examination based on objective and non-discriminatory criteria taking into account all the relevant medical elements and available scientific data - that this method of treatment corresponds to the benefits mentioned in that list, and if an alternative treatment with the same degree of effectiveness cannot be provided in good time in the Member State where the insured person resides. See CJEU, *Elchinov* judgment, op cit.

[18] See CJEU, C-372/04, *Yvonne Watts v Bedford Primary Care Trust and Secretary of State for Health*, 16 May 2006.

[19] CJEU, C-268/13, *Elena Petru v Casa Județeană de Asigurări de Sănătate Sibiu and Casa Națională de Asigurări de Sănătate*, 9 October 2014. Mrs Petru, who suffered from a severe cardiovascular condition, needed to undergo a delicate heart surgery procedure to replace her mitral valve and introduce two coronary stents. Her application for coverage of the costs for surgery in Germany was rejected by the Romanian National Health Insurance Fund because the requested service could be performed in Romania. She therefore filed a civil action for payment of the medical expenses incurred in Germany, pointing out the deficient conditions of the Romanian health facility where she had previously been admitted and the lack of medicines, suitable medical devices and available beds. The precariousness of the structural and organisational conditions and the complexity of the necessary surgery led Mrs Petru to turn to a clinic in Germany. The regional court, which became involved after the rejection of the application by the court of first instance, raised a prejudicial question as to the absolute or relative nature of the impossibility of receiving treatment in the country of residence if that impossibility is attributable to the precariousness of the structural and organisational conditions in which that treatment would take place. The Court of Justice ultimately ruled in favour of Mrs Petru.

[20] World Medical Association, *Discussion document on the ethical aspects of the allocation of health care resources*, in 'South African Medical Journal', vol. 86, no. 10, 1996, pp. 1263-1266.

The World Development Report published by the World Bank in 1993 in cooperation with the WHO was the first to refer to the key concept of the relationship between disability and *burden of disease*, developed in the *Disability Adjusted Life Year* (DALY)[21] criterion. This report introduces the idea of the need to work on the cost-effectiveness of interventions because they are financed with both public and private resources.

In 1998, the WHO launched a programme to provide a scientific basis for policy decisions based on a set of *cost-effectiveness* criteria, called *WHO-CHOICE (Choosing Interventions that are Cost-Effective)*[22]. In this context, an analytical tool was developed to support decision-making processes with information on the costs and effectiveness of various interventions.

Another relevant initiative was developed by the Global Forum for Health Research, which drew up a specific framework, the *Combined Approach Matrix* (CAM)[23]. The CAM was published in 2004 and revised in 2009; its main objective was to provide a multifaceted and multidimensional picture of the questions that may arise for those who have to make a choice in a context of scarce resources. The CAM combines the economic and institutional dimensions, organising information about a disease and the possible response to it. According to this framework, this information is categorised on the basis of five economic aspects of public health[24] and four institutional factors representing the various levels at which health interventions and services can be delivered[25]. In addition to these 9 dimensions, the 2009 revised version includes fairness, which is considered particularly at risk in light of the contraction that followed the global economic crisis in 2007. The three pillars of the revised CAM are *process*, *available tools* and *context* aimed at identifying the right weight to be assigned to different situations and the choice of the appropriate service for the individual health need.

Two other synthetic policy tools developed at this level are the *Program Budgeting and Marginal Analysis* (PBMA) and the *Multi-criteria Decision Analysis* (MCDA)[26]. These are provisions that have been proposed at

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[21] See World Bank, *World development report: investing in health*, New York, Oxford University Press, 1993. On the methodology used (DALY), see the explanatory note at the end of section 4.3(a.1) of Chapter 2.

[22] See World Health Organization, *Guiding principles for strategic resource allocations*, 12 January 2005; Ibid., *Strategic resource allocation*, 11 May 2006.

[23] See https://www.who.int/workforcealliance/members_partners/member_list/gfhr/en/.

[24] These are: the impact of diseases, the determinants of diseases, the current state of knowledge, the degree of cost-effectiveness of the provision, the development of resources and funding.

[25] These are: the individual household and community response, the health sector, sectors other than health, and general system governance.

[26] For an introduction to these two systems, see I. Cromwell, S.J. Peacock and C. Mitton,

international level and subsequently also used by some countries for allocation choices at macro and micro levels[27].

The creation of Health Technology Assessment International (HTAi), a global, scientific and professional society with support functions for all stakeholders in health technology assessment, should also be mentioned here[28]. The initiative was organised with the aim of providing a neutral forum for collaboration and sharing of information and expertise on HTA[29]. To this end, the International Network of Agencies for Health Technology Assessment (INAHTA)[30] is intended to provide a platform for identifying and pursuing the shared interests of health technology assessment agencies in order to accelerate inter-authority exchange and collaboration, promote information, sharing and comparison, and prevent unnecessary duplication of activities.

Finally, since 2003, the WHO European Regional Office has been coordinating HEN (Health Evidence Network), a network that advises public health decision-makers. The goal is to support health authorities in using the most effective evidence available. HEN periodically produces summary reports on the state of the art concerning issues related to resource allocation and priority setting[31].

3.2. *European level*

As mentioned, in the field of health care management and resource allocation the relevant decision-making competences are attributed to the

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'Real-world' health care priority setting using explicit decision criteria: *A systematic review of the literature*, in BMC Health Services Research, 2015, no. 15, pp. 164-184.

[27] In the UK, for example, the use of PBMA and MCDA at local level; see C. Mitton, F. Dionne and C. Donaldson, *Managing healthcare budgets: times of austerity*. *The role of program budgeting and marginal analysis*, in Applied Health Economics and Health Policy, 2014, no. 12, pp. 95-102; on the experience of the province of Alberta (Canada) see C.R. Mitton, C. Donaldson, H. Waldner and C. Eagle, *The evolution of PBMA: Towards a macro-level priority setting frame work for health regions*, in "Healthcare Management Science", 2003, no. 6, pp. 263-269.

[28] See https://htai.org/.

[29] Based on the definition provided by the European network for HTA (EUnetHTA), HTA is defined as: 'a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe and effective health policies that are patient-focused and seek to achieve the best value. HTA endeavours to provide a structured, evidence-based input to the policy-making process."

[30] The International Network of Agencies for HTA, established in 1993, is a network of 55 HTA agencies.

[31] See http://www.euro.who.int/en/data-and-evidence/evidence-infor-med-policy-making/health-evidence-network-hen.

Member States. As stipulated in Article 168 TFEU, the functions performed by the EU in this area - which expressly also include monitoring, alerting and combating serious cross-border threats to health - are complementary, i.e., EU action is intended to support and back up national policies.

The need felt in almost all the Member States to rationalise health expenditure, especially following the economic crisis that broke out in 2007, and the need to maintain a high level and high quality of protection of the right to health, have led the Member States to consider strategies for reconciling the principles of solidarity and equality with the need to ensure economic efficiency for their health systems in order to secure a financial balance and sustainability in the medium and long term. The EU has also repeatedly emphasised the role that health systems play both economically, as vectors for economic growth and development, and socially, in ensuring the implementation of important values that underpin the European project.

In 2011, the European Council established an EU-wide reflection process to help Member States ensure a modern, responsive and sustainable healthcare system. In this process, it was recognised that:

> *whilst ensuring equitable access to high quality health care services in circumstances of scarce economic and other resources has always been a key question, at present it is the scale and urgency of the situation that is changing and, if unaddressed, it could become a crucial factor in the future economic and social landscape of the EU*[32]*.*

In this context, eleven Member States received recommendations in December 2013 calling for reform of their health systems with a focus on sustainability and cost-effectiveness through the organisational optimisation of their hospital sector, and a reform of the rate system for outpatient services and primary care[33].

In 2014, the *Annual Growth Survey* (AGS), in the framework of the European Semester, emphasised the need to increase the growth and competitiveness of the economic systems of Member States. Specific reference was made to the need to increase the efficiency and economic sustainability of health systems and their capacity to meet the health needs of the population. Moreover, strengthening the sustainability and resilience of European health systems is one of the key objectives of the Europe 2020

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[32] Council of the European Union, *Towards modern, responsive and sustainable health systems*, 6 June 2011.

[33] Council of the European Union, *Reflection process on modern, responsive and sustainable health systems*, 10 December 2013. The following States received recommendations: Austria, Bulgaria, Czech Republic, Germany, Finland, France, Malta, Poland, Romania, Slovakia and Spain.

Strategy[34] and is set as a strategic goal by the OECD's *Health at a Glance* 2018 report, which could be reached by promoting digitalisation in healthcare and increasing the use of information technology in healthcare[35].

In the field of health technology assessment, a support network for national agencies, the European Network for HTA (EUnetHTA)[36], has also been established at European level. Exchanges of knowledge and experience through health technology assessment has been a priority political objective of the European Council since 2004[37]. The functions of this voluntary network between member countries, in accordance with Art. 15 of Directive 2011/24 of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare are intended to avoid duplication of assessments and to ensure that patients' rights are respected (d), to support cooperation between national authorities or bodies in charge of health technology assessment (a), to support the analysis of the nature and type of information that can be exchanged (c), and to support Member States in the provision of objective, reliable, timely, transparent, comparable and transferable information on the relative efficacy as well as on the short- and long-term effectiveness of health technologies (b).

Finally, a number of EU initiatives were launched to address the health emergency that began in late 2019 with the outbreak of the SARS-COV-2[38] virus. The EU's response to the emergency spans a wide range of

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[34] See European Commission, *Communication on effective, accessible and resilient health systems*, COM(2014)215 final; Ibid., *European Semester Thematic Fiche - Health and Health Systems*, May 2016.

[35] OECD, *Health at a Glance: Europe 2018: State of Health in the EU Cycle*, Paris, OECD Publishing, 2018, pp. 192 ff.

[36] The European network currently consists of 28 HTA agencies, plus Norway having observer status.

[37] Since 2004, the Council of Ministers of the European Union has defined HTA as a political priority: "the European Council concluded that the exchange of expertise and information through HTA may be enhanced through systematic EU-wide cooperation, in order to assist the Members States to plan, deliver and monitor health services effectively, based on the best available scientific evidence on the medical, social and economic implications of health technology."

[38] The epidemiological emergency that occurred following the spread, first in China in the last months of 2019 and then globally, of the new Severe Acute Respiratory Syndrome coronavirus, abbreviated as *SARS-COV-2,* has strongly impacted the public health and economic systems of the European Union Member States. Based on the opinion of the Emergency Committee convened under the International Health Regulations of 2005, the WHO declared on 30 January 2020 that the spread of the virus constituted a public health emergency of international concern. On 11 February 2020 the WHO identified the definitive name of the disease as 'COVID-19', short for 'coronavirus disease 2019', and on 11 March declared the health emergency a pandemic, the first caused by a coronavirus.

competences: public health, mobility, education, research and innovation, crisis management and solidarity and, above all, the economy[39].

In the area of economic policy measures, EU decisions have led to a relaxation of the normal European constraints, making the discipline of state aid[40] and the Stability and Growth Pact[41] more flexible. In addition, a variety of instruments to finance national economies have been put in place, such as national public debt financing by the European Central Bank (ECB)[42], financial assistance instruments in the form of credit[43] and interventions using the EU budget[44].

With regard to supporting national economies, Council Regulation (EU) 2020/521 of 14 April 2020 activating emergency support under Regulation (EU) 2016/369, which qualified the COVID-19 outbreak as a "disaster" within the meaning of Chapter XVII, Section C of Regulation (EC) No 1186/2009 and Chapter 4, Title VIII of Directive 2009/132/EC, allowed for the exemption from customs duties and VAT on the import of goods necessary to counter the effects of the pandemic. Lastly, EU Council Regulation 2020/521 amended Regulation (EU) No 1301/2013 on the provision of emergency support within the Union, adding a sub-paragraph to Art. 3(1) stating that 'in addition, the European Regional Development Fund (ERDF) may support the financing of working capital of SMEs when necessary as a temporary measure, in order to respond effectively to a public health crisis.'

The economic sphere has also seen the implementation of a number of

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[39] On the approved measures, see the EU webpage dedicated to the Coronavirus Response at https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response_en.

[40] See Commission Communication of 19 March 2020, "State Aid Temporary Framework to enable Member States to use the full flexibility foreseen under State aid rules to support the economy in the context of the coronavirus outbreak".

[41] See *Statement of EU ministers of finance on the Stability and Growth Pact in light of the COVID-19 crisis*, https://www.consilium.europa.eu/en/press/press-releases/2020/03/23/statement-of-eu-ministersof-finance-on-the-stability-and-growth-pact-in-light-of- the-covid-19-crisis/.

[42] See Decision (EU) 2020/440 of the European Central Bank of 24 March 2020 on a temporary purchase programme for the pandemic emergency (ECB/2020/17), which led to the purchase of public debt securities and private bonds for up to EUR 750 billion.

[43] In addition to the ordinary possibility of accessing the ESM (European Stability Mechanism), which is subject to strict conditions, it was decided at the European Council meeting of 23 April 2020 to set up a specific funding line for direct and indirect health expenditures related to the pandemic *(Pandemic Crisis Support*). This funding allows applicant countries to draw on resources equivalent to 2% of GDP.

[44] In addition to the resources provided, the Eurogroup decided to add a further EUR 2.7 billion from the European budget to support national health systems, to be increased through the activation of a "Recovery Fund", i.e., a temporary programme to support the real economy intended first and foremost for the States most affected by the crisis. See Eurogroup Conclusions of 9 April 2020, paragraph 19.

'soft law' acts, such as the Commission's proposal for a European instrument to tackle the unemployment risks presented by the COVID-19 pandemic [45]. In this context, the Commission has produced of a significant number of communications concerning a wide variety of aspects. These include communications with a general content intended to provide guidance to Member States, such as the one of 2 April on the use of EU resources to deal with the emergency (entitled 'Using every available euro in every way possible to protect lives and livelihoods')[46], but also others containing sector-specific guidelines, such as the Communication on coordinating the economic response to SARS-COV-2[47] or the Communication on the consequences of reintroducing border controls[48] which aims to help balance health protection against the functioning of the single market with regard to the transport and movement of goods.

4. *The allocation of health resources*

4.1. *The fundamental characteristics of decision-making processes*

In order to investigate the decision-making processes governing the *allocation of resources* in health care, it must first be considered that any allocation of resources - whether concerning personnel, goods or financial resources - presupposes choices regarding the distribution of means among alternative ends. This concept applies to the following decision-making processes that concern the definition of: the component of the state budget destined for healthcare; the component of the healthcare budget to be divided between the national and the regional levels; the part of the budget to be divided among the regions on the basis of normative criteria

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[45] European Commission, *Proposal for a Council Regulation on the establishment of a European instrument for temporary support to mitigate unemployment risks in an emergency (SURE) following the COVID-19 outbreak*, COM(2020) 139 final.

[46] See Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions. Response to the Coronavirus COM(2020) 143 final, *Using every available euro in every way possible to protect lives and livelihoods*, 2 April 2020.

[47] See Communication from the Commission to the European Parliament, the European Council, the Council, the European Central Bank, the European Investment Bank and the Eurogroup COM(2020) 112 final, *Coordinated economic response to the COVID-19 Outbreak*, 13 March 2020.

[48] See European Commission C(2020) 1753 final, *Guidelines for border management measures to protect health and ensure the availability of goods and essential services*, 16 March 2020.

(e.g., historical expenditure or standard cost[49]); the distribution of the regional budget within the single region among ASLs and competent bodies for the supply of services.

The following decision-making processes pertain instead to the definition of *priorities*: the distribution of resources between prevention, treatment and rehabilitation programmes; the distribution of resources between primary and specialized care programmes; the identification of criteria for access to care for the individual patient or the "quantity" of care to be reserved for the individual, once he or she has obtained access to the health service.

On the other hand, the following are considered *rationing* mechanisms: deterrence (e.g., co-payments, obstacles to accessibility); delay (e.g., waiting lists); deflection (e.g., no hospitalization without a request from the primary care physician); dilution (e.g., reduction of supply through reduction of quantity/quality of service); selection (e.g., treatment for patients with higher probability of success); interruption (of treatment); refusal (e.g., exclusion of a service from funding)[50].

Decision-making processes concerning resource allocation, prioritisation and rationing can be implicit or explicit and can take place at different decision-making levels, which may be macro, meso and micro levels. It is important to emphasise that each decision-making level has the concrete potential to impact on the other levels.

At the *macro level*, regional and national political actors decide how to allocate resources between different care areas and service providers. At the *meso level*, intermediary bodies such as health insurance funds, health agencies, health authorities and insurance companies decide on the distribution of funds among particular treatments and areas of care. At the *micro level*, health care professionals (and in particular, doctors) use their learning and experience to decide which treatments are to be carried out in a specific case, which patients are to benefit from them, in what progressive order they will benefit from them, and how much can be done in terms of use of resources and technology for each individual patient.

Explicit decision-making processes are characterised by public awareness of the criteria followed in decisions, the methodology, and the strategies followed to make decisions more inclusive, transparent and democratic. Explicit processes focus on defined principles, norms and values (e.g., clinical need, cost-effectiveness, justice, solidarity), which function as criteria for guiding decisions or as methods or strategies for making decisions more deliberative, transparent, inclusive and

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[49] For a specification of these criteria, see Chapter 3, paragraph 4.2.

[50] See S. Petrou and J. Wolstenholme, *A review of alternative approaches to healthcare resource allocation*, in Pharmacoeconomics, 2000, no. 1, pp. 33-43, esp. pp. 35 ff.

accountable.

By contrast, *implicit* decision-making processes are characterised by a lack of clarity and public awareness with regard to the actors involved, the criteria followed for the allocation and identification of priorities, the strategies and the aims of the decisions. Implicit processes are characterised by the lack of a clear method by which to identify priorities and strategies with which to address individual issues.

Running through this framework is the argument that public policy objectives in this area are most effectively achieved by '*muddling through elegantly'*[51]. Proponents of implicit decision-making processes know that excessive transparency of decision-making processes limits the ability to answer questions in a timely manner, as explicit decision-making processes may be too cumbersome from a procedural point of view and may be socially and politically divisive from a substantive and value-related point of view. However, it should be noted that implicit processes are increasingly subject to criticism because of the very high likelihood that they may be arbitrary, unfair, opaque and lacking the necessary accountability to legitimise decisions impacting the public budget.

4.2. *Criteria for allocating resources and setting priorities*

The criteria that impact healthcare allocation choices are manifold and relate to different areas. They include *legal criteria* (the constitutional definition of the right to health as a fundamental right or politically relevant objective in combination with the principle of formal and substantial equality); *clinical criteria* (scientific evidence of the effectiveness of treatments and appropriateness, in its many and varied modalities); *ethical principles* (individual autonomy, maximisation of individual well-being, personalism, justice/equity also with reference to intergenerational equity[52]); and *economic criteria* (cost minimisation, cost-benefit analysis, cost-effectiveness analysis, cost-utility analysis)[53].

With regard to identifying the meaning of the criteria listed here, it must be said that the right to health will be addressed in this discussion on several occasions and from different points of view. Here we can suffice by

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[51] See D. Mechanic, *Muddling through elegantly: Finding the proper balance in rationing*, in 'Health Affairs', 1997, No 5, pp. 83-92.

[52] N. Daniels, *Just health. Meeting health needs fairly*, New York, Cambridge University Press, 2008, pp. 161 ff.

[53] On the relevant aspects of health economics see N. Dirindin and P. Vineis, *Elementi di economia sanitaria*, Bologna, Il Mulino, 2004; N. Dirindin and E. Caruso, *Salute e economia. Questioni di economia e politica sanitaria*, Bologna, Il Mulino, 2019; O. Davini, *Il prezzo della salute. Per un sistema sanitario sostenibile nel terzo millennio*, Rome, Nutrimenti, 2013.

pointing out that the legal nature of the right to health is relevant in order to understand the protections that the individual legal system and health system provide in order to make this right effective in the context of scarce resources and the existence of potentially competing and conflicting subjective claims.

Clinical criteria include scientific evidence of the effectiveness and appropriateness of treatments. As we have seen, the criterion of scientific evidence about the effectiveness of treatments is also used at international and supranational levels, as well as by the Italian Constitutional Court in order to define the scope of healthcare services that the individual has the right to access[54].

Appropriateness, in turn, has become an increasingly important factor in the protection of the right to health. The concept of 'appropriateness' was introduced in the European context as a result of Recommendation No. 17/1997 of the Committee of Ministers of the Council of Europe to Member States on the development and implementation of quality improvement systems (QIS) in health care. The interpretations of appropriateness distinguish between 'clinical appropriateness', understood as the provision of medical care and interventions of proven effectiveness in contexts characterised by a favourable benefit-risk profile for the patient, and 'organisational appropriateness', concerning the choice of the most suitable methods of provision in order to maximise the safety and well-being of the patient and to optimise production efficiency and the consumption of resources.

As regards ethical criteria, explicit clarification concerning ethical models of reference is a fundamental aspect in the analysis of this topic[55].

The principle of individual autonomy is valued in contexts where liberal individualism prevails. As a result, at macro allocation level, the State is understood as not playing a key role and is therefore not called to intervene, leaving choices to the free market. This model is characterised by the absence of a public healthcare guarantee, minimal taxation, and the considerable development of the insurance sector. At the micro allocation level, the contractual relationship between doctor and patient is privileged and there may be a strict selection of those who gain access to care on the basis of their ability to pay.

Welfare maximisation and harm minimisation is pursued in systems where a utilitarian perspective prevails. At the macro allocation level,

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[54] For this aspect, see Chapter 3, para. 2.2, of this research report.

[55] See L. Palazzani, *Teorie della giustizia e bioetica: la questione della allocazione delle risorse sanitarie*, in *Verità e metodo in giurisprudenza*, edited by G. Dalla Torre and C. Mirabelli, Rome, Libreria Editrice Vaticana, 2014, pp. 497-514, especially pp. 499 ff.; L. Forni, *La sfida della giustizia in sanità. Salute, equità, risorse*, Turin, Giappichelli, 2016, pp. 103 ff.

priority is given to health sectors that allow for productive and efficient recovery at the expense of those considered marginal (such as the elderly, the terminally ill and the disabled). At the micro allocation level, there is a selection in favour of those with the greatest potential for social recovery and active life (QALY criterion, which stands for *Quality Adjusted Life Years*)[56].

The principle of justice/equity provides for a redistribution of limited resources that implies a significant intervention of the State both at macro and micro allocation levels. At micro allocation level, equity in access to care is affirmed, which implies the removal of barriers to access of various kinds. The personalist criterion insists on valuing human dignity. At macro allocation level, the allocation proposed should not neglect prevention and education for prevention, seeking a balance between distributive justice (criterion for regulating public relations through the distribution of existing resources) and commutative justice (criterion for regulating private relations through contracts and the restitution of goods in the event of an unlawful act)[57], which could lead to long-term cost savings. At the micro allocation level, the reference criteria are the seriousness of the disease based on clinical indications and urgency.

As far as economic criteria are concerned, as noted they are many and these are also used at several regulatory levels[58]. As we will see in the course of this analysis, resource allocation at the macro level employs a number of specific economic allocation criteria[59]. Here we focus on the economic criteria that can be applied both at macro and micro levels.

Cost minimisation evaluation is used when the health consequences of the interventions to be compared are identical in both quantitative and qualitative terms and the evaluation can only take into account the *inputs* (economic costs) while disregarding the *outputs* (health consequences) of the process[60]. In this context, the cost-effectiveness ratio for two services is the same and the lowest cost intervention is used. The aim of the cost

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[56] On the QALY methodology, please refer to the explanatory note at the end of section 4.3, (a.2), of Chapter 2.

[57] This *summa divisio* is traditionally traced back to Aristotle's *Nicomachean Ethics* (V, 3, 1131 a 10-1132 b 9).

[58] On economic evaluation criteria, see R. Levaggi and S. Capri, *Economia sanitaria*, Milan, Franco Angeli, 2010, pp. 110 ff.

[59] As for the total budget, it is allocated on the basis of various alternative criteria, such as historical expenditure or standard costs or per capita share. At the micro level, reimbursement per case treated can be identified on the basis of alternative criteria such as *fee-for-service*, per diem, or DRG *(Diagnosis Related Group*) criteria used for hospital services.

[60] With regard to costs, we refer here only to direct healthcare costs and not to direct non-healthcare costs (resources used by non-health care providers), nor to indirect costs (e.g., lost working days for healthcare treatment) or intangible costs (e.g., due to pain or stress).

minimisation evaluation is to identify the least costly way to achieve a given result in terms of intervention efficiency.

Cost-benefit analysis is used when the *outputs* and consequences of various health care interventions are expressed in monetary terms. The context in which the criterion is used is one in which several alternatives are possible and benefits must be weighed against costs. The aim is to be able to directly compare different alternatives (output measurement).

Cost-effectiveness analysis measures the relationship between the cost and its consequence (effect or effectiveness). It is used when the consequences of the interventions to be evaluated are related to a single common effect that may differ in magnitude between alternative programmes, but can be measured using the same natural unit of measurement (e.g., number of years of survival). The aim is to compare alternatives in terms of cost per unit of outcome (cost per life year saved).

Cost-utility analysis is used when the consequences of alternative options differ both in terms of quantity and quality of life. The aim is to compare alternatives in terms of cost per unit of utility (e.g., using the QALY index as a generic measure of output). Compared to a cost-effectiveness analysis, this technique makes it possible not only to measure the consequences in terms of years of life gained (effectiveness), but also to attach a value to the quality of those years of life gained. Cost-utility analysis operates in terms of utility, i.e., according to indices of individual or societal preference for health outcomes (e.g., QALY). The QALY is a summary index, but it is not the only one: another example is the *Healthy-Years Equivalent* (HYE), albeit one that is less widely used in the literature[61].

[61] See S. Birch, *Economics, health and health economics*: *HYE's versus QALY's*, in Journal of Health Economics, vol. 12, 1993, No 3, pp. 325-339. Ultimately, a number of benefits are linked to these criteria, such as life years gained (cost-effectiveness analysis), healthy life years (cost-utility analysis) and benefits expressed as willingness to pay (cost-benefit analysis).

Chapter Two

The main European experiences in health resource allocation and priority setting

by Alessandra Cerruti and Caterina Di Costanzo

1. *The international scene*

The problem of optimal allocation of scarce resources in the health sector emerged globally in the 1990s, although some countries had already started to reflect on this issue in the second half of the 1980s. In Europe, Norway led the pack. In Norway – as will be explained more fully in the remainder of this chapter – the first National Priorities Commission was established in 1985 to adopt explicit principles for the rationalisation of resources in the health sector. At almost the same time, in the United States one of the best-known cases in the literature on resource allocation was developing, which brought to light the problems associated with the literal application of economic analysis techniques in health care: the *Oregon Health Plan reform process*[1].

During the economic crisis of the late nineteen-eighties, a special commission (known as the "E-Commission") was convened to discuss the consequences of a health reform proposal that was supposed to achieve substantial savings by cutting funding in some areas of care. On the basis of a utilitarian assumption, one of the programs to be cut concerned public funding for organ transplants. Calculations showed that reallocating the expenditures that would be used to transplant 34 patients in one year would make it possible to extend free basic health care to 1,500 people from the poorest social strata, including many children. This meant that the overall benefits obtained by the new patients would exceed the benefits enjoyed by transplant recipients, at the same cost to society. This reasoning, however, became the object of severe criticism on ethical grounds, particularly in connection with the case of a seven-year-old boy,

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[1] See L. Jacobs, T. Marmor and J. Oberlander, *The Oregon health plan and the political paradox of rationing*: *What advocates and critics have claimed and what Oregon did*, in Journal of Health Politics, Policy and Law, vol. 24, 1999, no. 1, pp. 161-180; P.A. Glassman, P.D. Jacobson and S. Asch, *Medical necessity and defined coverage benefits in the Oregon Health Plan*, in Health Law and Ethics, vol. 87, 1997, no. 6, pp. 1053-1058.

Coby Howard, who was suffering from leukaemia and whose survival depended on a $100,000 bone marrow transplant procedure; by virtue of the cuts decided upon, this amount could not be covered by public funds[2], and Howard died in December 1987 after his parents had failed to raise the necessary amount of money for the operation through donations. His story received considerable media coverage, prompting the E-Commission to reopen the debate on transplants, although in the end the commission reaffirmed its decision to reallocate transplant funds.

Nonetheless, in 1989 this dramatic episode led to the establishment of a second commission, the Oregon Health Services Commission (OHSC), charged with drawing up a list of services with priority indications to be used in deciding the programmes to which public funds should be allocated[3]. The first attempt revealed the perverse effects generated by the application of the economic criterion of cost-effectiveness[4] only. A few years later, in 1994, this criterion was combined with social considerations to produce a second list of clinical condition-treatment pairs in order of priority, that would guide the financial decisions of the state legislative assembly, with the resulting savings to allow health care to be extended to citizens who were previously not beneficiaries of it[5].

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[2] L. Jacobs, T. Marmor and J. Oberlander, *The Oregon health plan and the political paradox of rationing*: *What advocates and critics have claimed and what Oregon did*, cit. p. 167.

[3] H. Allen, K. Baicker, S. Taubman, B. Wright and A. Finkelstein, *The Oregon health insurance experiment*: *When limited policy resources provide research opportunities*, in Journal of Health Politics, Policy and Law, vol. 38, 2013, no. 6, pp. 1183-1192, esp. p. 1187.

[4] In 1991, a first draft of the list, elaborated on the basis of a standard cost-effectiveness approach, consisted of approximately 1,600 items, identified by linking a specific condition to each service and attributing to it a score derived from the application of a series of parameters such as: expected net benefit (BN) expressed in percentage terms; expected duration of the benefit (DB) expressed in years; and unit cost of the treatment (CT), for which the priority score was assigned by applying a specific algorithm (CT/BN x DB). However, a number of paradoxes emerged; first and foremost, the fact that the counting technique proved to result in unreasonable and socially unacceptable results (for example, dental crowns scored higher than appendicitis). On this point, see M.N. Baur, J.B. Wang and J.F. Fitzgerald, *Insurance rationing versus public political rationing*: *The case of the Oregon Health Plan*, in Public Budgeting & Finance, vol. 16, 2004, no. 1, pp. 60-74, p. 62.

[5] The publication in 1994 of this second list was the result of a complex process at the end of which the various health services were placed in one of 17 general categories, according to the criterion of the expected net benefit to be obtained. These categories were elaborated and then in turn aggregated into three groups: essential services, life-sustaining services, maternity services, preventive services for children and adults, care and comfort services for the terminally ill, very important services (categories 1-9); treatment for non-fatal conditions for which there is a possibility of full or partial recovery and life-enhancing treatment, important services (categories 10-13); and services for non-fatal conditions for which treatment only accelerates recovery, infertility services and services that only slightly improve quality of life (categories 14-17). Finally, the list was revised and corrected according to three general principles: the number of persons to which a given treatment

The Oregon experience showed the importance of integrating social and economic considerations in identifying the degree of benefit expected from a given treatment, in order to classify the benefit in terms of its greater or lesser effectiveness from the point of view of the individual and the community. However, it also highlighted the inherent limitations of the tool of the prioritised service list. No list can be applied automatically without an assessment of the actual condition of the individual patient. In practice, this made the individual health professional responsible for (and gave them a certain margin of discretion in) deciding and verifying, albeit on the basis of guidelines and scientific evidence, that the treatment was being provided appropriately and effectively in relation to the individual's actual health needs.

Another case that received considerable attention at international level is that of Canada. In spite of extensive decentralisation and autonomy granted to the provinces and territories of the federation (there appear to be thirteen different health systems in place), the federal and provincial levels of government share responsibilities and competences for the regulation and financing of the health system[6]. The health care system is a mixed public-private system, and most Canadians have health insurance that covers a wide range of health care goods and services not covered by the public sector, particularly non-hospital pharmaceutical prescriptions and treatments that are not considered urgent and clinically necessary, such as dental care. Hospital care and primary care are provided by each province and territory to the citizens through general practitioners in the form of *medically necessary* services. These are provided free of charge, while the others are left to the free market, which determines access to the services according to its own criteria and also affects equality of access to health care and quality of care[7]. As a result of these limitations in the basket of services provided by the public sector, some categories of patients are in fact more exposed to the risk of not being able to access them; in particular, people with disabilities, people with critical illnesses and people in difficult economic circumstances face numerous problems with regard to the purchase of goods and services that are not available in the hospital setting.

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pertained; the importance of a certain service from the point of view of the collective interest; and the adjustments resulting from the application of the cost-effectiveness criterion.

[6] *The Constitution Act*, 1867, 30 & 31 Vict., c. 3 (UK).

[7] On the Canadian system see C. Milani, *La sanità in Canada*, in Saluteinternazionale.info, 12 July 2017, available at www.saluteinternazionale.info/2017/07/la-sanita-in-canada; S. Lewis, *A System in Name Only. Access, Variation, and Reform in Canada's Provinces*, in New England Journal of Medicine, vol. 372, 2015, pp. 497-500.

As a result, an estimated 32% of Canadians who do not have private insurance may face a situation where they have to forego treatment (especially dental treatment), or seek out low-cost providers, with a possible corresponding reduction in the quality of care. It should also be noted that in the delicate area of mental health care, which has experienced a gradual shift from institutionalisation to community-based care, the lack of comprehensive coverage has given rise to a substantial barrier to accessing home-based care.

There is no legal provision establishing the boundaries and criteria for identifying the scope of treatments viewed as medically necessary. Decisions on which treatments are included in the basket of services provided by the public programme ("MEDICARE") are left to the provinces and are normally the result of annual cost negotiations between the provincial medical associations and the provincial offices of the Ministry of Health. These negotiations focus on the possibility that the following year's costs for the basket of services will increase or decrease compared to the past year. From year to year, therefore, key considerations concern cost adjustments, but not the re-evaluation or redefinition of the types of services to be considered minimum or essential.

Since 1982, the Constitution of Canada has incorporated the Canadian Charter of Rights and Freedoms. In paragraph 24, para. 1, the Charter states that any person who sees their rights violated “may apply to a court of competent jurisdiction to obtain such remedy as the court considers appropriate and just in the circumstances.” Although there is no explicit reference to the right to health, in the past Canadians have referred to other paragraphs of the Charter to challenge limitations on public spending aimed to guarantee the basket of services, with special reference to the right to life, liberty and security of the person guaranteed under paragraph 7 and the rights of equality under paragraph 15. Paragraph 7 is commonly interpreted as providing for negative obligations against state interference in fundamental aspects of citizens' lives, or as providing for positive obligations on the part of the State to assist citizens in guaranteeing the necessities that contribute to a safe and autonomous life. Paragraph 15 may be invoked in resource allocation matters where a province makes decisions that allow access to a service in favour of one group or category of users and exclude another on the basis of unreasonable criteria. This explains the wealth of Canadian jurisprudence about guaranteeing the right of access to care in a context of scarcity of resources, which has generally confirmed the exclusion of certain services from the basket of services, justifying them as political and economic choices aimed at safeguarding scarce resources and the sustainability of the system in the long term[8].

[8] Of particular note are the following judgments: the *Eldridge* case *(Eldridge v. British*

In New Zealand, despite attempts made in the 1990s, there is no national list of guaranteed services. The mixed health care system, mostly financed through general taxation (about 73% of total health care expenditure), is often referred to in the literature along with the two cases mentioned above. Here, access to services is provided on an equal basis using the criteria of need and urgency rather than on the basis of the ability to pay for a given service, although some out-of-pocket expenditure remains (9%) and a small insurance sector has developed (5% voluntary, 13% compulsory)[9].

In the absence of an explicit list (*minimum basket* or *core services*)[10], the services guaranteed by the public sector are allocated through the decisions made at different levels of the New Zealand system: the Ministry of Health sets the budget and a specific ceiling of expenditure for the three macro-categories of services to be provided (public health, health care, services for the disabled), and this budget is then shared among the 20 District Health Boards (DHB) on the basis of a formula derived from the existing health risks and demographics of the area. The districts' own areas of responsibility include the planning and provision of services and the operation of public hospitals, making them responsible for secondary care.

Columbia (Att'y Gen.), [1997] J3 S.C.R. 624, (Cm1.)), in which the Supreme Court, partly because of the low cost of the service (para. 92), established the right of deaf and mute patients to access a sign language mediator in a public hospital; the *Cameron* case *(Cameron v. Nova Scotia (Att'y Gen.)*, [1999], 204 N.S.R. (2d) 1, (Can. N.S. e.A.)), in which the Court denied the qualification of *medically necessary* treatment to in vitro fertilisation because the "costs, the limited success rate and the risks do not, at this time, rank sufficiently high to warrant payment for them from public funding " (para. 87); the *Auton* case *(Auton v. British Columbia (Att'y.Gen.)*, [2004] 3 S.C.R. 657 (Can.)), concerning the funding of schooling programmes for autistic children (subsequently provided by most provinces), which led to a declaration of self-restraint by the Court in the face of a decision that was part of the fundamental political and economic policy choices of the province, in view of the "financial concerns and competing claims on insufficient resources" as well as the "emergent nature of the recognition that [the treatment] was appropriate and medically required"(paragraph 60); and the *Hogan* case *(Hogan v. Ontario* (Health and Long- Term Care, 2006 HRTO 32 (CanLII)), which denied the discriminatory nature of the allocation decision that had removed gender reassignment surgery from the province's list of benefits, declaring it was "integral to the cost-cutting means to preserve the health care system for the long term" (paragraph 103).

[9] OECD, *Health at a Glance 2017: OECD indicators*, Paris, OECD Publishing, 2017, pp. 131 ff.

[10] During the healthcare reform period in the 1990s, a public debate developed on the definition of essential and non-essential services. The Ministry of Health appointed a Core Service Committee to carry out a series of public consultations on the subject, in order to decide whether the list of services should be positive or negative (as in the UK) and contain all clinically effective services. In the latter case, the criterion for access to services would have been the availability of funds and, in the event of unavailability, the citizen would have been left with the alternative of requesting the service from a private provider or opting out of treatment.

They are also responsible for the purchase of primary care by local communities and primary care providers through service agreements. Each year, the DHB negotiates an annual plan with the ministry based on the expected management results for each year and the expected performance of district hospitals and district services. In order to decide how to allocate the budget made available at central level, the districts are required to produce an assessment of the health needs of the reference population and an indication of spending priorities, this in order to decide which services to provide directly and which to buy, and to negotiate service agreements with primary care providers. Each DHB is further required to develop its own set of principles and guidelines for resource allocation.

In 1992, the New Zealand Guidelines Group, with the National Health Committee's support, played a key role in promoting the development and implementation of clinical guidelines based on scientific evidence. The aim was to make explicit which services were provided by the health service and which were not included. Guidelines were designed as non-binding tools to support professionals in deciding priorities for treatment between patients within a given service area, rather than as tools for allocating resources between services. The Group completed its work by identifying as essential those services that were in fact already publicly financed, a decision that was the result of decades of common sense and decisions based on fundamental principles[11]. The approach adopted aimed at specifying under what circumstances treatment should be considered appropriate, because no treatment could be excluded a priori. The criteria for identifying appropriate services related to clinical effectiveness, cost-effectiveness, rational use of resources and compatibility with community values[12]. The Group then began to develop guidelines for those services that were of general relevance, had high unit costs and were being provided in large volumes.

A number of precedents from case law on access to care in a context of scarce resources highlight the critical issues that have arisen in the application of the guidelines since the 1990s[13]. Two of these in particular *(South Auckland Health Hospital* and *Shortland*) concern the denial of dialysis treatment for patients with severe renal failure. In the first, which was resolved by the management of the hospital before it came to a legal

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[11] New Zealand National Advisory Committee on Core Health and Disability Support Services, 1992, p. 63.

[12] New Zealand National Advisory Committee on Core Health and Disability Support Services, 1994, p. 7.

[13] See C.M. Flood and I. Essajee, *Setting limits on healthcare: Challenges in and out of the Courtroom in Canada and Down-under*, in Rationing health care. Hard choices and unavoidable trade-offs, edited by A. den Exter and M. Buijsen, Antwerpen-Oxford, Maklu Press, 2012, pp. 193 ff.

decision, the guidelines were declared discriminatory on the basis of the unreasonable use of the age criterion, stating that "in usual circumstances, persons over 75 years are not likely to be accepted onto a... dialysis programme."[14] In the second[15], another hospital decided instead to interrupt dialysis in accordance with the regional guidelines, which provided for the allocation of resources on the basis of the capacity to benefit from the treatment, generally requiring a prognosis of more than two years of life for admission to the dialysis programme. In this case, the survival of the patient, who also suffered from diabetes and moderate dementia, would have been extended by one year only and the individual was considered incapable of actively cooperating in his therapy, which by definition placed him outside the exceptions provided for by the guidelines. The family's request for a review of the decision to exclude him from treatment was rejected by the court and shortly afterwards the patient died. This decision is noteworthy because the Court of Appeal, in upholding the non-admission to the dialysis programme, emphasised the clinical rather than the administrative nature of the decision: the guidelines, on the basis of which the treatment was refused, were primarily clinically based and the assessment of the use of economic resource allocation considerations were found to be of only minor relevance[16].

2. *Key European experiences: analysis of systems and their allocation and priority-setting strategies*

In spite of the influence of the international experiences that were illustrated above and the debate that started in Scandinavia, the experiences developed in the main European countries have followed autonomous paths. Their detailed analysis will be presented in the following sections and the discussion (in the order in which the examples

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[14] The case is cited more extensively in J. Manning and R. Paterson, *Prioritisation*: *Rationing health care in New Zealand*, in Journal of Law, Medicine and Ethics, vol. 33, 2005, no. 4, pp. 681-697.

[15] *Shortland v. Northland Health Ltd*, [1998] 1 NZLR 433.

[16] See *Shortland v. Northland Health Ltd*, [1998] 1 NZLR 433. The Court's decision came at a salient moment in New Zealand, during the wave of criticism that followed the reforms of the 1990s. For this reason, the decision was interpreted as an attempt to provide reassurance on the sustainability and economic viability of the health system and to preserve the public's confidence in the capacity of the system to provide an appropriate response to the health needs of the population (J. Manning, *Litigating a right to health care in New Zealand*, in The Right to health at the public/private divide. A global comparative study, edited by C.M. Flood and A. Gross, New York, Cambridge University Press, 2014, pp. 19-49, esp. pp. 40 ff.).

are listed here, with the exception of Italy, to which the next chapter is dedicated in full) will include both systems ascribable to the Beveridge model (Scandinavian countries, the Great Britain, Spain and Italy) and systems ascribable to the Bismarck model (Germany, Switzerland and France)[17]. A first aspect that emerges from the comparison is precisely the impossibility of establishing a link between the different strategies for allocating resources and defining priorities, and the two classic models used to describe health systems.

The following sections present a comprehensive analysis of the health systems considered, with special subsections devoted to peculiar aspects deemed necessary for the overall understanding of the system but less relevant if the reader's attention is specifically focused on allocation systems. The analysis of each country is divided into four paragraphs devoted to: the national framework - and the constitutional principles on which it is based – viewed against the international landscape and the identification of the fundamental stages of its development; the description of its organisation and financing mechanism; the identification of key authorities and actors in allocation decision-making processes; and a specific focus on the allocation of resources and the definition of priorities

[17] The Bismarck model and the Beveridge model are the two main macro-families of systems in Europe that guarantee, in essence, universal or near-universal access to health care. The two models differ in terms of who finances the system, who provides the services, and the distribution of responsibilities for legislation, planning, production and service delivery. The Bismarck model, as the name suggests, was instituted by Otto van Bismarck in the second half of the 19th century and is based on compulsory social insurance. The State has a role in controlling competition, legislating in this area and providing subsidiary support for the system, usually for the less affluent. The Bismarck model is based on the principle of insurance that guarantees workers and their families health coverage based on their contributions. In this case, it is the compulsory contributions paid by employers and employees that finance the whole health system. The Beveridge model, which became the model for the basic characteristics of European national health systems, is based on the principle of financing the health service through general taxation and was established by William Henry Beveridge, a Keynesian social economist. Towards the end of 1942 he presented first to the British government and then to the press the final report of the work of a commission that had been charged with undertaking "with special reference to the inter-relation of the schemes, a survey of the existing national schemes of social insurance and allied services, including workmen's compensation, and to make recommendations." The *Report on Social Insurance and Allied Services*, known as the Beveridge Report, addresses the issue of the relationship between destitution and need, as well as aspects such as "disease, ignorance, squalor, idleness" and states that "social security must be achieved by co-operation between the State and the individual. The State should offer security for service and contribution. The State in organising security should not stifle incentive, opportunity, responsibility; in establishing a national minimum, it should leave room and encouragement for voluntary action by each individual to provide more than that minimum for himself and his family". Cf. Beveridge, William, *Social Insurance and Allied Services*, British Library.

in health in the country considered. Where necessary, due to the breadth of the topic the final paragraph will be further divided into subsections, in order to illustrate specific allocation methods and national case law, as in the case with the guidelines developed by the British National Institute for Health and Care Excellence (NICE) and the debate on the rationing of healthcare resources in the Swiss Confederation.

At the end of each analysis, a concluding paragraph sets out the essential features of the various experiences analysed with exclusive reference to allocation and prioritisation strategies, attempting to establish relationships between them and to outline allocation models, placing each individual country within the corresponding category.

3. *Scandinavian countries (Sweden, Norway, Denmark)*

3.1. *Underlying philosophy and evolution*

For the purpose of this analysis, the Scandinavian countries include Sweden, Norway and, due to cultural and historical affinity, Denmark. These are the Northern European countries most commonly associated with a specific welfare system that is often qualified as social democratic[18], universalistic[19] or *Beveridgian*[20]. Other classifications have emphasised the Scandinavian specificity, identifying its distinctive features compared to the Anglo-Saxon model in the guarantee of universal access to all social security services and in the financing through tax revenues of all social services (not only health services)[21]. The Scandinavian system has also been classified in the past as institutional-redistributive, to distinguish it from the so-called "residual models", characterised by the subordination of public intervention to the failure of the market and families to satisfy needs, and from meritocratic-occupational models, in which state intervention is typically complementary to that of the market because the identification of recipients of benefits is linked to their participation in the

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[18] We follow here the classic taxonomy of G. Esping-Andersen, *The three worlds of welfare chieftaincy*, Cambridge, Polity Press, 1990. In the same vein, see also the more recent contribution on the Scandinavian social democratic model by J.D. Stephens, *The Scandinavian welfare States: Achievements, crisis, and prospects*, in Welfare States in Transition, edited by G. Esping-Andersen, London, Sage, 1996, pp. 32-65.

[19] Cf. M. Ferrera, *Modelli di solidarietà. Politiche e riforme sociali nelle democrazie*, Bologna, Il Mulino, 1993, which distinguishes between universalist and occupational systems, based mainly on the way in which services are accessed.

[20] In this case it is associated with the English system, which according to Esping-Andersen's classification belongs to the liberal welfare regime, together with the United States, Canada and Australia.

[21] M. Ferrera, *Le politiche sociali. L'Italia in prospettiva comparata*, Bologna, Il Mulino, 2006.

labour market[22].

In essence, the Scandinavian model is characterised by the organisation of a compulsory public care system mainly supported through general taxation and based on the principle of universalism in access to services. Social benefits (including health care) are in fact guaranteed to citizens and to all those who are legally resident in their respective national territories, regardless of their employment and socioeconomic status or location[23]. The system is explicitly based on values of participation, equality and social solidarity. The redistributive and solidarity-based aspiration that drives it is particularly evident in Sweden, where it has often been a driving force for the development of the entire Scandinavian area and where this aim has been clearly defined at regulatory level and is still part of the fundamental objectives of the health service listed in the Swedish Health and Medical Services Act. Although the Swedish Constitution does not expressly mention the right to health, it does establish a classic model of the welfare state, where the activity of public authorities is aimed at ensuring the well-being of the citizens (Article 2 of the 1974 Instrument of Government). The services are mostly provided free of charge or financed through state subsidies. Consequently, in all these countries, health expenditure (which on average represents about 10% of the respective GDP) represents a significant portion of each country's overall spending.

Lastly, the peculiarity of the Scandinavian case compared to other systems inspired by Beveridgian principles, is the traditional responsibility of local authorities in the planning, financing and provision of health services, according to a decentralisation model that reached its peak in the 1980s, but which in Sweden has its roots in the second half of the 19th century[24].

The main reforms in the Scandinavian countries

Starting in the 1990s, some of the qualifying aspects of this approach to health began to be questioned and at the beginning of the new millennium this led to a flourishing of numerous reform initiatives in all the Nordic countries. On the one hand, the global growth slowdown and the challenge

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[22] R.M. Titmuss, *Social policy*: *An introduction*, London, Hyman, 1974.

[23] In Norway, the Patients' Rights Act of 1999 (sec. 1-2) guarantees to all residents equal access to good quality care. In Sweden, the Health and Medical Services Act establishes county responsibility for all permanent residents, but commits regional institutions to promoting the health of all residents (sec. 3).

[24] M. Gaggero, *Tendenze di centralizzazione e garanzie di efficienza nel modello sanitario scandinavo*, in Sistemi costituzionali, diritto alla salute e organizzazione sanitaria, edited by R. Balduzzi, Bologna, Il Mulino, 2009, pp. 173-188, esp. p. 175.

ageing populations present to national healthcare systems have brought to light the issue of the financial sustainability of care models typically characterised by very high public expenditure. It should also be noted that the Scandinavian countries' populations are currently among the longest-living, not only in Europe but worldwide. On the other hand, the combined effects of the recession experienced by the northern economies in the early 1990s and the need to comply with the Maastricht parameters in order to access the various phases of the economic and monetary union have further reduced the ordinary amount of resources available for welfare, and in fact led to a temporary reduction in national social spending, which also partly affected health spending (see Luiss Lab on European Economics, *Il modello di sviluppo dei paesi scandinavi,* Rome, LUISS, 2005, pp. 55 and 63). In Norway and Sweden, the ratio of health expenditure to GDP fluctuated sharply in the 2000s, eventually settling around the European average; Denmark, on the other hand, has experienced more regular growth and now has an above-average level of expenditure (European Observatory on Health and Policies, *Denmark*: *Health System Review*, in Health Systems in Transition, vol. 14, 2012, no. 2, p. 55, fig. 3.2).

In all the Scandinavian countries, the containment of healthcare costs has been accompanied by a significant process of reorganisation of the system inspired by the dictates of New Public Management. This is an approach to public management that arose in the United Kingdom at the end of the 1980s, which aims to achieve higher levels of effectiveness and efficiency in the management of public administrations through the adoption of decision-making logic and operational tools used in the private sector and in management contexts (cf. A. Scaletti, *Il controllo economico delle aziende dei sistemi sanitari regionali*, Turin, Giappichelli, 2010, pp. 1-10). The impact of this process has been different in each of the countries of this area, but everywhere it has focused on the pursuit of fiscal efficiency, on the corporatist evolution of hospital management and on placing greater responsibility on the recipients of the service (J. Magnussen, K. Vrangbaek, R.B. Saltman and P.E. Martinussen, *Introduction: The Nordic model of health care*, in *Nordic health care systems*: *Recent reform and current policy challenges*, edited by J. Magnussen, K. Vrangbaek and R.B. Saltman, New York, McGraw Hill, 2009, pp. 3-20, esp. p. 4). A number of reforms have widened the scope for private operators to intervene in the provision of a range of healthcare services. Examples of this trend include the liberalisation of pharmacies in Norway in 2001 and, in Sweden, the competition between public structures for the provision of primary care and private for-profit operators (the latter being actually favoured by precedence in the access to public funding under the Free Choice Act of 2009). There have also been numerous reforms aimed at making the role of patients more active, both by emphasising their freedom of choice between providers and by codifying their rights. The inclusion of the right to choose

within a list of patients' rights explicitly recognised by the legal system has thus been accompanied by the introduction of principles aimed at reducing this freedom in specific sectors (such as the hospital sector in Denmark in 1993, and basic medicine in Norway in 2001) or linking it to the inefficiencies of the public provider (as in Sweden and Denmark where it is now linked to the waiting list instrument). In fact, after their creation in 1993, the right of patients to seek treatment in private clinics and hospitals at home or abroad was established in Denmark in 2002, whenever the wait for access to the same treatment in the public sector was longer than two months (later reduced to one month). The Swedish approach is similar: since 2005, a minimum standard of waiting time has been guaranteed by law (immediate contact in the event of an emergency, 7 days for a general practitioner's visit, 90 days for a specialist diagnosis and a further 90 days for post-diagnosis treatment); if this waiting time is not respected, the citizen is authorised to turn to another *Landsting* or to private operators at the expense of his or her own *Landsting*.

Lastly, these trends have led to the specialisation and concentration of services, especially in the hospital sector, and in some cases also to higher levels of government focusing on them, in order to cope with the rising costs of treatment due to technological innovation and resource constraints. In this context, the Danish health system underwent a profound structural reform in 2007, which greatly reduced the number of regional and municipal authorities (European Observatory on Health and Policies, *Denmark*: *Health System Review* (2012), cit., pp. 144-146). The hospital sector was absorbed into the state level in Norway in 2002 and has undergone a marked process of corporatisation. In Sweden, on the other hand, where the push for decentralisation had been even stronger from the 1970s to the early 1990s, centralising tendencies finally gained ground with varying degrees of success across the country, given the wide autonomy of municipalities. The process of re-centralisation, which began in 1999 with the experimental creation of two regions *(Region Skåne* and *Västra Götalandsregionen*) and which should have proceeded with the aggregation of the remaining municipalities into a limited number of regions, each with a population of between one and two million, has, however, suffered a setback and has attracted fierce criticism for the loss of democracy that it would have entailed. However, due to the peculiarities of the Swedish territory and its low population density, attempts at centralisation continue to be met with reservations and the opposition of the population. Most recently, in July 2015, a project that would have reduced the number of regions and counties to 6 was abandoned (see the stages of this reform attempt reported in G.G. Carboni, *I sistemi di welfare alla prova delle migrazioni: il caso della Svezia*, in Rivista AIC, 2018, No 2, p. 9).

As a result of all these reforms, the main problem facing many of the

Scandinavian countries today is ensuring equity of access to health services, which was inherent to the traditional model but which has been severely affected by the partial privatisation of care and the gradual movement of the population from rural locations to more densely populated areas. Nevertheless, the values of solidarity, universalism and de-commoditization that characterise this model have not been significantly altered (A. Bergmark, *Market Reforms in Swedish Health Care*: *Normative Reorientation and Welfare State Sustainability*, in Journal of Medicine and Philosophy, 2008, no. 33, pp. 241-261, esp. p. 258).

3.2. *Organisation and financing of the health system*

Scandinavian health care systems are traditionally decentralised, with responsibilities spread across three administrative levels (state, regional and local) that are directly responsible for the provision of different types of health care using their own funds. In the 1990s, however, the push for centralisation started to gain momentum and exhibit varying degrees of staying power (more in Norway and Denmark, less in Sweden).

In all three countries, health expenditure accounts for more than 9% of GDP[25] and is predominantly public[26]. In Norway, 72% of health funding comes from general taxation, while in Sweden and Denmark taxation accounts for an even larger share. The private insurance sector is not very significant and, where it exists, its use is motivated by the desire to ensure faster access to outpatient specialist visits, to avoid waiting times for non-urgent treatment, or to provide cover for treatment excluded from the health service (typically dental treatment). However, over the past decades, the model of health financing in these countries has changed considerably, especially in Norway and Denmark, where regional taxes have been eliminated and the responsibility for financing specialist hospital care was transferred to other levels of government (state in the case of Norway, municipal in Denmark). Moreover, at hospital level, in parallel with the strengthening of patients' freedom of choice, the model of remuneration of services based on *Diagnosis Related Group* (*DRG) based financing*[27] has been

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[25] More specifically: 9.1% in Sweden, 8.9% in Norway (where the GDP is in fact much higher than in the other Scandinavian countries) and 11% in Denmark.

[26] 81.7% in Sweden, 84% in Norway and 80% in Denmark.

[27] As is well known, the system was created in the United States in the 1980s. It consists of classifying discharged patients on the basis of homogeneous groups according to resource absorption and thus makes it possible to quantify and remunerate the expenditure incurred by each facility. Only Denmark has recently reverted to a traditional system of untied, automatic and sectoral transfers (block grants) and did not adopt the Nordic DRG model (*Nord-DRG*) but instead developed two national versions, one for inpatient care (*DkDRG*) and one for outpatient care (Danish Ambulatory Grouping-System).

introduced in all the Scandinavian countries, often in combination with *Activity-Based Financing* (ABF)[28].

Service delivery and financing in Sweden

In Sweden, the traditional self-government of local communities has its roots in the 19th century. Codified in the Constitution of 1974, this normative, organisational and financial autonomy is currently regulated by the Local Government Act *(Komunallag SFS*, Act No 900 of 13 June 1991), which, since 1992, has laid down the tasks of counties, municipalities and their elected bodies, seeking to strengthen the influence of the central government authorities, achieve better coordination of services and reduce territorial inequalities. However, in Sweden the form and quality of care are also influenced by the geographical location of the patient as well as by the length of waiting lists, which delay access to services in some areas; for this reason, as in Great Britain, the healthcare system in Sweden is sometimes referred to as the "postcode lottery" (cf. Carboni, *I sistemi di welfare alla prova delle migrazioni: il caso della Svezia*, cit., p. 10, footnote no. 50).

At the central level, overall responsibility for health policy lies with the Ministry of Health and Social Affairs (*Socialdepartementet*), which is accountable to Parliament (*Riksdag*) for the results achieved by the National Health Service in relation to the objectives set by the legislative body. It is flanked by the National Institute of Public Health (*Folkhälsoinstitutet*), which is in charge of monitoring and evaluating public policies, and seven other government agencies that are competent on specific areas of intervention and which implement regulatory acts under their own responsibility but subject to monitoring and evaluation by the Government, in accordance with the laws of Parliament and government guidelines.

At regional level, health care is the main activity in the 21 counties (*Län*) into which the country is divided. In fact, despite the experimental merging of several counties into two regions in 1999 and the opinion expressed in 2007 by a special national committee in favour of replacing the county councils with 6-9 regions and transferring responsibility for the hospital sector to the central government (as happened in Norway in the same years), this transfer of competences did not take place. Traditionally, county councils have been responsible for hospital care, and by the end of

[28] This implies that a fraction of the sectoral transfers traditionally provided by the State to the counties will be replaced by transfers with a percentage of co-financing from the regional level of government, which will be commensurate with the quantity and type of hospital treatment provided and recorded in the DRGs.

the 1970s they were overseeing almost all health services. Many of them, however, were transferred to lower levels of government through a series of legislative initiatives, inaugurated by the 1992 Ädel reform, aimed at containing costs and integrating health and social services, the responsibility for which already fell on municipalities. As a consequence, the care of children, elderly people and people with physical and mental disabilities now falls under the municipality in which they live; the local government level is made up of the country's 290 municipalities. The provision of primary care is the responsibility of this local level of government. At night and on public holidays, the service is provided by the *Närakut*, a kind of out-of-hours medical service, while during the day it is possible to go to the offices of general medicine specialists (*Vårdcentral*) organised at municipal level, accessible to citizens on the basis of the principle of free choice between both public and private providers.

The county councils, regions and municipalities are then in turn grouped into 6 health zones (*Sjukvårdsregionen*), which each serve a population of approximately one million people and were created in order to facilitate cooperation between the counties responsible for specialised medical care (Stockholm region, South-Eastern Region, Southern Region, Western Region, Uppsala-Örebro Region and Northern Region). The size of the individual health zones varies widely, due to the concentration of the Swedish population along the coasts and in large population centres, especially in the south of the country (for example, the Northern Region has a population of less than one million but covers about half the nation's territory). Each health zone operates at least one regional public and university hospital, which provides highly specialised or technologically advanced care. The decision to concentrate these services in a few facilities is intended to develop and maintain a high level of clinical expertise. In 2011, this goal also guided the creation of six specialised services at regional level for the prevention, treatment and care of cancer patients at all stages of the disease (*Regional Cancer Centres*, RCCS). In addition to the seven university hospitals, there are 70 other hospitals that are run directly by the individual counties and which are mostly public, and provide specialist services and outpatient somatic and psychiatric care. More than half of these facilities offer mainly emergency services (*Akutvård*); one-third are local hospitals with more limited emergency and specialist services. Due to the low population density of large parts of Sweden, local hospitals have resisted the trends throughout the 1990s and 2000s that have directed the hospital sector towards greater centralisation and a substantial specialisation and differentiation of services.

The 2009 reform of the Health and Medical Services Act (brought about by the Free Choice Act) made the principle of free patient choice legally binding in identifying primary, specialist or hospital care facilities, while at the same time giving full freedom of establishment to all private facilities

accredited by county councils. This has led, on the one hand, to the proliferation of private facilities dedicated to primary care (especially in the city areas and in the capital; cf. P. Gobbi, *Il modello di welfare scandinavo: è ancora un'eccellenza?* in International Journal of Nursing, 2013, no. 8, pp. 15-19, spec. p. 17) and, on the other hand, the conclusion of agreements between regional governments and the Ministry of Health and Social Affairs, in order to regulate the financial flows resulting from the use of services in a county different from that of the patient's residence. The Swedish act provides that if predefined standards of assistance are not met by the public structures in charge, the citizen can turn, at the expense of the *Landsting* in their place of residence, to private structures that may be present in their county or even located in another county.

However, dental treatment is not covered by the health service (except for children and young people under 20 years of age) and is therefore provided for a fee, albeit with partial reimbursement by the state, by the national dental service, hospital dental emergency rooms or private dentists.

As for the financing of the health system, this comes primarily from taxation, which (as in the other countries of this area) is articulated both at central government level (with successive transfers from the centre to the periphery) and at local level, where both municipalities and counties have the power to levy taxation. Additional funding comes from the tariffs charged to the recipients of the services provided by the different levels of government. As a result, the resources available to the counties (90% of which will then be allocated to the health sector) are composed of 70% of tax revenues from local taxes and 20% from transfers and subsidies, with only 2% from revenue generated through the users' contribution to the costs of the service (see European Observatory on Health and Policies, *Sweden*: *Health System Review* (2012), cit., p. 56). In Sweden, none of the tax revenues are explicitly earmarked for the financing of the health service, as they are instead in Norway.

A state equalisation mechanism managed by the Ministry of Finance ensures that all local communities have adequate and fair economic means, despite the different geographical and socio-economic conditions and the unequal distribution and composition of their populations. In addition, there is a mechanism of redistribution of resources based on financial solidarity between counties, which also pertains to expenditures on high-cost drugs such as HIV treatment. Finally, since 2008, some state transfers have been linked to the compliance of county councils with standard time parameters for the provision of services, which has reduced waiting times by 50% in just two years *(ibid*., pp. 116-117).

As regards the payment of benefits to providers, the 1990s marked an important watershed. While the allocation of resources to hospitals and primary care centres used to take place through fixed annual quotas, the

spread of the *New Public Management* theory at the end of the last century led in many counties to the separation of funding providers and service providers and to the adoption of payment mechanisms based on the volume of activity. As a result, the number of private providers has grown significantly, especially in the primary care sector, and their access to national health funds is subject to prior accreditation of the facility by county councils.

Users are asked to contribute 17% of the total health expenditure, mainly those owed for access to specialist care and hospital facilities and the purchase of medicines. The majority of this share is made up of the cost-sharing medical charges, which are foreseen for almost all services but are subject to a ceiling of about 120 euros per year. For the purchase of medicines provided by the health service, patients are required to bear the full cost up to a similar threshold, beyond which the level of the patient's contribution gradually decreases, topping out at a ceiling of approximately 244 euros per year. For dental care, non-exempt patients receive an age-based general annual subsidy for prevention and check-ups. For all other services, patients have to bear the full cost up to the amount of approximately €333 per year; if they exceed this amount, they receive a subsidy of 50% of the cost up to €1,667 and 85% for all costs above this threshold.

Only 4% of the population has voluntary health insurance, in most cases paid for by the employer and aimed at ensuring access to dental services for adults. The share of financing provided this way in total health expenditures is 0.2% of the total.

Service delivery and financing in Norway

In Norway too, primary health care - which includes nursing care, general medicine and mental health services - is provided mainly by public facilities and is the responsibility of the municipalities (see T.P. Hagen and K. Vrangbaek, *The hanging political governance structures of Nordic health care systems*, in *Nordic health care systems*: *Recent reform and current policy challenges*, edited by J. Magnussen, K. Vrangbaek and R.B. Saltman, cit., pp. 107-125, esp. p. 114), which are much more numerous than the Swedish ones. General practitioners (GPs) are self-employed and paid by the National Health Service. Specialist and dental care is provided at regional level by 35 hospital health care companies, both public and private, that fall under the authority of five regional health authorities. The reform of the hospital sector in January 2002, however, created a highly centralised system (see K. Møller Pedersen, *Reforming decentralised integrated health care systems*: *Theory and the case of the Norwegian reform*, Health Economics Research Program - University of Oslo, Working Paper 2002, no. 7), and the central government took over responsibility for specialist care.

In addition, the Ministry of Health has overall responsibility for health policies, while the Parliament can influence the health system by exercising its legislative or policy-making powers, as well as by adopting the budget and setting tax and expenditure levels (S.I. Angell, *Two variants of decentralised health care: Norway and Sweden in comparison*, in UniRokkan Centre Working Paper, 2012, no. 4).

The tax is levied both at local and central levels, and is then transferred from the latter to the regional authorities in the form of automatic and sectoral transfers that are either non-binding (block grants) or binding (earmarked grants). Part of the funding is also allocated on the basis of the activities carried out, e.g., through the so-called DRG system (see European Observatory on Health and Policies, *Norway*: *Health System Review* (2006), cit., p. 34).

The remaining 12% of public health expenditure, by contrast, is borne by a social insurance system for sickness and disability, which explains the lower impact of health expenditure on general taxation in Norway. This is the National Insurance Scheme (NIS), introduced in 1967 as a public and universal insurance system that is compulsory for all residents or workers (employed, self-employed, freelance), as well as for certain categories of Norwegians who work abroad. It can also be voluntarily taken out by anyone staying on the territory for more than three months, and various private insurances offer voluntary insurance packages to supplement benefits (but cannot guarantee a different level of benefit coverage).

The level of user contribution to benefits is set at national level. Although there are no official statistics on overall incidence, it is estimated at 15% of total health expenditure. Persons insured with the NIS do not have to pay any contribution for hospitalisation and medicines administered in public hospitals. Instead, the costs of basic, specialist, psychological, pharmacological and transport services are partly borne by all patients, although municipalities or NIS grants cover most of the costs. Finally, the costs of physiotherapy and dental care are mostly borne by patients (about 75% of the total).

As in Sweden, since 1980 a non-progressive ceiling has been imposed on co-payments for general services, physiotherapy, dental treatment covered by the health service and rehabilitation, as well as for treatment received abroad. However, some very expensive services, such as care for disabled or elderly people at municipal level, are excluded. Private expenditures for the purchase of medicines are reimbursed only for those medicines that are on the official list (known as the *blue prescription list*) produced by the Norwegian Medicines Agency. Lastly, for some types of treatment, the choice of whether to apply the co-payment is left to the prescribing doctor on a case-by-case basis (for example, while in some cases the doctor might consider cosmetic surgery necessary for the patient's health and therefore deem reducing the cost desirable, even if on

a purely psychological basis, in other cases the cost may be charged to the patient in full).

Service delivery and financing in Denmark

The Danish health care system was traditionally decentralised (with the counties as the main actors), but has been gradually centralised and subjected to the Government-Parliament decision-making process since 2007. Consequently, the central government retains general regulatory, supervisory and fiscal functions, as well as an increasing role in planning and quality assessment. The Ministry of Health, which has often been merged with the Ministry of the Interior, is currently a separate and autonomous entity, with competences governing the organisation of hospitals and psychiatric services, as well as the authorisation and supervision of the pharmaceutical sector.

The five regions are responsible for their hospitals, which they own and manage directly, and they exercise regulatory power regarding the organisation of professionals in the sector, who for the most part are not civil servants but self-employed. The 98 local municipalities deal mainly with primary and secondary care (e.g., prevention and health promotion) and are completely autonomous from the regional level.

Basic care is provided through private professionals acting as self-employed providers and municipal services (such as nursing homes, home care services, home health aides and municipal dentists). GPs refer patients to hospitals and specialists. Emergency and specialist care is provided in hospitals, which are owned and organised on a regional basis and staffed by employees. Hospitals generally have an emergency service, in-patient departments and outpatient clinics for pre- or post-hospital diagnosis and treatment.

Pharmacies are privately organised and subject to national regulations on pricing and location, in order to ensure adequate access to the service for all, including those in rural areas. Dental services are provided free of charge and at communal level to children under 18 years of age, while adults have to rely on the private sector.

The Danish health model was completely transformed by the structural reform of 2007, which deprived the counties of the power to impose taxes (M. Gaggero, *Tendenze di centralizzazione e garanzie di efficienza nel modello sanitario scandinavo*, cit., pp. 179-182). As a result, taxation today takes place both at central level (with progressive taxes, one of which is specifically earmarked to raise funds for the health service) and at local level (with proportional taxes). Thus, 80% of regional expenditure is provided by the state directly to hospitals and health professionals, partly through non-binding, automatic and sectoral transfers (block grants) derived from taxation (75%), and to a small degree (5%) from payments

for hospital services. The remaining 20% of regional expenditures is financed by the municipalities, through per capita contributions and subsidies, partly derived from municipal taxes. Part of the funding for hospitals is allocated on the basis of the activities performed (DRGs). The reimbursements move from the local to the regional level, thus creating a virtuous incentive for municipalities to focus on prevention and keep their citizens healthy.

Since 2002, it has also been possible to take out Voluntary Health Insurance (VHI) (mainly for physiotherapy and cosmetic surgery), which is subsidised by the state (European Observatory on Health and Policies, *Denmark*: *Health System Review* (2012), cit., p. 46).

The degree of direct user contribution, which has increased as a result of reforms undertaken since the 1990s, is estimated at around 14%. It varies considerably by sector, being for example very high for dental services for adults, eye care services and expenditure on medicines. A co-payment is also required for physiotherapy treatments. Often, the use of voluntary forms of health insurance is in fact with the very object of reducing the impact of out-of-pocket payments on family budgets, as well as making access to the private hospital sector economically feasible.

3.3. *Actors and locations of decision-making processes*

First of all, it should be noted that the extent of involvement of the various levels of government in health decision-making processes varies from country to country. For example, while the Norwegian decision-making system gives a predominant role to the national parliament in many of the key choices of resource finding, allocation and target setting, there is more inter-institutional sharing of decision-making responsibility in both the Swedish and Danish contexts[29]. However, the centralisation of competencies resulting from the reforms adopted at the end of the 1990s has lowered the traditionally high level of demographic relevance of the Scandinavian health system and increased the size of the geographical areas with a common planning centre (i.e., health zones in Sweden and counties in Norway and Denmark)[30]. As will be seen, these reforms also led to the identification of explicit priority criteria for the planning and provision of care services, adopted with the dual aim of increasing the

[29] The following observations are based on data provided by V. Paris, M. Devaux and L. Wei, *Health systems institutional characteristics*: *A survey of 29 OECD countries*, OECD Health Working Papers, 2010, No 50, pp. 67-70.

[30] T.P. Hagen and K. Vrangbaek, *The hanging political governance structures of Nordic health care systems*, in Nordic health care systems: Recent reform and current policy challenges, edited by J. Magnussen, K. Vrangbaek and R.B. Saltman, New York, McGraw Hill, 2009, p. 114.

efficiency of national systems and, at the same time, containing costs[31].

More specifically, in all three countries the determination of the total amount of revenue and social contributions to be allocated to the financing of the public health system is reserved to Parliament, although in Sweden counties and municipalities also contribute to decision-making. As far as the allocation of resources between regional authorities is concerned, this is always centralised at national level, but in Norway and Denmark it is left to the parliaments while in Sweden it is left to the government. Even more significant are the differences in the allocation of resources between specific care sectors. While in Denmark it involves all levels of government (Parliament and Cabinet, regional government, local government), in Norway the decision is reserved to Parliament and in Sweden to county councils. Lastly, decisions on the financing of individual types of care (primary, outpatient, hospital) are left to the level of government responsible for their provision, while the planning of services is centralised in Denmark and Norway (by the cabinet and the parliament, respectively), Sweden being the exception here.

Decision-making processes in Sweden

According to Sections 7 and 8 of the *Health and Medical Services Act*, the planning of services is the responsibility of the regional level of government. It is up to each county council to plan the development and organisation of the service according to the needs of its residents. However, it is possible for counties to cooperate with government agencies and private structures for planning purposes, while resource allocation and planning have always been shared with the central government, both in terms of highly specialised regional services and technological investments. Since 2003, however, a national public policy - under the responsibility of the Government and subject to monitoring and evaluation by the National Institute of Public Health (*Folkhälsoinstitutet*) - has been in place based on 11 priority objectives, covering the main determinants of health and designed to guide all public authorities involved, at any level of government, in the management of the health service (see Swedish National Institute of Public Health, *Ten years of Swedish public health policy*, Östersund, Swedish National Institute for Public Health, 2013). As well as being used by county councils when planning services, they influence the setting of priorities at each level of government and have been defined in

[31] J. Magnussen, K. Vrangbaek, R.B., Saltman and P.E. Martinussen, *Introduction: The Nordic model of health care*, in Nordic health care systems: Recent reform and current policy challenges, edited by J. Magnussen, K. Vrangbaek and R.B. Saltman, cit., p. 6.

terms of:

- democratic participation of civil society (objective 1), deemed useful in promoting good health by strengthening the feeling of belonging within society and increasing the general level of mutual trust;
- guaranteeing economic and social security (transfer of financing, support for parenthood, high-quality schools and childcare, access to leisure activities conducive to healthy development) that enable each family to achieve certain economic and social conditions (obj. 2) and secure favourable living conditions, especially during childhood and adolescence (obj. 3), this also as a strategy to improve the health of the population;
- promotion of a healthier working life (obj. 4), in order to reduce occupational diseases and discrepancies between social groups and to contribute to the improvement of public health and sustainable growth;
- healthy and safe environments and products (obj. 5);
- health and medical care that more actively promotes good health (obj. 6), as a necessary component of care and treatment pathways, in particular through a strong and effective primary care service and with specific attention to the most vulnerable groups and individuals;
- effective protection against communicable diseases (obj. 7) and attention to safe sexuality and good reproductive health (obj. 8), by means of information campaigns, vaccination programmes, and early detection tests;
- increasing the physical activity of the population (obj. 9), from the youngest to the elderly, and promoting good eating habits and safe food (obj. 10);
- reduced use of tobacco and alcohol, a society free from illicit drugs and doping and a reduction in the harmful effects of excessive gambling (obj. 11) (for a more extensive discussion see European Observatory on Health and Policies, *Sweden*: *Health System Review* (2012), cit., pp. 31-32).

In 2013, a report by the Swedish National Institute of Public Health (*Ten years of Swedish public health policy*. *Summary Report*, cit.) highlighted the positive contribution of national health policy in systematising the efforts of municipalities, county councils and regions in the field (p. 4), but also noted a greater use of objectives during planning rather than monitoring and identified a need for better definition of objectives for clinical practice (p. 50).

All levels of government are responsible for determining the total budget for health protection. In their coordination and negotiation activities with the central government (e.g., on the amount of funding transferred), the local authorities are convened in the Swedish Association of Municipalities and Counties (*Sveriges Kommuneroch Landsting*, SALAR),

which represents them. In fact, the responsibility for financing each type of care (primary, outpatient, hospital) lies with the level of government responsible for providing it (i.e., the local level in the case of primary care, and the regional level in the case of the other two types of care).

Lastly, the direct involvement of citizen-users is only envisaged during the decision-making processes for the authorisation of medicinal products (see V. Paris, M. Devaux and L. Wei, *Health systems institutional characteristics: A survey of 29 OECD countries*, cit., pp. 83-85). Their main opportunity to participate is therefore the general elections (which are held every four years and always result in very high rates of voter turnout) and, in particular, the regional elections. However, there are also more than 100 patient and consumer associations in the country, their main aim being to safeguard the interests of their members by influencing policy-makers. Their success is variable and also depends on the size of the reference group of patients (U. Winblad and Å. Ringard, *Meeting rising public expectations*: *The changing roles of patients and citizens*, in Nordic health care systems: Recent reform and current policy challenges, edited by J. Magnussen, K. Vrangbaek and R.B. Saltman, cit., pp. 126-150).

Decision-making processes in Norway

In general, although the Norwegian planning system is significantly centralised, this does not seem to diminish its effectiveness. This result is due, on the one hand, to the consensus-oriented nature of the decision-making processes (often conducted through lengthy negotiations with interest groups and associations of the professional categories involved) and, on the other, to their institutional design. While the definition of policy objectives and the monitoring of results are the responsibility of the central level of government, local authorities are free to implement national guidelines as they see fit. According to the dictates of the "steer, don't row" principle, the activities of policy formulation and implementation are kept separate (European Observatory on Health and Policies, *Norway*: *Health System Review* (2006), cit., p. 157).

The function of political guidance, including the definition of general health objectives, is attributed to the national Parliament (*Storting*) and, as far as the sector is concerned, it is exercised through the drafting of a four-year national health plan. The plan provides the basis for the identification of priorities carried out at each level of government: the municipal level in relation to primary care; the regional level for secondary care (P.C. Smith *et al*. *Leadership and governance in seven developed health systems*, in Health Policy, 2012, no 106, pp. 37-49, esp. p. 44). The origins of the national plan are found in a white paper based on the World Health Organisation's 2002 report, which set out the direction of national policy development for the

coming years, identifying key risk factors such as tobacco consumption, alcohol abuse, drug addiction, obesity and lifestyle as priority areas for intervention by the Norwegian Health Service. Based on this report, Norway was among the first countries in the world to ban all forms of tobacco promotion and advertising, both direct and indirect. Since the 2000s, public intervention in the field of mental health has also been prioritised.

Other important decision-making functions are also reserved for the legislative body, such as determining the level of taxation and the total health budget, and the allocation of all these resources, both horizontally (between care sectors) and vertically (between counties). Within the set budget, it is the responsibility of the regional health authorities to decide on the financing of specialist care, while municipalities are responsible for finding the necessary funding to provide primary care.

Additionally, at central level, numerous government agencies have been set up to offer advice and/or support to various policy makers. Matters of national importance and high cost, for example, the introduction of cancer screening campaigns or innovative and high-cost procedures/drugs, are referred to the Council for Quality Improvement and Priority Setting in the health sector (for an overview of its functioning and activity, see Å. Ringard, B. Mørland and B.I. Larsen, *Quality and priorities in the health services*, in Tidsskr Nor Legeforen, vol. 132, 2012, no. 3, pp. 312- 314). Created in 2007 from the former Priorities Council (*Prioriteringsrådet*), it consists of 25 representatives of the various actors involved in the system (politicians, civil servants, experts and representatives of patients associations), meets in public sessions and reports annually to the Minister of Health on the fulfilment of its tasks. These include consulting on the above-mentioned issues, monitoring social and regional disparities in access to health services, and evaluating medical technologies and creating national guidelines in specific care sectors.

At national level, there are two other authorities: the Norwegian Medicines Agency (*Statenslegemiddelverk*), tasked with controlling and approving medicines and regulating their prices, and a newly established department of the independent fiscal control agency (*Riksrevisjonen,* established in 1816) which is charged with ensuring the sound financial management of public funds. Since 1998, Norway has also had a special centre for health technology assessment (HTA), the *Senter for Medisinskmetodevurdering*, which was replaced in 2004 by the Norwegian Knowledge Centre for Health Services (NOKC).

Lastly, in Norway representatives of citizen-users also sit on many decision-making bodies. This is the case both in the evaluation of healthcare technology and in the planning of hospital care and the definition of health objectives (V. Paris, M. Devaux and L. Wei, *Health systems institutional characteristics*: *A survey of 29 OECD countries*, cit., pp.

85).

Decision-making processes in Denmark

In Denmark, decisions on taxation levels and the allocation of funds to the counties are made centrally by the parliamentary-representative body, while decisions on the drafting of the health sector budget are made jointly with the municipalities. Allocation decisions between different care sectors involve all levels of government, but only the central government and municipalities can impose taxes and are therefore involved in the financing decisions. Lastly, the definition of health objectives is reserved to the central government.

Particularly since the 1990s, an important mechanism for coordinating health policy developments has been in place; this emerged gradually from negotiations and agreements reached between the central government and decentralised authorities in the course of the annual budget discussions (P.T. Hagen and K. Vrangbaek, *The changing political governance structures of Nordic health care systems*, cit., p. 109). The National Institute of Health (*Sundhedsstyrelsen*) also gained stronger formal powers in influencing coordination processes between counties and municipalities (*ibid*., p. 114).

With regard to the participation of users in decision-making processes, Denmark is the country that has achieved the greatest level of user involvement, attributing a formal role to user representatives in all the main decision-making forums concerning the authorisation of medicines, the level of coverage or reimbursement of services, the evaluation of health technologies, hospital planning, and the definition of health objectives (V. Paris, M. Devaux and L. Wei, *Health systems institutional characteristics*: *A survey of 29 OECD countries*, cit., pp. 83-85). The role reserved for representative elective bodies of the elderly population - known as councils of the town's elderly - is particularly unusual. They support the municipal council and cabinet and have the task of directing policies on health care for the elderly, a sector in which Denmark is a world leader (see P. Gobbi, *Il modello di welfare scandinavo: è ancora un'eccellenza?* cit., p. 18).

3.4. *Resource allocation and prioritisation*

The Scandinavian countries were the first in the world to bring the issue of priority setting in the health sector to the attention of public and political authorities[32]. As early as the end of the 1980s, in fact, the

[32] B. Hofmann, *Priority setting in health care: Trends and models from Scandinavian experiences*, in Medicine Health Care and Philosophy, 2013, no. 16, pp. 349-356, esp. p. 349.

controversy over the length of waiting lists and the media coverage given to high-profile cases of refusal of life-saving treatment by public institutions led to an awareness in northern Europe of the need for a fairer allocation of available resources. In particular, it was on 24 May 1985 that the first government committee (known as the *Lønning I Committee*, named after its chairman) was set up in Norway to deal with the issue. Two main phases can be distinguished[33].

Initially, all the Scandinavian countries entrusted committees composed of representatives of the Parliament and professional categories (and also the Government in Norway) with the identification of a set of principles and moral values that would serve as a guide for the allocation and treatment decisions of professionals in the field. In no case was the selection of priorities based on a single principle; instead, the choice was made to incorporate considerations from very different areas, not only medical but philosophical and ecological. As is natural (in the universalistic systems of Scandinavia), one of the most important of these was the principle of need, which assigns considerable weight to the health demand of the person turning to healthcare facilities and thus to the seriousness of his or her condition. However, since the end of the 1990s, this aspect has been inevitably linked to the question of the economic sustainability of health systems.

Therefore, at the beginning of the new millennium, Sweden and Norway developed new priority-setting strategies, characterised by the use of empirical evidence and cost-effectiveness analysis in the selection of drugs and treatments, as well as an increased focus on transparent decision-making and the dissemination of information to the public[34]. At this stage, the principle of treatment efficiency was particularly emphasised and is now explicitly included in the set of reference values for all the Scandinavian countries except Denmark.

Obviously, such initiatives have not eliminated potential conflict between alternative uses of available health resources, but they do ensure that the conflicts are resolved by balancing explicit, known and knowable principles. While this remains a difficult exercise[35], the process has at least

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[33] *Ibid*.

[34] It is generally agreed that these strategies have been significantly influenced by the normative theory developed in the late 1990s by Daniels and Sabin and known as *accountability for reasonableness* (A4R); see N. Daniels and J.E. Sabin, *Limits to health care: Fair procedures, democratic deliberation, and the legitimacy problem for insurers*, in Philosophy & Public Affairs, vol. 26, 1997, No 4, pp. 303-350.

[35] On the limited impact of the principles selected by governmental commissions on national policies, due to their abstractness, excessive generality or insufficient implementation, see L.M. Sabik and R.K. Lie, *Priority setting in health care: Lessons from the expertise of eight countries*, in International Journal for Equity in Health, vol. 7, 2008, no. 4, pp. 1-13, esp. pp. 9

brought more uniformity and, above all, more controllability to the system, to the benefit of public opinion and each individual citizen-user. The existence of a set of reference principles and their use in the selection of priorities makes resource allocation choices open to scrutiny and discussion, thus promoting democratic control[36].

a) Sweden

In Sweden, the issue of prioritisation has been in the public eye since 1992, when a parliamentary commission (known as the Priorities Commission) was specifically tasked with setting out the principles that should guide the allocation of resources in the sector. The commission's final report, three years later, stated for the first time the need to present and discuss the grounds for such choices openly, in view of the ethical problems they inevitably raise and in order to preserve the confidence of the taxpaying citizen in the health system (even more so in one as expensive as Sweden's)[37].

First and foremost, the Priorities Commission's work consists of defining the national ethical platform of reference, in order to provide clear and uniform criteria for guidance to the various political decision-makers and health professionals involved at any level of the priority-setting process. It should also be noted that, although they were developed for the health sector, the criteria are considered applicable - with some adaptation - to the entire social services sector. The set of values was then also incorporated into the *Swedish Health and Medical Services Act*, under which:

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ff.

[36] In the literature, see studies such as those (in the Swedish context) by L. Bernfort, *Decisions on inclusion in the Swedish basic health care package - roles of cost-effectiveness and need*, in Health Care Analysis, vol. 11, 2003, no. 4, pp. 301-308 (which highlights a use of the criterion of efficiency that is still limited and often recessive compared to those of the clinical effectiveness of the treatment or the seriousness of the patient's health condition, with reference to specific decisions of inclusion/exclusion of treatments and drugs in the national benefit package) and N. Eckard, M. Janzon and L.Å. Levin, *Use of cost-effectiveness data in priority setting decisions*: *Experiences from the National guidelines for hearth diseases in Sweden*, in International Journal of Health Policy and Management, vol. 3, 2014, no. 6, pp. 323-332, esp. p. 330 (which confirms this assessment on the basis of an analysis of the functioning of the *Priority Setting Group*, a collegial body of the National Institute of Public Health in charge of creating national guidelines to operationalise the reference principles and guide the setting of health priorities at each level).

[37] Ministry of Health and Social Affairs, *Health Care's Difficult Choices*, SOU 1995, no. 5, quoted and translated in English in National Center for Priority Setting in Health Care, *Resolving Health Care's Difficult Choices*, Prioriterings Centrum, 2008, available at www.imh.liu.se/halso-och-sjukvardsanalys/prioriteringscentrum/?l=en, esp. p. 4.

> Health and medical services are aimed at assuring the entire population of good health and of care on equal terms. Care shall be provided with respect for the equal dignity of all human beings and for the dignity of the individual. Priority for health and medical care shall be given to the person whose need of care is greatest[38].

Out of the three principles proposed by the commission, the *human dignity principle* is the most important. It recognises the equal value and rights of every human being, regardless of their personal characteristics and social function. However, it proves to be insufficient for the purpose of guiding allocation decisions, as it does not provide any indication on how to prevent funding constraints from undermining the guarantee of safeguarding those rights. To this end, the other principles are more useful: these are the *cost-effectiveness principle*[39] and, above all, the *need and solidarity principle*. The latter directs public spending towards areas of intervention characterised by higher levels of need (e.g., life-saving treatments) or towards the needs of the most vulnerable groups and those less able to assert their rights (e.g., children or the disabled)[40], while the principle of efficiency (which requires the existence of a reasonable relationship between the cost of treatments provided with public resources and their effects) is mostly used as a criterion for choosing between treatment alternatives[41]. However, since the comparison can only look at existing alternative treatments for the same condition (e.g., a titanium hip replacement and its cheaper but less durable steel counterpart[42]), the principle of efficiency cannot be applied either to choices that aim to distribute funds between different treatment sectors or to prioritise the treatment of certain diseases over others within a given sector.

While the principle of human dignity may be considered restrictive in

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[38] See Section 2 of the *Health and Medical Services Act*, 1982, No 763, as amended by the *Health and Medical Services Act*, 1997, No 142.

[39] On the methodological difference between *cost-effectiveness analysis* (CEA: the benefit is expressed in terms of lives saved, accidents avoided or clinical cases registered) and *cost-benefit analysis* (CBA: the results of which are expressed in monetary value), on the one hand, and *cost-utility analysis* (CUA, which employs the QALY methodology), on the other, see L. Bernfort, *Decisions on inclusion in the Swedish basic health care package*, cit. p. 304.

[40] This is reasonable in the majority of cases, but in some situations, it may lead to a preference for interventions that can bring only a slight benefit to a seriously ill patient, rather than allocating the same resources to treatments that could bring about a full recovery in someone with a less serious condition. In such circumstances, the unenforceable character of the classification among the reference criteria has proved highly objectionable (P.E. Liss, *Allocation of scarce resources in health care: Values and concepts*, in Text & Context Nursing, vol. 15, 2006, pp. 125-134, esp. p. 129).

[41] Centre for Priority Setting in Health Care, *Resolving Health Care's Difficult Choices*, cit., p. 4.

[42] The example is found in L.M. Sabik and R.K. Lie, *Priority setting in health care: Lessons from the expertise of eight countries*, cit., p. 8.

that it sets negative limitations on allocation choices (by defining factors that may not be used for guidance), the other two principles are certainly active[43]. Moreover, the need and solidarity principles prevail over the efficiency principle[44]. This prevents the latter from leading to the denial of a service or the provision of a lower quality of service to those groups to whom it is not "convenient" to offer health care, such as the chronically ill, the dying, the elderly or those with severe disabilities. Indeed, the primacy accorded to the principle of solidarity ensures that resources are prioritised for the treatment of the most serious or disabling illnesses. Lastly, the Priorities Commission recommended excluding the principle of utility[45] and life expectancy considerations influenced by parameters from the list of guiding criteria, such as the age of the patient or the birth weight of a newborn child. The *principle of autonomy/responsibility* evaluates the behaviour of the person in need of care, deeming those who have contributed to the deterioration of their state of health (e.g., by practising extreme sports or dangerous activities, smoking, or abusing alcohol or drugs) to be less deserving of the expenditure of public resources. This principle was considered inappropriate as the basis for treatment choices and, even though greater consideration was later advocated[46], the patient's past lifestyle remains irrelevant to resource allocation and treatment decisions. Since expectations regarding the patient's future lifestyle can influence the extent and duration of the benefit of the medical treatment for individual patients, these are taken into account. However, they cannot lead to the outright rejection of the intervention (for example, a liver transplant for a habitual drug user) if it can be preceded by effective interventions with positive effects on lifestyle (such as rehabilitative services)[47]. Similarly, the commission has made it clear that, in order for intervention on a smoker with peripheral arterial stenosis to be ethically justifiable, it

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[43] P.E. Liss, *Allocation of scarce resources in health care: Values and concepts*, cit., p. 129.

[44] An exemplary case in which the high efficiency of a treatment aimed at satisfying "insufficient" needs was not sufficient to justify its inclusion in the national benefit package is reported in L. Bernfort, *Decisions on inclusion in the Swedish basic health care package*, cit., pp. 305-306: it concerns reimbursement for Viagra, a drug against erectile dysfunction.

[45] That is, the principle that conveys "the idea that scarce resources should be used in a way that maximises the utility of society" (P.E. Liss, *Allocation of scarce resources in health care: Values and concepts*, cit., p. 129).

[46] The parliamentary committee had denounced the risk that the adoption of such a criterion might lead to random allocation choices, stressing the contiguity between a lifestyle dangerous to health and certain socio-economic or hereditary factors that are certainly not attributable to the individual. However, in 2008 the National Centre for Priority Setting in Health Care promoted the inclusion of the principle of responsibility in the national ethics platform (see *Resolving health care's difficult choices*, cit., p. IV).

[47] M. Broqvist et al, *National model for transparent prioritisation in Swedish health care. Revised version*, National Centre for Priority Setting in Healthcare, 2011, no. 4, p. 25.

must be preceded by a request from the treating physician for the patient to stop smoking[48].

Since 1996, the Swedish government has attempted to implement ethical principles by creating national guidelines specifically designed to facilitate and standardise allocation choices across the country. Initially, the guidelines were essentially translated into the creation of two lists with five groups of priority levels: one for clinical practice and one for political and administrative decision-making[49]. Due to their lack of usefulness, however, in 2008 the National Centre for Priority Setting in Health Care proposed its elimination[50]. In addition, between 1998 and 2001, the Priorities Commission was replaced by the National Priorities Commission (*Prioriteringsdelegationen*), which is responsible for disseminating information on parliamentary resolutions in this field, developing methods of implementation and monitoring their practical effects[51]. The responsibility for the implementation of the ethical platform has, however, been largely placed at local government level and in particular with the county councils, many of which have developed autonomous priority setting processes through more or less independent *ethical committees* or *priorities committees*, which have drawn up further and more specific guidelines than the national ones[52].

At the central level, the initiatives entrusted to the National Institute of Health, which published national evidence-based guidelines in specific

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48 J. Calltorp, *Priority setting in health policy in Sweden and a comparison with Norway*, in Health Policy, 1999, No 50, pp. 1-22, esp. p. 7.

49 The groups listed in Government Bill 1996/97, no. 60, *Priority Setting in Health Care* (Social department 1996/97) - which are purely indicative according to the government act ("We want to emphasise that these are only examples, and that the need for care in each individual case must be determined based on the conditions of that particular case") - are the following: *Priority Group I:* Care of acute, life-threatening disease; Care of diseases that, if left untreated, lead to permanent disability or premature death; Care of severe chronic illnesses; Palliative care and care of the terminally ill; Care of people with limited autonomy (the list of clinical procedures distinguishes two priority subgroups within this first level: one for acute, disabling or fatal diseases and the other for all other conditions). *II:* Prevention; Habilitation/rehabilitation. *III:* Care of less severe acute and chronic diseases. *IV:* Borderline cases. *V:* Care for reasons other than disease or injury.

50 National Centre for Priority Setting in Health Care, *Resolving Health Care's Difficult Choices*, cit., p. IV.

51 The final report of this second committee (*Prioriteringar i vården - perspektiv för politiker, profesion och medborgare*, SOU 2001:8) was published in 2001, when the body was replaced by the National Centre for Priority Setting in Health Care.

52 J. Calltorp, *Priority setting in health policy in Sweden and a comparison with Norway*, cit., p. 9. The case of the Östergötland County Council, in particular, is widely documented in the literature, as it has developed very advanced planning tools, based on the systematic collection of epidemiological data, cost and treatment results included in several diagnostic categories (*ibid*., p. 11).

clinical areas (in particular for the treatment of chronic diseases, starting with heart disease[53]), as well as for granting sick leave and medical prescriptions, have been more incisive. They are aimed at assisting the various decision-makers (county councils, municipalities and individual providers) involved in planning and prioritisation and are produced in collaboration with other government agencies such as the National Authority for Development Regulation and Oversight of the development, production and sale of pharmaceuticals (*Läkemedelsverket*, MPA), the Agency for Dental and Pharmaceutical Subsidies (*Tandvårdsoch Läkemedelsförmårm*, TLV) and the Swedish Agency for the Evaluation of Medical Technologies and Social Services (*Statens Beredning för Medicinskoch Social Utvärdering*, SBU[54]). Although they include explicit recommendations on the optimal allocation of resources, the guidelines are not legally relevant and therefore recognise the specificity of each individual case, guaranteeing professionals who make allocation choices "at the patient's bedside" a sufficient margin of discretion[55].

In addition, since 2006 the creation of the guidelines has been based on a National Model for Transparent Priority Setting[56]. Currently the model is divided into five phases:

- identification of the overall objective of the health service in question;
- identification of the object of the prioritisation activity (a specific health condition combined with a corresponding medical treatment);
- collection of the most relevant information and scientific knowledge about the severity of the medical condition, the benefit to the patient of the treatment and its efficiency;
- classification of the treatment on a priority scale;
- presentation to the public and patients of the classification, its practical consequences and the reasoning behind it.

The model was developed by the National Institute of Health together with the National Centre for Priority Setting in Health Care (*Prioriterings Center*), an institute established in 2001 by the Swedish government and the SALAR to develop strategies for the allocation of resources between

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[53] For an evaluation see N. Eckard, M. Janzon and L.Å. Levin, *Use of cost-effectiveness data in priority setting decisions*: *Experiences from the national guidelines for hearth diseases in Sweden*, cit.

[54] Founded in 1987, the SBU is one of the oldest HTA organisations in the world (see the agency's online website http://www.sbu.se/en/ About-SBU/).

[55] European Observatory on Health and Policies, *Sweden*: *Health system review* (2012), cit., pp. 29-30, esp. p. 36.

[56] The first version of the model dates back to 2006, but was revised in 2011 (see M. Broqvist *et al*. *National Model for Transparent Prioritisation in Swedish Health Care. Revised version*, National Center for Priority Setting in Healthcare, 2011, no. 4).

different care sectors (*vertical prioritisation*) and to foster transparency in decision-making processes. Since the end of the 1990s, the dissemination of information to the public on the actors and processes involved in the allocation of health resources has been pursued in Sweden through a number of initiatives. If at national level the objective can be said to have been at least partially achieved, the same does not apply to decision-making processes at local level, where often the adherence of allocation choices to the ethical principles of reference and the implementation of an explicit and transparent decision-making methodology are still limited[57]. Some authors have also pointed out the risk that organisational aspects of the system (such as the joint operation of the new system of financing primary care and the political objective of reducing waiting times for access to the service) may end up interfering with the actual allocation of resources, pushing providers to guarantee access even in the face of "insufficient" needs, in order not to lose access to funding linked to the health requests of individual patients and to prevent them from being shifted to other providers[58].

b) Norway

In general, priorities are set at the local level for primary care, while choices for secondary care are left to negotiation between the Ministry of Health and the four regional health authorities. The resulting contracts set out the quantity and quality of services to be provided in each of the hospitals in the regional area, as well as the specific care objectives to be achieved[59].

As in Sweden, there is no explicit list of treatments covered by the Norwegian national health service and decisions on coverage are on a case-by-case basis and reserved to the doctor or facility treating the patient. In Norway too, however, these decisions are framed in and governed by a set of reference principles, which were developed by a national commission of experts and civil society representatives as early as the late 1980s. The country's long-standing experience with priority-setting allows its evolution to be analysed in four distinct stages[60].

The first stage started in 1985, when the matter became the object of

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[57] European Observatory on Health and Policies, *Sweden*: *Health system review* (2012), cit., p. 116.

[58] E. Ardvidsson et al. *Setting priorities in primary health care - on whose conditions? A questionnaire study*, in BMC Family Practice, vol. 13, 2012, no. 114, pp. 1-8, esp. p. 7.

[59] P.C. Smith et al., *Leadership and governance in seven developed health systems*, in Health Policy, 2012, no. 106, p. 44.

[60] This follows the approach adopted by B. Hofmann, *Priority setting in health care: Trends and models from Scandinavian experiences*, cit., p. 351.

public debate with the establishment of the world's first National Priorities Commission (*Lønning Commission*). In its final report[61], the Commission proposed the adoption of explicit principles for the rationing of health sector resources (the *severity of need* and the *clinical effectiveness* of the treatment) and based on these it designed five different levels of priority[62] to guide the evaluation and financing of all new treatments.

In the second phase, the principles of *expected usefulness* and *effectiveness* of interventions was added to the listed criteria, to be evaluated according to HTA techniques and, in contrast to the Swedish context, to be measured in terms of *Quality-Adjusted-Life-Year* (QALY). At the end of the 1990s, a second royal commission (Lønning II) was tasked with evaluating the implementation of the Norwegian Parliament's previous recommendations and analysing the priority setting experiences that had flourished internationally in the previous decade, in search of best practices and innovative solutions to resource scarcity problems. Besides including efficiency as a general criterion and renaming the effectiveness principle as *benefit principle*, Lønning II acknowledged the ineffectiveness of the previous priority list and redefined it more clearly[63]. In the same period (1997-2000), the first advisory body for priority setting (*Prioriteringsrådet*)[64] was created.

It was only in the third phase, which coincided with the entry into force of the *Patients' and Users' Rights Act* of 1999 (LOV No. 63 of 2 July 1999), that the principles of reference were given normative value. In spite of the issuance of a regulation explicitly addressed to the establishment of priorities (FOR No 1208 of 1 December 2000), little was done in the years

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[61] See Lønning Commission, *Guidelines for Prioritization in Norwegian Health Care*, NOU, 1987, p. 23.

[62] The report distinguished between:

1. life-saving and essential treatments;
2. treatments in less severe situations where withholding them would be harmful;
3. treatments for chronic disorders with a proven benefit;
4. treatments with unclear benefits that can be marginally effective;
5. services not needed or without any proven value (no priority and therefore no public funding).

[63] Thus, the new guidelines only identified the following four levels of priority (see Lønning Commission, *Prioritisation again*, NOU, 1997, p. 18):

1. basic health services (intended to be fully covered by the public health service);
2. additional health services (treatments with less certain effectiveness for less serious health conditions, to be covered as much as possible);
3. low priority or borderline cases (such as cosmetic surgery, to be covered only if all previous priorities are met and resources are available, otherwise to be subject to direct user contribution mechanisms);
4. no-priority (such as methods still in testing phase, to be kept outside the priority-setting system and to be financed separately).

[64] On its history, see also the remarks in the Norwegian section on actors and locations in decision-making processes.

immediately thereafter to implement the parliamentary recommendations incorporated in the law[65]. The regulation, however, specified the complementary character of the three criteria: in other words, all three must be partly met for a financing decision to be considered legitimate.

However, the issue returned to the centre of public attention after 2006. In 2007, the Prioriteringsrådet was replaced by the Council for Quality Improvement and Prioritisation in Health Care (*Nasjonaltråd for Kvalitetogprioritering i Helsetjenesten*), after the Norwegian government ignored some of its scientifically based evaluations for political reasons. The Council was given a broader mandate, greater authority on the national scene and a political mandate to ensure the most transparent and open decision-making, in order to foster the understanding of the reasons behind allocation choices by the citizens. Nevertheless, some critical voices have denounced the deviation of these choices from the reference platform, pointing out the inconsistencies of particular financing decisions for certain medicines[66]. Specifically, the positive decision on the health service's coverage of a new anti-cancer drug *(ipilimumab*) appeared too heavily focused on the criterion of the severity of the disease, and the National Medicines Agency deemed the cost of the treatment excessive and strongly criticised its scientific validity as being motivated by political and electoral considerations. By contrast, insufficient health need was cited as the reason for excluding funding for drugs to quit smoking, despite the fact that their efficiency and effectiveness had been proven.

Another initiative that demonstrates the attention recently paid to the prioritisation of interventions is that of a benefit financing scheme expressly reserved for workers on sick leave and aimed at reducing waiting times for hospital services for that specific category of users *(Faster Return to Work*, FWR). Created in 2007, this mechanism testifies to the influence of human capital theories in the Norwegian context[67]. Even if only in the hospital sector, it gives priority in the allocation of resources to those subjects for whom waiting for treatment would present a higher opportunity cost. According to the *human capital approach*, since in the case of workers the wait for intervention results in a loss of general productivity (while with children, pensioners or the unemployed it would not produce any indirect costs), it is legitimate to allocate additional public

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65 European Observatory on Health and Policies, *Norway*: *Health system review* (2006), cit., p. 41.

66 T. Wisløff, *Priority-setting criteria in the Norwegian health services*, in Tidsskr Nor Legeforen, vol. 135, 2015, no. 15, pp. 1373-1376.

67 A. Aakvik, T.H. Holmås and E. Kjerstad, *Prioritisation and the elusive effect on welfare. A Norwegian health care reform revisited*, in Social Science & Medicine, 2015, no. 128, pp. 290-300, esp. p. 290.

resources to the exclusive treatment of the needs of this category[68]. As a result, the health needs of workers have a higher priority in Norway than those of other segments of the population[69].

c) Denmark

Unlike the other Scandinavian countries, Denmark has no bodies or procedures that explicitly address the issue of priority setting[70]. This also applies to the ethical principles identified in 1996 by the Danish Ethics Committee (equality, solidarity, security, autonomy), which were conceived as useful tools to clarify the general objective of the National Health Service and to achieve it (through the balancing of secondary values such as social and territorial equity, quality and efficiency of the services, democracy and consumer influence[71]), rather than as guiding criteria for allocation decisions[72]. Although the creation of a body similar to the English NICE has been discussed in recent years[73], at present there are no national or local level guidelines on this subject, as Sweden and Norway have, and allocation decisions are implicit.

A case in point concerns the decisions on the reimbursability of medicines, which are taken by the Danish Medicines Agency based on the opinion of the regional health authorities, their importance for the patient and efficiency, and the existence of viable alternative treatments. Authorisation decisions, on the other hand, are taken on the basis of the

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[68] The legitimacy of this approach is controversial among health economists, but it is applied by some national authorities such as the Canadian Medicines and Health Technologies Agency (see *Guidelines for the Economic Evaluation of Health Technologies*: *Canada*, Ottawa, Canadian Agency for Drugs and Technologies in Health, 2006, esp. pp. 31 ff.).

[69] A. Aakvik, T.H. Holmås and E. Kjerstad, *Prioritisation and the elusive effect on welfare*. *A Norwegian health care reform visited*, cit., p. 292. The results of the study are interesting as they suggest the ineffectiveness of FWR. Indeed, even if the allocation of additional funds to the hospital sector through the scheme does reduce waiting times, this does not translate into a reduction of sick leave. Its cost, therefore, would be greater than its benefit in terms of reducing productivity loss.

[70] European Observatory on Health and Policies, *Denmark*: *Health system review*, cit., p. 170.

[71] The ethics committee did not provide any further indications on the balancing of the partial objectives, but merely specified that their consideration should not prevent the achievement of the overall objective of the health service: that is, giving everyone the opportunity to continue to express themselves, regardless of their socio-cultural background and abilities (Danish Council of Ethics, *Priority-setting in the Health Service*, 1997).

[72] B. Hofmann, *Priority setting in health care: Trends and models from Scandinavian experiences*, cit., p. 351.

[73] European Observatory on Health and Policies, *Denmark*: *Health system review*, cit., p. 151. On the National Institute for Health and Care Excellence, see section 4 of this chapter.

market price and the clinical efficacy of the medicinal product[74].

The various decision-making processes designed to define the national benefit package in inpatient and outpatient care also end up implicitly implementing resource allocation. In the first case, decision-making responsibilities are decentralised and involve the central government, counties and individual hospitals. As far as outpatient treatment is concerned, however, the scope of treatment is the result of negotiations between the associations of providers and the Health Care Reimbursement Negotiating Committee (*Sygesikringens for Handlingsudvalg*). Here, services are selected mainly on the basis of the principle of need and then included in a positive national list, which serves as an explicit benefit package (*Health Care Reimbursement Scheme)*[75]*.* However, doctors are free to introduce new treatments on their own, even if they are not covered by the national plan, as long as this does not increase the hospital budget beyond its set limits[76].

Lastly, with regard to health technology assessment, HTA methods have been adopted in Denmark in the last few years, in the wake of renewed attention to the issue of health service costs[77]. These are mainly applied in the evaluation of innovative, high-cost pharmaceuticals, where HTA is routinely used by both regional authorities and the National Institute of Health (*Sundhedsstyrelsen*). In 1997, the Danish Centre for HTA was set up and later integrated into the organisational structure of the Sundhedsstyrelsen. However, health technology assessment does not take place at central level, but at every level of the health service, as it is conceived as a tool for planning and facilitating the daily clinical decisions of health professionals[78].

4. *Great Britain*

4.1. *The underlying philosophy and its evolution*

The United Kingdom became a fully-fledged devolved state in 1998, with the approval by the Parliament in Westminster of the Scotland Act, the

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[74] L. Bilde et al, *The Health Benefit Basket in Denmark*, Danish Institute for Health Service Research, 2005, p. 61.

[75] See the considerations on the site devoted to this subject: http://www.healthsystemwiki.com/index.php?title=Denmark#Priority_Setting, which resulted from a research project by the Johannes Gutenberg University Mainz on *Decision-making Processes and Distributive Effects*. *The allocation of health care in OECD countries*.

[76] European Observatory on Health and Policies, *Denmark*: *Health system review*, cit., p. 63.

[77] *Ibid*, p. 26.

[78] *Ibid*, p. 36

Northern Ireland Act and the Government of Wales Act. These legislative acts have outlined a "diversified institutional set-up", resulting in a clear asymmetry between the four territorial entities identified, which have been granted - albeit in a differentiated manner - regulatory powers that have been attributed to their respective representative assemblies. The National Health Service currently includes four health services, namely the national health services in England, Scotland, Wales and Northern Ireland[79], each characterised by some peculiar features that we will try to highlight[80].

It is interesting to note that one of the main issues that influenced the Brexit referendum of 23 June 2016 was the sustainability of the National Health Service (NHS)[81]. As the vote approached, red buses began to circulate throughout Britain emblazoned with the slogan: "We send the EU £350 million a week. Let's fund our NHS instead. Vote Leave." Sensationalist propaganda was combined with the Conservative government's promise to, in the event of a Leave victory, reverse years of major budget cuts to the NHS and increase public health funding by 14% annually. This back-and-forth of commitments, promises and sensationalistic slogans, which had a direct impact on the outcome of the Brexit referendum, must be placed in the context created by a series of economic and organisational changes which, according to some observers[82], would have led to a profound transformation of the British health service away from the founding principles of the Beveridge model[83] and towards a constitutional system that does not envisage a fundamental right to health.

The British constitutional system, which developed over centuries with no formal written constitution, provides for a series of subjective legal contexts for the protection of health conditioned by the provision of obligations on the part of public health authorities. The content of health

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[79] It should be noted that here, for reasons of brevity and due to the limited amount of significant data, the Northern Irish system will be mentioned only incidentally but not analysed in depth. For any further information the reader can consult the report *United Kingdom*. *Health system review* (2015) by the European Observatory on Health Systems and Policies.

[80] The NHS Act provided for the establishment of the NHS in England and Wales, effective on 5 July 1948; its Scottish counterpart was created almost simultaneously with the NHS (Scotland) Act of 1947. The history of the NHS, from its origins to the present day, is reconstructed in precise detail at www.nhshistory.net.

[81] Following the referendum result, which saw a Leave victory (albeit a very narrow one), in March 2017 the British government announced the country's withdrawal from the European Union. Parliament ratified the withdrawal agreement, which was adopted following negotiations with the European Union, and Britain left the EU on 31 January 2020.

[82] Cf. for the English system, G. Maciocco, *Il cammino dei sistemi sanitari tra universalismo e neo-liberismo*. *Il caso Inghilterra*, in Tendenze Nuove, 2013, no. 6; F. Vecchia, *Il sistema sanitario inglese alle prese con il libero mercato*, in "Saluteinternazionale.info", 2013, no. 12.

[83] On the Beveridge model, see footnote 17 above.

rights[84] is defined, on the one hand, through statutory law (with respect to which the incorporation of the European Convention on Human Rights into the Human Rights Act of 1998 is a relevant step) and, on the other, according to the specific provisions contained in the fundamental documents of the individual national health systems that have undergone a series of revisions over the years and which have impacted the organisation of the health system and its financing.

The fundamental documents for the English health service, the NHS Costs and Conditions Act of 1949 and the National Health Service Act of 1946 (the latter also establishing the Welsh national health service, Public Health Wales), do not make it possible to define a general notion of a constitutional right to health, but they do identify a series of obligations for the public authorities to guarantee health services and performances universally and free of charge on the territory of reference.

In particular, the latter (the NHS Act, approved in 1946 and in force since 5 July 1948[85], and which underwent major reforms in 1977, 2006 and 2013) directly affects individual rights by setting up the organisation necessary to guarantee individual access to healthcare[86].

The national health service in Scotland, NHS Scotland, was also established by a separate act, the NHS Scotland Act of 1947, which is based on the NHS Act of 1946 governing the health service for Wales and England, but provides for specific qualifying aspects[87]. Following the devolution referred to above, it should be noted that of the constituencies of the United Kingdom, it is Scotland that has been granted the most extensive form of

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84 In the British system there is no uniform legal term which summarises in a single expression the different legal situations referring to health protection. From time to time, reference is made to the *right to health care*, the *right to physical integrity*, the *right to medical treatment* and so on. See I. Kennedy and A. Grubb, *Principles of medical law*, Oxford, Oxford University Press, 2004; M.J. Selgelid and T. Pogge (ed.), *Health rights*, Farnham, Ashgate, 2010.

85 On which see S.L. Greer (ed.), *The values of the national health services*, London, The Nuffield Trust, 2007.

86 On the reforms in the English system see K. Niemietz, *Internal markets, management by targets and quasi-markets*: *An analysis of health care reforms in the English NHS*, in Economic Affairs, 2015, pp. 94 ff.; D. Homes, *All change for the NHS in England as legislation takes effect*, in The Lancet, 2013, pp. 1169-1170; R. Klein, *Point-counterpoint*. *The twenty-year war over England's National Health Service: A report from the battlefield*, in Journal of Health Policy, Politics and Law, 2013, no. 4, pp. 847-867; R. Klein, *The New Politics of the NHS*, Oxford, Radcliffe Publishing, 2013; R. Millar *et al*., *What was the programme theory of New Labour's Health System Reforms?*, in Journal of Health Services Research and Policy, 2012, no. 17, pp. 7-15; S. Stevens, *Reform strategies for the English NHS*, in Health Affairs, 2004, no. 3, pp. 37-44.

87 See J. Stewart, *The National Health Service in Scotland, 1947-74*: *Scottish or British?* in Historical Research, 2003, 76; K.J. Woods and D. Carter (eds.), *Scotland's health and health services*, London, The Stationary Office, 2003.

autonomy.

Wales, in turn, through the Government of Wales Act of 1998, saw the establishment of the Welsh Assembly, a 60-member, single-chamber legislative assembly[88] with less extensive powers than the Scottish Parliament, reflecting the asymmetry of devolution. The reforms of 2008-2009 reshaped the current Welsh healthcare system, leading to the creation of Public Health Wales (PHW) Trusts – of which three currently exist (Welsh Ambulance Services NHS Trust, Velindre University NHS Trust, Public Health Wales) - that operate both nationally and locally.

The main reforms in England

The arc of the English reforms began in 1977 when the obligations of the Ministry of Health were redefined and the distinction between primary and secondary care and their respective sources of funding were more clearly defined. The National Health Service Act of 1977 makes a clear distinction between the regulation of primary care (Part 2 of the NHS Act) and secondary care (Part 1 of the NHS Act which also regulates community services). On the basis of this legislative act, it is the responsibility of the Ministry of Health to "promote a comprehensive health service" (see sections 1 and 3 of the NHS Act of 1977) through the establishment of "special health authorities" to which a number of functions relating to health protection were delegated (see section 11 of the NHS Act 1977). A large number of special authorities were established in the field: the Mental Health Commission, National Blood Authority, National Clinical Assessment Authority, National Patient Safety Agency, NHS Litigation Authority, Retained Organs Commission, UK Transplant, and others. Over the decades, problems in the system gradually emerged, particularly in terms of allocation of public resources.

In the 1980s and 1990s, the UK government introduced a number of tools to measure and evaluate the efficiency of the health system, such as the formulation of cost-containment programmes and the development of performance indicators. The Bristol Royal Infirmary and the Shipman scandal led to a focus on monitoring and control of care (for commentary on these cases, which left their mark on the history of British healthcare, see O. Davini, *Il prezzo della salute. Per un sistema sanitario sostenibile nel terzo millennio*, Rome, Nutrimenti, 2013).

The NHS and Community Care Act of 1990 reorganised the health system as an internal market, separating the functions of purchasing and delivering services. District health authorities and general practitioners

[88] On this point see A. Torre, "*On devolution". Evoluzione e attuali sviluppi delle forme di autogoverno nell'ordinamento costituzionale britannico*, in Le Regioni, 2000, no. 2, pp. 268 ff.

were assigned the functions of service purchasers. From the point of view of service delivery, hospitals, community services and mental health services were declared semi-independent (not-for-profit trusts) and enjoyed relative autonomy from the district health authorities under which they were previously managed. The stated aim of the internal market reform was to increase efficiency by stimulating competition between providers.

This political cycle came to an end with the arrival of Blair's government and his New Labour. In 1997, the Labour Government published its first White Paper, entitled *The New NHS*: *Modern, Dependable*, which further redefined the market principle in the health sector. According to the need for rationalisation of resources, the concept of "integrated care, based on partnership and driven by performance" went beyond the "command and control" approaches of the 1970s and reorganised the market system of the 1990s in a framework of planning and collaboration. In 1998, the Blair government's Department of Health published a document, *A first class service*: *Quality in the new NHS*, which stated that clinical governance was "the system through which organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which clinical excellence can flourish."

In the following years, the reforms were manifold and mainly concerned the establishment and development of some important agencies for monitoring and controlling the health system. In 1999, in order to remedy the most obvious distortions arising from the so-called "postcode lottery", the National Institute for Health and Care Excellence (NICE) was established through the NICE (Establishment and Constitution) Order (S.I. 1999 n. 220). This body was conceived as a "non-departmental public body" accountable to the Department of Health but operationally independent (see the revised NICE Charter following the enactment of the Health and Social Care Act 2012; on the NICE website https://www.Nice.org.uk/Media/Default/About/Whoweare/NICE_Charter.pdf).

The Blair government abolished fundholding in its 1999 reform but strengthened medical associations by setting up Primary Care Groups (PCGs), a model for managing primary health care for general practitioners which in 2001 became the Primary Care Trusts (PCT). Additionally, the 2001 reform first reduced the Health Authorities from 95 to 28 and transformed them into Strategic Health Authorities, and then their number was further decreased from 28 to 10 in 2006. They were ultimately abolished in 2012 by the Health and Social Care Act.

The task of PCTs is managing, with their own budget, all local services (general practitioners, nursing and rehabilitation services, dental activities, etc.) and carrying out commissioning and purchasing activities for

hospitals. PCTs receive a capitation quota and manage about 75% of the entire health budget. The population size of the PCT is 100,000-350,000 inhabitants. It is envisaged that PCTs may also manage the social services of municipalities.

The latest major reform of the English public health service, which came into effect on 1 April 2013 (the "Cameron Reform"), was implemented through the Health and Social Care Act. The aim of this reform was to contribute to an overall reduction in public spending in order to reduce the deficit and debt in the framework of a general spending review concerning every item in the state budget, through a de-bureaucratisation of organisational structures, the rationalisation of commissioning of services and real competition in their production. PCTs were abolished (see section 34 of the Health and Social Care Act) and replaced by Clinical Commissioning Groups (CCGs). As of 2013, the commissioning functions and related funding of secondary care were the responsibility of the CCGs (see section 10 of the Health and Social Care Act). CCGs receive the capitation quota necessary to finance specialist, diagnostic and hospital care, thus managing 70% of health resources. A large part of the decision-making power is therefore in the hands of general practitioners, who are authorised freelancers organised in consortia, and can also work in public-private partnerships with private entities. The Cameron Reform still attracts fierce criticism from professionals who believe that financial resources have been cut excessively, that health care has been opened up to the private sector too much, leading to an increase in the use of insurance policies, the loss of a geographical connection with the community of reference (consortia lack this geographical reference) and longer waiting lists.

The Strategic Health Authorities (see section 33 of the Health and Social Care Act) were replaced by the NHS Commissioning Board (see section 9 of the Health and Social Care Act), a public executive body under the Ministry of Health, whose operational name is NHS England.

The regulatory powers of other administrative agencies in the field of health have been further increased, such as the functions of NICE in relation to the development of standards for the Ministry of Health or NHS England, depending on whether the recommendations relate to the specific competence to be exercised (see sections 232 et seq. of the Health and Social Care Act).

Resources previously allocated to PCTs are now allocated to the thousands of CCGs that are partly run by general practitioners and partly by private providers and that are established at local level, managing an average population of about 225,000. CCGs are provided for within local authorities on the basis of a brief submitted to NHS England which assesses the group's organisational capacity and credibility. After they are established, NHS England monitors the groups annually on how it carries

out its functions and the amount of resources used (see Articles 25 and 26 of the Health and Social Care Act).

CCGs, as PCTs previously, receive financial resources on the basis of the allocation formula which also takes into account the size of the local population. As of 2013, the health resource allocation formula, weighted for the age of the local population and the frequency of use of services, was modified to exclude previously included indicators of deprivation and inequality in health needs (see NHS England, *Fundamental review of allocations policy - Annex C*, Technical guide, 2013).

The main reforms in Scotland

In Scotland, in the early 1990s, the hierarchical organisation of the health service was replaced by an organisation based on market principles, called "internal market." Its implementation has been slower than in other parts of Britain, indicating a reluctance to follow the lead of the British Conservative government. Health Boards (HBs) became the purchasers of health services, while hospitals and community services, which were previously run by health districts, were redesigned as Trusts with a range of organisational, accounting and financial autonomy. Along the same lines, general practitioners had become purchasers of a number of services from the health service on behalf of their patients and are known, by virtue of this function, as *GP fundholders*. Following devolution according to the Scotland Act of 1998, the Scottish Government announced the abandonment of the principles of the internal market and proceeded with the reunification into 14 single local bodies of health districts and Trusts as part of a process that was completed in 2004 through the NHS Reform Scotland Act 2004.

In 2011, in parallel with the elimination of drug subsidies, the Patient Rights Scotland Act was passed. This act set out the Scottish Government's commitment to improving the quality of the patient experience in the use of health services and patient involvement at all stages of care, indicating to health professionals a number of principles such as patient-centredness, quality of care, patient participation, the relevance of communication, the possibility of complaints as an opportunity to improve the service. In 2014 the Scottish Parliament passed the Public Bodies Act, which provides for social and health integration through agreements between the relevant local authorities and health districts.

The main reforms in Wales

With regard to Welsh health policies following devolution, it should be

clarified that these have been driven primarily by the need to reduce and, where possible, eliminate the role of the internal market in the health sector. The first step was to eliminate the fundholder function of general practitioners. The second was to provide for the establishment of a new organisational form such as Local Health Boards (LHBs). 22 LHBs were established in 2004 for community services and secondary care on the basis of cooperative agreements with the NHS rather than on the basis of market principles. In addition, LHBs were responsible for managing the local primary care system, seeking to overcome inequalities in access to care in cooperation with the 22 local authorities with which the health districts share the delimitation of the territorial jurisdiction and the target population.

In 2009, these structures went through a simplification process so that there was no longer a distinction between buyers and providers of services. 7 LHBs were created covering wider areas of reference and changed responsibilities in view of the transformation of competencies in service design and delivery within the boundaries of the identified area, both in hospitals and in primary and community care services.

An important aspect differentiating the Welsh system from the English system is the elimination of the drug levy. In Wales, prescriptions have been completely free of charge since 1 April 2007. The decision to abolish the costs of pharmaceutical prescriptions was guided by the objective of ensuring a broader protection of the right to health.

4.2. *Organisation and financing of the health system*

The process of political-administrative decentralisation implemented in Great Britain has also involved the aspect of healthcare organisation, and consequently the protection of the right to health and fair access to care[89]. The four national health systems in England, Scotland, Wales and Northern Ireland are all based on the model of universal, free care financed by general taxation. The provision of health services is therefore mainly financed through general taxation for those who reside in the UK[90].

Trends in UK health spending indicate that health spending increased in the 1990s as a result of growth in user demand for services and the

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[89] C.M.G. Himsworth, *Devolution and its jurisdictional asymmetries*, in Modern Law Review, 2007; W. Ross and J. Tomaney, *Devolution and health policy in England*, in Regional Studies, 2002, no. 36.

[90] The Ministry of Health defines as "ordinarily" resident: "someone who is living in the United Kingdom lawfully, voluntarily and for settled purposes as part of the regular order of their life for the time being, with an identifiable purpose for his or her residence here and that purpose must have a sufficient degree of continuity to be properly described as settled"; see Department of Health, *Eligibility for free hospital treatment under the NHS*, London, 2007.

development of health technologies, but has fallen sharply since 2010. The UK invests 9.6% of its gross domestic product in the health sector[91].

There is a residual private sector, in the context of which payments are made privately or through private insurance companies[92], which is entrusted with the provision of diagnostic services through agreements with the public sector, while mental health services are provided through close synergy between local public, voluntary and private sectors. Private insurance expenditure, which is generally classified as replacement, complementary or supplementary[93] in Great Britain, is normally supplementary in the sense that it provides cover for services that are not covered by general taxation and, possibly, for faster access to services. About 16% of the population use private insurance to access elective surgery treatments in the private sector[94]. In Great Britain, as in many other European and non-European countries, cost participation of users has, since the 1990s, increased in order to meet the problems of sustainability that the health system has been called to face. Most health services are free of user fees, e.g., inpatient and outpatient care, while dental care and pharmaceuticals are co-payments (prescription costs are envisaged only in England). Optical services (spectacles and contact lenses) are traditionally not covered. Free sight tests are provided in Scotland, while in England and Wales they are available for children and young people[95].

Service delivery and financing in England

The financing of the English system is public and is based on the combination of general taxation with the National Insurance Contribution (NIC), which is another type of tax paid by workers, employers and professionals on earnings. The NIC is a form of compulsory taxation paid by employees, employers and self-employed persons (it does not apply to pensions or dividends). The purpose of this type of contribution is to secure funds for pensions, sickness and unemployment. A part of these

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91 See Health System Financing Profile by country, *United Kingdom*, WHO, 2018, available online at http://apps.who.int/nha/database/Country_Profile/Index/en.

92 See A. Chapman, *The impact of reliance on private sector health services on the right to health*, in Health and Human Rights Journal, 2014, no. 16.

93 E. Mossialos and S. Thomson, *Voluntary health insurance in the European Union*, in *Funding health care*: *Options for Europe*, edited by E. Mossialos et al., Buckingham, Open University Press, 2002.

94 See Health System Financing Profile by country, *United Kingdom*, WHO, 2018, cit.

95 Data are extracted from the European Observatory on Health Systems and Policies, *United Kingdom*. *Health system review*, 2015, pp. 41 ff.

contributions (about 10%) goes to finance health care.

Since 1998, the resources available to the Ministry of Health for the next three years are determined every two years through a process of negotiation with the Treasury known as the *spending review*. In England, the Department of Health allocates resources to Public Health England (an executive agency of the Department of Health established by the Health and Social Care Act 2012) which redistributes them to local health planning authorities and to NHS England which allocates resources to the respective CCGs.

Healthcare provision is divided between primary and secondary care provided by CCGs and specialist care provided by hospitals organised in Trusts and Foundation Trusts. The latter was introduced in 2003 by the Health and Social Care Act as a new form of hospital organisation, alongside the Trusts. The aim of establishing Foundation Trusts was to increase the quality of care by increasing competition between providers who had become more autonomous, including in terms of budget. Hospitals with Foundation Trust status enjoy a high degree of autonomy although they are subject to external monitoring.

Primary care is the first point of contact in the system and is delivered by multidisciplinary teams. Registration with a general practitioner (GP) is compulsory and allows access to secondary and tertiary care.

Service delivery and financing in Scotland

Although funding for the health sector is derived from transfers made by the British Government through the Treasury, Scotland has considerable autonomy in setting its own health policies but limited taxation power, which remains in the hands of the British Government. The general principle is therefore the centralised management of taxation: all taxes in the UK are collected in London, where they are distributed among the various countries. However, it must be borne in mind that only Scotland has been granted a significant tax varying power, by virtue of which the Scottish Parliament can intervene and modify up to 3% of the Scottish tax system. Therefore, general taxation did not prevent the Edinburgh Parliament from adopting policies that differ from the English context, including in the health sector.

Healthcare is funded through general taxation. Eighty per cent of expenditure is public, with the remainder coming from private insurance and the NIC. The need to implement specific "flag policies" in the health sector that reflect Scottish specificity in relation to Britishness has come up against, on the one hand, a single British taxation system and, on the other, endemic Scottish territorial differentiation.

In terms of service delivery, this is devolved to the 14 regional boards of the health system, which are responsible not only for planning, but also for

the delivery of primary, secondary and tertiary care services. Following the 2004 reform that abolished the health organisation as an internal market, general practitioners (GPs) are no longer fundholders. Since 2004, there has been no separation of buyer and service provider, as this function is combined in the boards. Secondary and tertiary care is provided by hospitals and private clinics. Primary care is provided by trained professionals. Primary care providers are freelancers who have a contract with boards through Community Health Partnerships.

In addition to the 14 regional boards, which answer to the Ministry, there are other national institutes (NHS Education for Scotland; NHS Health Scotland; NHS National Waiting Times Centre; NHS24 Scottish Ambulance Service; The State Hospitals Board for Scotland; NHS National Services Scotland) within the health sector responsible for specific organisational aspects concerning the organisation of ambulance transport, training and health education, and quality improvement, and a special national agency (Healthcare Improvement Scotland). The system aims to integrate national and local components into the boards (which replaced the Trusts as of 1 April 2004) which include, as members of the governing bodies, local authority representatives and NHS representatives.

Service delivery and funding in Wales

Health protection is a shared competence between NHS institutions and the Welsh Government. Within the borders of Wales, the relevant powers are exercised by Public Health Wales (PHW), which operates both nationally and locally through LHBs. LHBs are responsible for the planning of services for the resident population, the delivery of services in their area, and the coordination between primary, secondary and tertiary care in their area. The notion of resident population is set out in Welsh Health Circular N. 32 (National Assembly of Wales, 1999).

Regulatory functions are performed by a mix of Welsh and British agencies - consider, for example, the role played by NICE and the Healthcare Quality Improvement Partnership. The aim of the Welsh Health Board, which is funded through general taxation, is to provide the means and resources to ensure that all treatments are effective in accordance with NICE guidelines.

The Welsh Government prepares annual priorities and performance requirements for the system. All NHS organisations prepare an operational plan at the beginning of the financial year to indicate how priorities will be met with the available resources. Each LHB draws up a five-year programme and reviews it annually.

4.3. *Actors and locations in decision-making processes*

Health decision-making bodies are located at central, national and local government level. As far as health resources are concerned, the amount of resources to be allocated to health is decided by the Government of the United Kingdom during the spending review approved by the Parliament.

The British government decides on the allocation of resources for the English system and then, based on the resources allocated to the English system, defines the resources to be allocated to the other three systems, which decide their own health policies. In England and Northern Ireland, a distinction between purchasers and providers of health services has existed since 1990 according to an internal market logic. This distinction was abolished in Scotland and Wales as a specific aspect of their health policies following devolution. Throughout Great Britain (i.e., excluding Northern Ireland), there is a division between health care, provided by the health service, and social care, funded by local governments and mostly provided by private organisations.

Decision-making processes in England

In England there are a number of bodies that take part in the decision-making process: the Ministry, the Parliament, a number of agencies, NICE (which is responsible for drawing up guidelines and quality standards for health technologies), the Care Quality Committee (which has been responsible for advising on the quality of care since 2009), and local authorities.

The 2012 Health and Social Care Act provided for the establishment of NHS England, which, together with the Ministry of Health, is charged with health planning and has oversight powers. In particular, it deals with the allocation of resources to CCGs on the basis of the allocation formula defined through the advice provided by the Advisory Committee on Resource Allocation (see NHS England, *Technical Guide to Allocation Formulae and Pace of Change for 2019/2020 to 2023/2024 revenue allocations*, May 2019, pp. 6 ff.) and the monitoring of the exercise of CCG functions. Before the start of each financial year, the Ministry prepares and presents to Parliament a document known as a “mandate” which sets out the objectives that NHS England will be required to achieve in the financial year and the financial requirements to be met in order to achieve these objectives (see section 24 of the Health and Social Care Act). This document defines the amount of resources that the Ministry proposes in relation to the priorities identified and the quantity of "weighted" population of the territory, also with reference to the population's age indexes and their use

of health services. The NHS England Board uses the "weighted capitation formula" in order to fund the different levels of care for each CCG: in other words, care needs are calculated based on the size of the relevant population, the costs arising from infrastructure and human resources, and the population's health status.

In order to set targets and resource needs, the Ministry consults with the Board, the Healthwatch England Committee, the Care Quality Committee and any other parties it deems appropriate.

NHS England is responsible for allocating resources to each CCG on the basis of expenditure forecasts submitted by the Commissioning Groups and assessed by its governing bodies. Before the beginning of each financial year, it is tasked with drafting a programme by which it determines how to achieve the objectives set and, at the end of the financial year, presenting to Parliament a final report illustrating the results achieved and the resources used.

One of the most interesting aspects of the English system is the prominence attributed to the involvement of the citizens in health choices, in order to increase the democratic legitimacy of these decisions. With the NHS Act 2006 and the Local Government and Public Involvement in Health Act 2007, the conditions for the participation of private individuals and local authorities in health care decision-making processes were improved. Clear duties are placed on health system operators to consult and involve patients and service users on the necessary changes to be made at local level (see Department of Health, *High quality care for all*: *NHS next stage review final report*, 2008, London).

Patient involvement in care pathways and local service planning was expanded in 2012 with the Health and Social Care Act. The aim of statutory obligations on CCGs to involve patients is to create a link between supply and demand for care so that the needs of the local population are met. The tools used are online surveys and consultations through local government bodies (see NHS England, *Transforming participation in health and care*, London, 2013; NHS England. *Transforming participation in health and care. Guidance for commissioners*, London, 2013).

As regards NICE, the direct involvement of citizens in the recommendation process was ensured through the establishment of the Citizens' Council in 2002. In Great Britain, the inclusion of citizens in decisions of direct interest, such as those in the health sector, is considered one of the essential prerequisites for true co-determination. The Citizens' Council is a body of thirty people, who apply for membership on the Council and serve a three-year term. There are three criteria regulating the composition of the Council: it must represent the English and Welsh population in terms of gender, social class, ethnicity, age and disability; members may not be employees of the NHS or work in any capacity in the health sector, even privately; and, once recruited, they must ensure their

constant commitment (on citizen participation opportunities, see www.nice.org.uk/getinvolved/).

The result is that the technical evaluations carried out by doctors, scientists and economists on the effectiveness of health technologies are thus supplemented by evaluations from the public as a means of mitigating what would otherwise be a fairly undemocratic decision-making body.

Another instrument of participation in the implementation of decisions is the *judicial review*. Patients who are denied access to treatment can find protection by challenging not the guideline (unless there are clear indications of a breach of procedures), but rather the decision of the relevant CCG. The persons who can directly challenge NICE's deliberations are, in essence, pharmaceutical companies, for whom the interest in taking part in the decision-making process is very high, in order to obtain a positive guideline for the drugs they produce. The decisions taken by NICE can be appealed to an appeal body that is set up specifically for this purpose (on the characteristics of appeals against NICE decisions, see *Guide to the Technology appraisal and highly specialised technologies appeal process*, February 2014).

Decision-making processes in Scotland

The most relevant decision-making bodies are located both at national and local levels and include a variety of actors, such as the Scottish Parliament, the Scottish Government, 32 local authorities, 14 territorial boards and 9 national health bodies, among which the role played by health agencies is particularly relevant. In particular, reference is made here to Health Improvement Scotland (HIS), which produces clinical standards (equivalent to NICE for England and Wales) and which also includes the Scottish Intercollegiate Guidelines Network, which has produced guidelines since 1993, and the Scottish Medicines Consortium (SMC).

As previously noted, among the devolved matters is health, while among the matters "retained" at central level is the competence concerning taxation forecasts. This last element, in particular, can condition health policies, since the Scottish Parliament, although free to legislate on health matters, is still limited by the financial resources granted to Scotland at central level. Public funding - in fact, almost all public funding - comes from a direct transfer made by HM Treasury, calculated on the basis of the *Barnett Formula*, a system used to derive the increase or decrease in spending allocations from the allocations for England proportionally based on the population of each territory in Scotland and Wales. For more details on the Barnett Formula, see *Research Paper 07/91*, 14 December 2007, *The Barnett Formula*, available at www.parliament.uk/documents/commons/lib/research/rp2007/rp07091.pdf.

Decision-making processes in Wales

Relevant funding decisions are made at both Welsh and UK levels, while the relevant decision-making forums are established at both national and local levels, including both the Scottish Parliament and Government and the LHBs. Responsibilities in this area are devolved to the National Assembly and exercised by the Welsh Government, including the Department of Health. The Minister receives a wide range of specialist advice to support his or her decision-making in this area from bodies such as the Ministerial Advisory Group, committees such as the Health Protection Committee and the National Joint Professional Advisory Committee.

The health budget, together with other resources (block grants), is allocated by the British Government to Wales. A further allocation of healthcare resources is then decided by the Welsh Parliament. The budget is allocated, through the negotiation of Health Care Agreements, from the central level to the level of the 7 health districts and the 3 Trusts (Ambulance Trust, NHS Trust, Public Health NHS Trust) which represent the competent authorities at local level in making decisions on the allocation of resources between GPs, the independent sector and the voluntary sector.

The involvement of local communities is traditionally strong in Wales. Eight health councils, the jurisdiction of which mainly corresponds to the seven health districts, represent the community's point of view on services and support patients who have complaints about the services received. Councils can be consulted about changes to services, and they also have the power to inspect the premises of NHS facilities – including those of freelancers such as GPs who have a contractual relationship with the health service – and those of bodies providing services on behalf of the NHS. The private sector, despite past attempts to introduce internal market principles and competition between different actors, is still largely marginal.

4.4. *Resource allocation and prioritisation*

In the British system, which is traditionally based on universal access, the issue of the relationship between resource allocation, prioritisation and resource scarcity is a major concern[96]. In the 1990s, a lively public debate

[96] On this point see R. Baltussen and L. Niessen, *Priority setting of health intervention*: *The need for multi-criteria decision analysis*, in Cost Effectiveness and Resource Allocation, 2006, No 4, p. 14; J.L. Gibson, D.K. Martin and P.A. Singer, *Setting priorities in health care organisations: Criteria, processes, and parameters*, in BMC Health Services Research, 2004,

arose in the UK on the connection between quality assurance and effectiveness of care and the constraints imposed by the scarcity of existing resources[97]. This public debate led to an in-depth reflection on aspects relating to the democratic legitimacy of allocation decisions and the questions concerning the relationship between the sustainability of the health system and universal and global access to care.

As mentioned above, the resources are allocated by the British central government to national health departments which then, in the various health systems, proceed on the basis of the weighted capitation formula[98] to further allocation to locally competent authorities, i.e., the CCGs in England, the HBs in Scotland and the LHBs in Wales.

a) England

Decisions on resource allocation and prioritisation are made at national level, based on forecasts from the Department of Health supported by NHS England, and at local level, through decisions made by CCGs that set priorities in consultation with local communities and partner organisations (private providers and local authorities). With regard to this issue, it is necessary to analyse the role played by the NICE guidelines and English case law on the allocation of health resources.

a.1) NICE guidelines

Since its inception, NICE has taken a leading role in health resource allocation and priority setting in the English and Welsh systems[99].

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no. 4, p. 25; D. Martin, *Making hard choices. the key to health system sustainability*, in Practical Bioethics, 2007, no. 3, pp. 1-8; S. Robinson, I. Williams, H. Dickinson, T. Freeman, and B. Rumbold, *Priority-setting and rationing in health care: Evidence from the English experience*, in Social Science & Medicine, 2012, pp. 2386-2393.

[97] An effective summary of the debate can be found in C. Newdick, *The positive side of healthcare rights*, in S. McLean (ed.), First do not harm: Law, ethics and healthcare, Aldershot, Ashgate, 2006, p. 575: "How does rights theory permit public authorities to balance competing claims to finite resources and promote community interests? Within a regime of scarce resources this prompts questions such as: what are the fundamental objectives of the NHS? Should they be *utilitarian* and designated to maximise health gain for the greatest number, or *egalitarian* – to reduce health inequality in the community?"

[98] On this concept see N. Rice, P. Dixon, D.C.E.F. Lloyd and D. Roberts, *Derivation of a needs based capitation formula for allocating prescribing budgets to health authorities and primary care groups in England*: *Regression analysis*, in British Medical Journal, 2000; D.L. Baines and D.J. Parry, *Analysis of the ability of the new needs adjustment formula to improve the setting of weighted capitation prescribing budgets in English general practice*, in British Medical Journal, 2000.

[99] It should be noted that NICE performs a number of functions in addition to prioritisation. These include advisory competences on continuous health improvement and accreditation

In summary, NICE develops various types of guidelines. These include non-binding public health guidelines, which aim to protect collective health, as well as non-binding clinical practice guidelines, which recommend certain treatments over others that may not be approved for specific conditions. While it is easy to affirm that the "positive" recommendation of certain types of treatment is not of a strictly binding character, it is not possible to affirm that the declaration of non-appropriateness of a given treatment does not have, with the exception of exceptional circumstances, a certain weight, especially from the point of view of the evaluation by NHS England of the activities carried out by the CCGs[100]. There are also other types of guidelines, which concern medical procedures – mainly referring to surgical procedures, also in outpatient settings – and the evaluation of health technologies[101]. These are binding guidelines, which GCCs are legally required to follow, and concern indications on the use of new or existing medicinal products, treatments and therapies[102].

Among the most important principles, NICE has based its actions on respect for the procedural principle of transparency, which is embodied in the very precise explanation of the arguments on the basis of which a particular intervention is recommended or not[103] and in the publication of decision-making protocols that represent sophisticated tools for summarising the interests and values at stake in the concrete cases that arise in practice[104]. In order to allow for verifiability of the arguments and

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that are exercised vis-à-vis the Secretary of State. On this point, see: P. Littlejohns, T. Sharma and K. Jeong, *Social values and health priority setting in England: Values-based decision making*, in Journal of Health Organisation and Management, 2012, no. 3, pp. 365 ff.

[100] The factor of scarcity of resources must also be considered. This factor makes it highly unlikely that a treatment not recommended by NICE will be provided by a local health authority. On this, see K. Syrett, *Expanded HTA, legitimacy and independence*. *Comment on "Expanded HTA: Enhancing fairness and legitimacy"*, in International Journal of Health Policy and Management, 2016, no. 5, p. 566.

[101] The choice of technologies to be evaluated depends on the choices made by the Ministry of Health. According to the process implemented by NICE, the request for technology assessment is reviewed by a multidisciplinary panel (composed of experts in the field, patients, the general public, professionals with a good knowledge of health services, etc.) and the resulting preliminary recommendations are submitted to the Ministry of Health, which makes the final decision on the topics and technologies to be subjected to an in-depth assessment (see www.nice.org.uk).

[102] Section 7(6) of NICE *(Constitution and Functions)* Regulations 2013 requires Clinical Commissioning Groups, the NHS and local authorities, limited to their public health functions, to comply with these guidelines.

[103] S. Clark and A. Weale, *Social values in health priority setting*: *A conceptual framework*, in Journal of Health Organization and Management, 2012, no. 3, p. 300.

[104] P. Littlejohns, T. Sharma and K. Jeong, *Social values and health priority setting in England*: *Values-based decision making*, in Journal of Health Organization and Management, 2012, no.

the possibility of challenging them[105], NICE has made use primarily of quantitatively measurable criteria accompanied, where appropriate, by qualitatively appreciable principles. To measure the quality and relevance of the technologies under evaluation, the evaluation methods are not limited to the use of scientific and econometric criteria, including clinical and economic effectiveness[106], but include substantive social values such as justice, equity, solidarity, respect for individual autonomy, and dignity[107], as well as procedural values such as transparency, dependence, inclusiveness, scientific rigour, timeliness, and contestability[108].

With regard to allocation decisions, it should be noted that NICE does not classify categories of services or areas of care, but distinguishes, on the basis of questions submitted, the recommended treatments from non-recommended treatments according to predefined thresholds that make it possible to assess their economic and clinical effectiveness.

The identification of services to be guaranteed throughout the national territory is carried out according to guidelines, which leave ample room for further intervention by local health authorities[109], both with regard to the quantity of services to be offered and guaranteed and with reference to the

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3, pp. 363-371.

[105] On the possibility of appealing NICE decisions, see *Guide to the technology appraisal and highly specialised technologies appeal process*, February 2014.

[106] Clinical and economic effectiveness are defined as follows by NICE: "Clinical effectiveness is the extent to which a specific treatment or intervention, when used under usual or everyday conditions, has a beneficial effect on the course or outcome of disease compared to no treatment or other routine care. Cost effectiveness: value for money; a specific health care treatment is said to be 'cost effective' if it gives a greater health gain than could be achieved by using the resources in other ways". See *Social value judgements*. *Principles for the development of NICE guidance*, p. 4. Cost effectiveness usually comprises two variants, CBA and CUA. The most widely used tool within the AUC is the QALY.

[107] M.D. Rawlins and A.J. Culyer, *National Institute for Clinical Excellence and its value judgements*, in British Medical Journal, 2004, pp. 224-227.

[108] See NICE, *Social value judgements*. *Principles for the development of NICE guidance*, London, 2008.

[109] While the studies on the role of NICE in this area are now extensive, less attention has been paid so far to the priority-setting processes that take place at local level. In England, some local health authorities have Priorities Committees, or bodies that assess the priority of various interventions and services that are requested. The explicit "prioritisation" of resources at local level is mainly based on certain economic evaluation methodologies such as Programme Budgeting Marginal Analysis (PBMA) and Multi-Criteria Decision Analysis (MCDA), which have generally become the most widely used at local level. In other words, given the highly decentralised nature of healthcare organisation, the substantive choices regarding priority in funding treatment, and the criteria on which to base waiting lists for patients, are also determined at local level. Cf. K. Hauck, P.C. Smith and M. Goddard, *The Economics of Priority Setting for Health Care*: *A Literature Review*, Washington, World Bank, 2004; S. Robinson, H. Dickinson, I. Williams, T. Freeman, B. Rumbold and K. Spence, *Setting priorities in health: A study of English primary care trusts*, London, Nuffield Trust, 2011.

definition of the subjective requirements that allow access to them. With regard to the way in which guidance is implemented, NICE provides advice and tools to support local implementation, while the Care Quality Commission is responsible for ensuring implementation.

With respect to the assessment of health technologies[110], NICE clarifies which aspects are taken into account in the assessment of medical technologies and devices through the definition of reference cases that allow the contextualisation of the individual methods used by the institute consistent with the objective of the health system to maximise health utility in a context of scarce resources[111].

The binding nature of these guidelines required the development of a series of procedural principles, such as transparency, inclusiveness, and scientific rigour, be developed. These principles, which must be complied with, have constituted the fundamental arguments on which case law decisions in proceedings challenging the guidance produced on the subject of drugs[112] have been based.

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[110] NICE's general duties in relation to technology appraisal are specified in the Health and Social Care Act 2012, which states in section 233 that NICE must take into account "the broad balance between the benefits and costs of the provision of health services or of social care in England; the degree of need of persons for health services or social care in England, and the desirability of promoting innovation in the provision of health services or of social care in England."

[111] See NICE, *Guide to the methods of technology appraisal*, April 2018, par. 5.1.1: "The Institute has to make decisions across different technologies and disease areas. It is, therefore, crucial that analyses of clinical and cost effectiveness undertaken to inform the appraisal adopt a consistent approach. To allow this, the Institute has defined a 'reference case' that specifies the methods considered by the Institute to be appropriate for the Appraisal Committee's purpose and consistent with an NHS objective of maximising health gain from limited resources". See also *Social value judgements. Principles for the development of NICE guidance*, July 2008, the first edition of which was published in 2005. Section 234(7) of the Health and Social Care Act 2012 states that NICE must "(a) establish a procedure for the preparation of quality standards, and (b) consult such persons as it considers appropriate in establishing that procedure."

[112] An early example of an appeal against a NICE guideline on medicines is the *Eisai* case. The pharmaceutical company challenged a NICE guideline with reference to the drug Aricept, produced to treat Alzheimer's disease. The NICE guideline provided for an exclusion from treatment for patients in the first stage of the disease, against which Eisai lodged an appeal based on the alleged unreasonableness of the decision and the violation of its rights to participate in the procedure. The Court of Appeal ruled in favour of the pharmaceutical company and annulled the guideline, justifying the annulment on the grounds that certain procedural principles had not been complied with, as Eisai had not been guaranteed full participation and transparent access to documentation during the proceedings. See *Eisai Ltd, R (on the application of) v National Institute for Health and Clinical Excellence (*NICE *2008)* EWCA Civ 438. The case is annotated in K. Syrett, *NICE and judicial review: Enforcing "accountability for reasonableness" through the Courts?* in Medical Law Review, 2008, no. 16, p. 127. Two other relevant drug cases followed: *R (on the application of Servier Laboratories Limited) v NICE* [2009] EWHC 281 and *R (on the application of Bristol-Myers Squibb*

It must be clarified that the main parameters on which NICE has based its decision-making processes are numerical measurement parameters, namely the QALY (*Quality-Adjusted Life Year*) and the DALY (*Disability-Adjusted Life Year*)[113]. Alongside the indication of the values, criteria and substantive interests at stake in health decisions, NICE specifies the procedural decision-making process in the event that the evaluation is carried out by taking into account several evaluation criteria[114] or in the event that a single criterion among those indicated is used[115]. As a result of the choice of method and the use of related criteria, the assessment

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Pharmaceuticals Limited) v NICE [2009] EWHC 2722. The cases are annotated by K. Syrett, *The English National Health Service and the transparency turn in regulation of healthcare rationing*, in Amsterdam Law Forum, 2011, pp. 107 ff. and by Id., *Health technology appraisal and the courts*: *Accountability for reasonableness and the judicial model of procedural justice*, in Health Economics, Policy and Law, 2011, pp. 477 ff. In the *Servier* case, the Court of First Instance dismissed the appeal, ruling that NICE's assessment not to recommend a new treatment for osteoporosis was reasonable because it had taken into account all available data. The Court of Appeal did not uphold this decision but annulled the NICE guideline. In the reconstruction by the court of second instance, NICE did not take into account all the data submitted by the pharmaceutical company but excluded some of them because of their alleged low scientific quality. However, the apodictic nature of this exclusion, which was not accompanied by adequate reasoning, was noted by the Court of Appeal, which declared the decision unreasonable. See NICE, ex parte Servier Laboratories Ltd. [2010] EWCA Civ 346.

[113] The QALY is a measurement parameter that was developed within cost-utility analysis tools in the 1970s and since the mid-1990s has become an internationally recognised standard tool. A QALY is the arithmetic product of life expectancy combined with a measure of quality of life in the remaining years. The DALY is an alternative tool that emerged in the 1990s and is used to quantify the burden of disease. The DALY is the result of adding the years of life lost (YLL) due to premature mortality with the years lived in disability or illness (YLD). QALYs have often been criticised in the literature as discriminating against specific user groups, such as the elderly, because distributing resources to younger people would obviously be more likely to increase health in terms of number of quality life years. In the NICE Guides, other evaluation criteria such as the ICER (*incremental cost-effectiveness ratio*) and the EQ-5D are indicated as alternative or cumulative appropriate instruments. The former measures the cost-effectiveness of the intervention using a comparison with the first best alternative to the intervention to be evaluated. The latter, like the QALY, measures cost-effectiveness by assessing the quality of life after the intervention under consideration. EQ-5D takes into account five dimensions of health: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. See NICE, *Guide to the methods of technology appraisal*, April 2018, on these two criteria; pp. 29 ff. For the literature see A. Wailoo and P. Anand, *The nature of procedural preferences for health-care rationing decisions*, in Social Science & Medicine, 2005, no. 60, pp. 223-236; R. Baker, S. Chilton, C. Donaldson, M. Jones-Lee, E Lancsar, H. Mason, H. Metcalf, M. Pennington and J. Wildman, *Searchers vs surveyors in estimating the monetary value of a QALY*: *Resolving a nasty dilemma for NICE*, in Health Economics, Policy and Law, 2011, no. 6, pp. 435-447.

[114] This case is outlined in *Guide to the multiple technology appraisal process*, September 2014.

[115] See *Guide to the single technology appraisal process*, September 2014.

document adopted by the NICE Appraisal Committee[116] is submitted within a defined timeframe for open discussion to a group of experts and stakeholders specifically invited to comment[117].

a.2) English case law on resource allocation

The English jurisprudence on the relationship between resource allocation and the right to access healthcare is characterised by some specific elements.

The first element concerns the identification of the obligations of public authorities with reference to the provision of suitable and necessary instruments to ensure access to healthcare services for users, rather than the identification of the subjective rights of patients. Another aspect that has characterised judicial intervention, in cases of appeal in judicial review against the refusal of benefits, concerns the medical-scientific factor underlying the decisions and the weight it has taken on within the judicial scrutiny[118].

The gap between performance levels between geographical areas and the reduced mobility between geographical areas are also factors behind some of the legal challenges, and these relate to the difference in availability of resources that affects equity of access to health services[119].

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[116] The Appraisal Committee is a standing committee of NICE that provides advice on matters referred to it. It is a multidisciplinary committee made up of doctors, economists, statisticians and lawyers who are selected through an open competition and appointed for a period of three years, renewable once. Its members come from the ranks of the NHS, academia, patient and health service user associations, and the pharmaceutical and medical device industry. There are 4 evaluation committees within NICE, each including a President and a Vice President. Each Evaluation Committee meets once a month to discuss matters referred to them. Members are required to disclose any existing conflicts of interest. See *Guide to the process of technology appraisal*, September 2014.

[117] A technology assessment guideline is usually adopted by NICE within a period of 7 to 14 months.

[118] On these factors, see L. Busatta, *La salute sostenibile. La complessa determinazione del diritto ad accedere alle prestazioni sanitarie*, Turin, Giappichelli, 2018, pp. 110 ff.

[119] The residency criterion is the basic criterion for registering with the NHS and registering with a general practitioner. For non-residents, only treatment that is considered urgent can be guaranteed. The relevant provision is found in section 175 of the *NHS Act 2006*. See also *The National Health Service* (*Charges to Overseas Visitors) Regulations*, recently amended (2020). It should be pointed out that in Great Britain patient mobility is not a viable option and this rigidity of the system increases problems in terms of formal and substantive equality for NHS users. In practice, this leaves room for the "postcode lottery", by which different approaches adopted at local health authority level result in different access to services, a phenomenon that NICE tried to counteract mainly through the development of health guidance.

The literature has highlighted how the increase in the number of appeals on the reasonableness of allocation decisions and the respect of procedural rules in the procedures is the consequence of an increase in the rationing of health resources in the English context[120]. Another strand of literature highlights the existence of two fundamental phases in resource allocation jurisprudence[121]. In the first phase, from 1980 to 1990, judges are seen to have shown great deference to the allocative choices of the health administrations concerned. In this case law, the medical-scientific factor and the characterisation of resource leasing as a political matter act as impassable limits to judicial scrutiny. Additionally, here the reasonableness of the decision is assessed by the judges on the basis of the "Wednesbury test"[122]. In the second phase, from 1990 onwards, the judges' scrutiny became more penetrating and went as far as assessing the reasonableness of the choices and compliance with procedural guarantees in order to protect patients' rights at a time when resources were clearly and explicitly rationed.

The first phase of English jurisprudence has produced the Hincks[123], Harriot[124] Walker[125], Collier[126] and Seale[127] Decisions.

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120 C. Newdick, *Who should we treat?* Oxford, Clarendon Press, 1995, p. 93; K. Syrett, *The English National health service and the "transparency turn" in regulation of healthcare rationing*, in Amsterdam Law Forum, 2011, no. 3, p. 101; K. Syrett, *Impotence or importance? Judicial review in an era of explicit NHS rationing*, in Medical Law Journal, 2004.

121 See D.W.L. Wang, *From wednesbury unreasonableness to accountability for reasonableness*, in Cambridge Law Journal, November 2017, no. 3, pp. 642-670.

122 Established in *Associated Provincial Picture Houses Ltd v Wednesbury Corp*, 1947, 2 All ER 680, it maintains that an administrative measure is considered unreasonable if it can be considered probable that no public authority would have taken it.

123 *R. v Secretary of State for Social Services and Ors*, ex parte Hincks [1980] 1 BMLR 93.

124 *R. v Ethical Committee of St Mary's Hospital (Manchester)*, ex parte Harriot [1988] FLR 512. In *Harriot*, the applicant complained that the ethics committee's recommendation to remove her from the waiting list for access to assisted reproduction on account of her past criminal convictions constituted unreasonable discrimination. The recommendation of the ethics committee stated that, in a context of scarce resources, "some individuals will have a more compelling case for treatment than others." See Ethical Committee of St. Mary's Hospital [1988] FLR 512, 514. The High Court, however, dismissed the appeal and found that the conduct of the health authority had not breached its obligations under English law. In particular, the Court held that there was no unlawfulness in the delay by the administration in presenting to the applicant the real reasons for her removal from the waiting list.

125 *R. v Central Birmingham Health Authority*, ex parte Walker [1988] 3 BMLR 32.

126 *R. v Central Birmingham Health Authority*, ex parte Collier [1988] 151.

127 *R. v Sheffield Health Authority*, ex parte Seale [1994] 25 BMLR 1. In the *Seale* case, the applicant stated that the health administration's decision to fund in vitro fertilisation only for women between 25 and 35 years of age was made "illegally, improperly and irrationally". According to the applicant, several scientific opinions disagreed on the matter

The individual appeals activating the proceedings in the Hincks, Walker and Collier cases were aimed at obtaining recognition of the fact that insufficient funding and long waiting lists entailed that the delay in obtaining the required health care constituted a breach of the duties of health administrations to provide a health service appropriate to the needs of the population.

In the Hincks case of 1980[128], four patients brought a claim based on delay in the provision of health care in the form of the alleged breach by the Minister of Health of his duties under section 3 of the NHS Act[129]. In the motivations of the judgment, the judges argued that the duty of the Minister of Health is not absolute, since it is conditioned on the guarantee of available financial resources, which are always limited. Therefore, the judges concluded that it was not possible to find a breach of duty under the law, since the Ministry acted in the best possible way within the constraints of limited existing economic resources.

This approach was confirmed by subsequent decisions. In the Walker case, the appeal was against a local health authority's decision on clinical priorities for cardiac surgery. The judges affirmed their lack of competence to intervene in matters that must be decided by those who are considered in the system to be responsible for the allocation of resources[130]. The motivations of the Court of Appeal state that: "It is not for this Court, or indeed any Court, to substitute its own judgement for the judgement of those who are responsible for the allocation of resources." This argument defines a specific area of competence regarding the allocation of health resources, the content of which relates to the exercise of political discretion in this matter. Legal control can therefore not extend to the assessment of the content of the political decision on the matter.

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and the absolute exclusion of women over 35 from accessing assisted reproduction techniques did not take into account individual circumstances.

128 *R. v Secretary of* State *for Social Services, West Midlands Regional Health Authority and Birmingham Area Health Authority (Teaching)*, ex parte Hincks and others [1980] 1 BMLR 93. This was an appeal by four patients on the waiting list for orthopaedic surgery, who complained of non-compliance with section 3 of the *NHS Act* 1977, insofar as it provides for the duty of the Ministry of Health to provide the services necessary for the treatment of diseases.

129 The applicants had been on the waiting list for orthopaedic surgery for many years, and in their complaints, they highlighted the inadequacy of the health services available in their area. This area had been affected since 1971 by the enlargement of existing medical facilities and structures, but the works had not been completed within the prescribed time-limits. The applicants, with the support of the medical staff, complained that no measures had been taken to ensure health services during the period of renovation of the medical facilities. The appeal was rejected because political and regulatory discretion is exercised by defining the most efficient way to allocate resources across the whole territory.

130 *R. v Central Birmingham Health Authority*, ex parte Walker [1987] 3 BMLR 32.

The Collier decision[131] confirmed the assumption that there must be a clear separation between the judicial scrutiny of the reasonableness of the measures adopted in the health field and the use of political discretion exercised through decisions on the definition of priorities and allocation of resources.

Another case, known as the "Child B" case, can be seen as the intersection between the elements we have qualified as distinctive of the two fundamental phases of English resource allocation jurisprudence. The case was triggered by the appeal lodged by the father of a girl suffering from leukaemia against the Cambridge Health Authority's refusal to allow her access to a further course of chemotherapy and a possible second bone marrow transplant[132]. The court of first instance had confirmed that judicial review was limited to detecting possible procedural defects and did not have the possibility of assessing the merits of the health administration's decision and replacing it. In light of this premise, the judge accepted the child's father's request, declaring the health administration's measure to be unlawful because the reasons for the refusal of the treatment were insufficient and lacked a "substantial objective justification" on which to condition the patient's right to life. The Court of Appeal, however, rejected the approach of the judge in the first instance, finding the administrative measure to be lawful and declaring the following:

> *Difficult and agonising judgments have to be made as to how a limited budget is best allocated to the maximum advantage of the*

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131 The case (*R. v Central Birmingham Health Authority*, ex parte Collier) was decided on 6 January 1988 and is annotated in very critical terms in C. Newdick, *Who should we treat?* cit., pp. 100 ff; K. Syrett, *Law, legitimacy and the rationing of healthcare. A contextual and comparative perspective*, New York, Cambridge University Press, 2007, pp. 163 ff. This was a judicial review appeal brought by the parents of a child with a heart condition against the refusal to perform the operation for which the child was at the top of the waiting list. The hospital (as in the *Walker* case) could not guarantee the service, as there were no beds available. The Court of Appeal rejected the appeal on the grounds that it was impossible for a judge to review the merits of the medical and clinical criteria on which the decisions of health administrations were based.

132 The decision of the court of first instance is *R. v Cambridge Health Authority*, ex parte B (a minor) [1995] 25 BMLR 5; the decision of the Court of Appeal is *R. v Cambridge Health Authority, ex p B,* 1995, 2 All ER 129. The patient, suffering from severe leukaemia, received her first bone marrow transplant in March 1994. When the disease flared up again, the father inquired about the possibility of further treatment, even abroad, and following the advice of some doctors in other health units, he considered the possibility of giving the girl further chemotherapy with a view to a second bone marrow transplant. The cost of the whole treatment was estimated to exceed £75,000. The health authority refused treatment because that cost exceeded the benefit the patient would receive, also taking into account the suffering she would have to go through. B.'s father appealed against the refusal in order to obtain a judicial review of the decision.

> *maximum number of patients. That is not a judgment which the court can make. In my judgment, it is not something that a health authority such as this authority can be fairly criticised for not advancing before the court.*

The path followed by case law after the case described[133] shows a trend towards decision-making procedures characterised by procedural correctness and transparency.

In the second phase, the judicial review was pushed to the point of assessing the reasonableness of the allocation choices and the respect of the patients' procedural rights[134]. The decisions made at this stage are found in Coughlan[135], Fisher[136], A, D and G[137], Rogers[138], Otley[139], Ross[140] and Murphy[141].

In Fisher, a treatment for multiple sclerosis was denied on the basis of lack of funding and the low degree of efficacy and cost-effectiveness of the treatment. Faced with the denial of access to treatment, an internal health system circular asked health authorities to develop and implement ways to prescribe treatment. The High Court upheld the appeal on the grounds that the health administration had not provided sufficient reasons to deviate

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133 On this, see C. Ham, *Tragic choices in health care*: *Lessons from the Child B. case*, in British Medical Journal, 1999, no. 7219, pp. 1258-1261; C. Ham and S. Pickard, *Tragic choices in health care*: *The case of Child B.* London, King's Fund, 1998.

134 It should be pointed out that some of the decisions of this period are based on the guidelines that characterised the first phase. See *R. v Secretary of State for Health*, ex parte Pfizer [2002] EWCA Civ 1566; *R. v North Staffordshire Primary Care Trust*, ex parte Condliff [2011] EWCA Civ 910. In these decisions, the judges stated that the allocation of resources is a political matter and consequently it would be inappropriate to carry out an in-depth judicial review to assess the merits of the decision.

135 *R. v North and East Devon Health Authority*, ex parte Coughlan [2001] Q.B. 213. In Coughlan, the judicial review focused on the assessment of the reasonableness of the decision to close a hospital where a disabled person lived and to place her in another facility. The Court of Appeal considered a number of factors, such as the assessment of the patient's condition, the legitimate expectation of the patient who had been promised that she would be able to live out her life in the hospital, the existing public interest and whether placement elsewhere would meet the patient's needs.

136 *R. v North Derbyshire Health Authority*, ex parte Fisher [1997] 8 Med L.R. 327.

137 *R. v North West Lancashire Health Authority*, ex parte A, D and G [1999] All E.R. (D) 911.

138 Swindon NHS Primary Care Trust, Secretary of State for Health, ex parte Rogers [2006] EWCA Civ 392.

139 *Barking & Dagenham NHS PCT*, ex parte Otley [2007] EWHC 1927.

140 *West Sussex Primary Care Trust*, ex parte Ross [2008] EWHC B15. In Ross, in which a divergence of scientific opinion is a salient aspect, the courts highlighted the lack of consideration of scientific findings by health administrations in their decision-making procedures.

141 *Salford Primary Care Trust*, ex parte Murphy [2008] EWHC 1908.

from national policy. In this case, the absolute ban on treatment was declared unreasonable because it did not take into account all the relevant elements, including the individual circumstances of the patient.

Similarly, in A, D and G the decision was based on the unreasonableness of the absolute prohibition of access to surgical sex reassignment procedures. This prohibition resulted from a national policy that gave the type of surgical intervention a low priority compared to the possibility of its financing. The Court of Appeal stated that the inadequate way in which the health administration had taken individual circumstances into account was, in reality, a way of imposing an unjustified ban. Moreover, in the judges' assessment, the decision of the health administration did not take into account the effectiveness of the treatment in relation to the health needs raised and communicated by the applicants.

In the Rogers case, the denial of access to drugs for cancer treatment highlighted a potential idiosyncrasy that can occur between the individual's reasons and the collective reasons that require a (reasonable) limitation in access to health technologies, given the considerable economic impact they have on the system as a whole. The ruling was made in relation to the drug Herceptin, which was already available for the treatment of advanced breast cancer, but was still being evaluated for treatment in the early stages of the disease. The appeal lodged by a woman against the decision to deny her access to the treatment ended with the annulment of the measure, which was considered arbitrary and unreasonable[142]. In this case, the NICE assessment process had not yet been completed and the policy for access to the drug, drawn up by the woman's PCT of reference, was that the drug would not be made available except in exceptional circumstances. These circumstances, however, were not sufficiently clarified in the health administration's decision, nor were criteria provided for distinguishing between patients according to the stage of their illness. The Court of Appeal noted the arbitrariness of the PCT's decision and annulled it on the basis that the measure resulted in a general ban on access to the drug[143]. The solution adopted was based on enhancing the transparency and

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142 *R. (on the application of Ann Marie Rogers) v Swindon NHS Primary Care Trust and the Secretary of State for Health* [2006] EWCA Civ 392.

143 "Where the clinical needs are equal, and resources are not an issue, discrimination between patients in the same eligible group cannot be justified on the basis of personal characteristics not based on healthcare. As to clinical characteristics, it was suggested in argument that one woman in the eligible group might have a greater clinical need for Herceptin than another. We can see that that might be theoretically possible but there is no indication that any such possibility in fact exists... The PCT has not put any clinical or medical evidence before the court to suggest any such clinical distinction could be made. In these circumstances there is no rational basis for distinguishing between patients within the eligible group on the basis of exceptional clinical circumstances any more than on the basis of personal, let alone social, circumstances." *Rogers*, par. 79-81.

reasonableness of the internal phases of the procedure, since the judges assumed that the judicial review consists of a verification of compliance with procedural requirements rather than in a substantive assessment of the exercise of medical discretion, which constitutes the basis for this type of decision[144].

Both Murphy[145] and Otley[146] exhibit a number of similarities with Rogers. In all three, the legitimacy of the health authorities' decisions to set conditions for access and limit access to services on the basis of transparent and non-discriminatory criteria was confirmed. The case law stated, however, that the conditions of access laid down must include the possibility of admitting individual patients to treatment in exceptional circumstances or on the basis of the specific circumstances of the applicant.

In the Murphy and Otley cases, the decision of the health authority was held to be unreasonable because it did not take all relevant aspects into account when making its decision to refuse access. In the latter case the courts concluded that, although the issue of scarcity of resources is one of the elements to be considered along with the various interests at stake, the economic factor cannot assume a decisive weight in decisions concerning exceptional access to very expensive but very effective medicines[147].

b) Scotland

In Scotland, as already noted the counterpart of NICE is Health Improvement Scotland (HIS)[148] which includes and coordinates a number of bodies and institutes with supervisory and monitoring competences in

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144 See C. Newdick, *Judicial review: low-priority treatment and exceptional case review*, in Medical Law Review, 2007, no. 15, p. 243. See also C. Casonato and C. Piciocchi, *Devolution, Diritti, Identità: la tutela della salute tra asimmetrie ed esigenze di uniformità,* in Sistemi costituzionali, diritto alla salute e organizzazione sanitaria: spunti e materiali per l'analisi comparata, edited by R. Balduzzi, Bologna, Il Mulino, 2009, pp. 51 ff.

145 In the Murphy case, the plaintiff was denied access by the health administration to an effective but very expensive drug for the treatment of renal cancer. The woman lodged a judicial appeal against the administration's refusal. The High Court pointed out that the health administration's decision was unreasonable because it did not take the woman's specific situation into proper consideration.

146 This decision was taken on the appeal of a woman with colorectal cancer for whom conventional chemotherapy treatments were not producing satisfactory results. She had therefore started, at her own expense, treatment with a drug, Avastin, which is effective in relation to the type of cancer from which she was suffering, and which was not included among those made available by the health service. Since she responded well to the treatment, the general practitioner petitioned the health administration to grant her access to the full course of therapy.

147 *Barking & Dagenham NHS PCT*, ex parte Otley [2007], cited above, para. 27.

148 HIS was established by the Public Service Reform (Scotland) Act 2010.

various fields of action[149]. In August 2012, HIS produced a position paper on the evaluation method for new technologies[150]. Economic evaluation of technologies comprises a number of criteria: *cost-effectiveness analysis*, which is measured in units of QALY and ICER[151]; *cost-minimisation* analysis and *cost-utility analysis*, which represent specific forms of cost-effectiveness; and *cost-benefit analysis*, which measures costs and consequences in monetary units. The evaluation process carried out by HIS starts with the drafting, over a period of 3 months, of an "evidence note", which presents a compilation of all scientific evidence available in the primary and secondary literature on the clinical and economic effectiveness of the technology under evaluation[152]. These aspects are then reviewed on a biannual basis to verify whether or not the assessment is still relevant or if any scientific evidence since the publication of the assessment calls for an update.

With regard to the standard-setting function of the HIS bodies mentioned, three specific bodies in particular play a role in the "prioritisation" of resources. The Scottish Health Technologies Group (SHTG) is an advisory committee to support decision-making and design processes in Scottish boards and which provides recommendations on health technologies, both in terms of clinical and organisational procedures and medicines (these are then reviewed by the Scottish Medicines Consortium (SMC)).

The recommendations of the SHTG are based on a process of scrutiny of the technology under assessment based on scientific and technical evidence interpreted as critically and impartially as possible[153]. The 24 members of the committee are appointed by HIS in cooperation with the SHTG chair for

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[149] These include the following: the Healthcare Environment Inspectorate monitors the environmental safety of hospitals with regard to viruses, bacteria and pathogens; the Scottish Health Council supports the NHS in involving patients, staff and communities in the development of health services; the Scottish Health Technologies Group provides advice on the clinical and economic efficiency of technologies used in healthcare; the Scottish Intercollegiate Guidelines Network develops recommendations on the basis of scientific and technical evidence for clinical practice; the Scottish Medicine Consortium (SMC) recommends new-generation drugs with market authorisation characterised by good value for money.

[150] Health improvement Scotland, *Standard operating procedure for production of technologies scoping reports*, August 2012.

[151] The unit of measurement of QALY and ICER is discussed above in the section on resource allocation and prioritisation in the English system.

[152] The paragraphs into which the evidence note should be structured are as follows*:* introduction, literature search, health technology description, epidemiology, clinical effectiveness, safety, cost effectiveness and conclusion. See Health Improvement Scotland, *Standard operating procedure for production of evidence notes*, September 2012, p. 10.

[153] Scottish Health Technologies Group, *Standing Orders*, March 2019.

a period of three years, renewable once. The "advice statements" of the SHTG are intended to indicate the evaluations on the basis of clinical effectiveness, safety of devices and procedures, and cost-effectiveness[154]. The first criterion, that of *clinical efficacy*, must be demonstrated by reporting the parameters of the quantity of the studies carried out and the patients involved, the quality of the studies by recording the possible biases capable of intervening in the intervention-results relationship, and the consistency of the results emerging from the studies. The second criterion is the safety of the technology, which is measured by the relationship between the benefits provided by the technology and its negative impact, whether in the form of side effects, adverse effects or complications. Cost-effectiveness is normally assessed by reference to the values of a comparator, usually a reference developed for a specific case in Great Britain. The terms of comparison include comparing intervention A and B for outcome C in relation to population D. Contextual factors which may influence the evaluation process are many including the existence of NICE guidance, the existence of Scottish Government documents on the given technology, the physical location and configuration of services, the existence of information on the issue of budget/resource impact, equality and non-discrimination issues[155]. The draft advice statement is then sent to previously identified competent and interested groups who, according to the notice and comment procedure, draw up their comments which will be taken into account for the drafting of the final advice statement.

For the drugs sector, the Scottish counterpart of NICE is the SMC[156]. Its primary function is the evaluation of cost-effectiveness on all new medicines. At the end of a consultation process in which doctors, representatives of the fourteen Scottish Health Boards (HB), representatives of the pharmaceutical industry and representatives of patients' associations participate, the SMC produces recommendations (not guidelines, as NICE does), which are non-binding and published without delay on the institution's website. Since May 2014, the SMC has increased

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[154] HIS, *Framework for producing SHTG Advice Statements*, Scottish Health Technologies Group, December 2013, pp. 1 ff.

[155] *Ibid*, pp. 5 ff.

[156] The Scottish Medicines Consortium was set up in 2001 with the aim of providing scientific and technical support to the Scottish National Health Service on new medicines. Prior to the SMC, Area Drug & Therapeutics Committees (ADTC) were set up at local level to advise health boards on new medicines to be approved in the local area. The SMC was established as a consortium of ADTCs by bringing together the best practices and evaluation techniques that had been developed. See Working with SMC, *A guide for manufacturers*, July 2014 (revised July 2017). The SMC consists of 40 members who are appointed by the ADTCs to represent all 14 Health Boards. The SMC has adopted a policy of openness and transparency that provides for decisions and decision-making paths to be published on its website: www.scottishmedicines.org.uk.

the participation in its meetings and meeting outcomes by opening its meetings to the public[157].

Recommendations can be of three distinct types: in the first, the medicine is recommended without restrictions for adoption within the health care system; in the second type, the medicine is given a "restricted" recommendation; lastly, there are cases in which the new medicine is not recommended because the cost-benefit ratio has not received a positive evaluation or because the degree of innovation of the product has not been considered sufficient because it is similar to other less expensive medicines already on the market. SMC recommendations are not binding, but local health authorities tend to follow them. This is mainly due to the high degree of involvement of local authorities in the decision-making process on drug evaluation. In this way, local authorities can intervene during the evaluation process, avoiding dangerous deviations (from the point of view of territorial differentiation) from the recommendations of the CMS. The SMC's work has thus made it possible to address the "postcode lottery" and standardise access to treatment, albeit only in the pharmaceutical sector.

c) Wales

The NICE guidelines for medical devices, diagnostics and treatments are also effective in Wales and are a technical and scientific reference point for Scottish assessment agencies, but it should be noted that Wales has a specific national agency for prioritising medicines: the All Wales Strategy Medicines Group (AWSMG). The Welsh agency focuses on clinical effectiveness by taking the provision of coordinated care pathways as a parameter.

Therefore, for the specific sector of pharmaceuticals – an area in which a specifically Welsh "flag policy" has been developed, characterised by the elimination of the contribution for prescriptions of medicines[158] – the specific competence belongs to the AWSMG. The AWSMG takes the assessments of NICE into account but can deviate from it on the basis of its own evidence and arguments. The AWSMG was established in 2002 to provide scientific and technical advice to the Ministry of Health and Social Services. It is a body made up of professionals from various fields of scientific and technical knowledge (lawyers, economists, clinicians, representatives of pharmaceutical organisations, representatives of LHBs,

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[157] This turns out to be one of the most relevant consequences of the *Scottish Government Health's and Sport 2013 review*.

[158] On 1 April 2007, the contribution on medication for those who are registered with a Welsh GP, or for those who received a prescription from a Welsh pharmacist, was abolished (criterion of medical or "reinforced" residence).

representatives appointed by Community Health Councils)[159]. Between April 2013 and March 2017, the AWSMG conducted 162 evaluations of which 147 (91%) resulted in a positive recommendation for the use of the evaluated medicines within national borders[160]. Its initial mandate was to evaluate medicines that have a high cost to the health system (more than £2000 per patient per year). In 2007, the Ministry of Health extended the mandate of the institute to all new drugs. A positive recommendation subsequently approved by the Ministry places an obligation on LHBs to finance expenditures in accordance with the recommendation. If NICE issues a negative recommendation, it is possible to request an appraisal from the AWSMG if there is a Patient Access Scheme and new elements to be assessed compared to those already assessed by NICE[161].

In the absence of guidelines from NICE and the AWSMG, prescribers routinely refer to the available scientific evidence as a basis for their prescribing decisions. The aim of the evaluation process is to increase the economic sustainability and effectiveness of the Welsh pharmaceutical system by subjecting the drug card to clinical effectiveness and cost-effectiveness testing. In May 2015, the AWSMG adopted a specific procedure, revised in July 2019, for the evaluation of orphan, ultra-orphan and rare disease drugs[162]. In view of the fact that the QALY measurement criterion usually exceeds the threshold value, additional qualitative criteria have been added to the QALY criteria, which are considered to be more appropriate[163]. In this case, after the evaluation scheme has been sent to the pharmaceutical company so that it can respond with its comments, the preliminary evaluation is conducted by the New Medicines Group[164]. In the event of a negative assessment, the pharmaceutical company can request the Clinical and Patient Involvement Group (CAPIG) to intervene in the

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159 See Article 3 (under the heading "Membership") of the Institute's *Constitution* published on its website www.awmsg.org.

160 All Wales Medicines Strategy Group, *AWMSG Five-year Strategy 2018-2023*, March 2018, p. 5.

161 See All Wales Medicines Strategy Group, *Wales Patient Access Scheme*: *Process Guidance*, June 2019. The *Patient Access Scheme* is triggered when a pharmaceutical company submits the drug evaluation directly to the Ministry of Health and not to the Evaluation Agency in order to facilitate the access of certain patients to certain drugs.

162 Orphan and ultra-orphan drugs are intended for the treatment of rare diseases. A disease is defined as "rare" when its prevalence, defined as the number of cases in a given population, does not exceed a set threshold. In the EU, this threshold is a disease that affects no more than 5 out of 10,000 individuals, which means that in the EU there are around 246,000 people suffering from a rare disease.

163 These criteria are found in the *AWMSG appraisal process for a medicine for a rare disease*, July 2019, p. 3.

164 The New Medicine Group (NMG) is a committee with a referral function to the AWSMG. See NMG, Constitution update, December 2017.

process. The aim of the intervention is to involve the clinical and patient perspective. In order to acquire the relevant elements, the process is suspended for approximately 8-12 weeks to allow the necessary hearings to take place.

5. *Spain*

5.1. *The underlying philosophy and its evolution*

The Spanish health system, originally based on a system of social security, underwent a radical transformation towards a Beveridge-type[165] model after the entry into force of the Constitution in 1978[166] . Article 43 of the Spanish Constitution states:

> *1. Se reconoce el derecho a la protección de la salud.*
> *2. Compete a los poderes públicos organizar y tutelar la salud pública a través de medidas preventivas y de las prestaciones y servicios necesarios. La Ley establecerá los derechos y deberes de todos al respect.*

These rules must be read in conjunction with Art. 53(1)(b). 3, of the Constitution, which states that the guarantee of the rights recognised in the third chapter of the Constitution (which includes Article 43) must guide legislation, jurisdiction and the activities of public authorities. The effectiveness of the constitutional protection of health depends on the concrete implementation of the legislation in respect of which the health guarantee is a general objective the content of which is determined by the legislator[167].

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[165] On the Beveridge model, see footnote 1 above. On the aforementioned transformation, see S. Munoz Machado, *La formación y la crisis de los servicios sanitarios publicos*, Madrid, Alianza Editorial, 1995; J. Tornos Mas, *Sistema de seguridad versus sistema nacional de salud*, in Revista de Derecho y Salud, 2002, no. 10; M. D'Angelosante, *L'incidenza delle regole di organizzazione e di distribuzione delle competenze sulla conformazione del mercato dei servizi sanitari: sistemi universalistici e sistemi occupazionali a confronto nello spazio comunitario*, in I servizi sanitari: organizzazione, riforme e sostenibilità. Una prospettiva comparata, edited by A. Pioggia, S. Civitarese Matteucci, G.M. Racca and M. Dugato, Santarcangelo di Romagna, Maggioli, 2011; M. Petmesidou and A.M. Guillén, *"Southern-style" National Health Services? Recent Reforms and Trends in Spain and Greece*, in Social Policy & Administration, April 2008, No 2, pp. 106-124.

[166] On the Spanish Constitution, see *Una Costituzione democratica per la Spagna*, edited by G. De Vergottini, Milan, Franco Angeli, 1979; R.L. Blanco Valdés, *Introduzione alla Costituzione spagnola del 1978*, Turin, Giappichelli, 2017; O. Alzaga Villaamil, *Comentario sistemático a la Constitución española de 1978*, Madrid, Marcial Pons, 2017.

[167] On the nature of health protection, the Constitutional Court expressed its opinion in the

Article 43 of the Constitution was implemented by the Spanish legislature in 1986, with its approval of the General Health Law (Law No 14 of 25 April 1986), which established the national health system. The basic aim of the general law was to introduce a system of health protection, with characteristics differing from the previously existing social security system and inspired by a universalistic vocation of protection.

The General Health Law of 1986, which was part of the package of measures for the progressive democratisation of the country, legislated the transition from a system financed on the basis of workers' contributions to one financed on the basis of general taxation. This law defined the health service as "the totality of all structures and public services for the protection of health" and "the combination of the state administration and the services guaranteed by the Autonomous Communities"[168]. The basic principles of the health system therefore consist of:

> *universal access, public funding through general taxation, integration of different services within the health system, devolution of responsibilities to the Autonomous Communities and regional organisation of health areas and zones, a new model of primary care integrating prevention, promotion and rehabilitation activities within it*[169].

Between 1981 and 2002, a gradual process of decentralisation

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well-known judgment no. 139 of 2016, following an appeal filed by the Parliament of Navarra, followed by the appeals of the Government of the Canary Islands, Asturias and the Basque Government, on the constitutionality of Royal Decree-Law no. 16 of 2012, which determined the exclusion of irregular foreigners from access to non-emergency care. The Constitutional Court considered the definition of the right to health protection, stating that it is a "*derecho rector, razón por la que carece de contenido constitucionalmente esencial que pueda ser afectado por la legislación de urgencia*". In the Court's opinion, therefore, the Spanish Constituent, in protecting health through Article 43 of the Constitution, did not go so far as to determine a minimum and essential content of the right, but granted wide discretion to the legislature, both in defining the rights and obligations of the users of health interventions, and in the way the services are organised to provide benefits and services. Therefore, for the legislator, the constitutional provision on health protection does not represent a constraint, neither in relation to the extent of protection nor to the methods of providing health care, but a guideline which the legislator and the public authorities must follow.

168 J. Cantero Martìnez, *Crisi economica e servizio sanitario in Spagna, in Unione Europea e diritto alla tutela della salute: problematiche giuridiche comparate,* edited by L.P. Tronconi, Santarcangelo di Romagna, Maggioli, 2016.

169 See Articles 1.1, 4.1, 45 of the General Law. J.L. Beltrán Aguirre, *La universalización de la asistencia sanitaria en España en el marco de los objetivos de la Unión Europea en materia de salud y del artículo 35 de la Carta de Derechos Fundamentales,* in *Diritto e salute nell'Unione Europea*, edited by J.F. Pérez Gálvez and R. Barranco Vela, Granada, Comares, 2013; J.M. Antequera Vinagre, *El concepto de ciudadania sanitaria y el cómo articularla*, in Ciudadanía Sanitaria, 2007, No 15.

transferred significant financial autonomy to the Autonomous Communities, together with responsibilities for managing more and more public services, including health services[170]. An important step was taken with Organic Law No. 7 of 2001 amending the law on the financing of the Autonomous Communities, and Law No. 21 of 2001 regulating the financing of the Autonomous Communities, which established a new financial regulatory framework[171]. In 2003, the approval of the Law of Cohesion and Quality of the National Health System[172], which does not abrogate but integrates the General Law, led to a new discipline of the competent bodies in the health sector and redesigned the Interterritorial Council of the National Health System (already provided for by the General Law of 1986) attributing to it, as the highest coordinating body, important central functions within the Spanish health system[173]. This law develops the principle of the tendency of free healthcare supply: free healthcare is in fact defined by the aforementioned law as a "principal and basic criterion" of

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[170] See J.-I. Anton, R. Munoz de Bustillo, E. Fernandez Macıas and J. Rivera, *Effects of health care decentralization in Spain from a citizens' perspective*, in European Journal of Health Economics, 2014, no. 15, pp. 411-431; D. Cantarero Prieto and S. Lago-Penas, *Decomposing the determinants of health care expenditure*: *The case of Spain*, in European Journal of Health Economics, 2012, no. 13, pp. 19-27.

[171] When, with the laws of 2001, the 17 Autonomous Communities became fully responsible for the planning and organisation of services, they also received a corresponding autonomy on expenditures. This is largely based on transfers from the central state, mainly on the basis of population size and age. However, the financial autonomy of the Autonomous Communities is growing.

[172] This is the *Ley de cohesión y calidad del Sistema Nacional de Salud*, Law No. 16 of 2003. An innovation introduced by the 2003 law with respect to the general law is the provision of the possibility of mobility throughout the national territory in order to corroborate the principles of equality and universalism of services: all users of the health service can obtain the services to which they are entitled regardless of their place of residence or the municipality in which they are registered (section 24).

[173] At present, the Council consists of 18 members: the Minister of Health (Council chair) and one councillor from each Community (from among whom the vice-chairman is elected). The representatives of the Autonomous Communities who make up the Council are generally those responsible for health at territorial level, or persons delegated by them. Decisions are taken by consensus and take the form of recommendations. Article 69 of Law No 16 of 2003 sets out the Council's objectives: "El Consejo Interterritorial del Sistema Nacional de Salud es el órgano permanente de coordinación, cooperación, comunicación y información de los servicios de salud entre ellos y con la Administración del Estado, que tiene como finalidad promover la cohesión del Sistema Nacional de Salud a través de la garantía efectiva y equitativa de los derechos de los ciudadanos en todo el territorio del Estado." See J. Peman Gavin, *Asistencia sanitaria y Sistema nacional de salud*, Granada, Comares, 2005, p. 208; M. Vaquer Carabellerìa, *La coordinación y el Consejo Interterritorial del Sistema Nacional de Salud*, in *La reforma del Sistema Nacional de Salud*. *Cohesion, calidad y estatutos profesionales*, edited by L. Parejo, A. Palomar and M. Vaquer, Madrid-Barcelona, 2004, p. 111.

the public healthcare service to be adjusted to the revenues of the State and the Autonomous Communities[174].

Royal Decree-Law No. 16 of 2012 *Medidas urgentes para garantizar la sostenibilidad del Sistema Nacional de Salud y mejorar la calidad y seguridía de sus prestaciones* also determined a temporary downgrading of the Spanish system to an insurance-type system[175]. Subsequently, with the approval of Royal Decree-Law No. 7 of 2018, a number of previously existing protections for the benefit of irregular immigrants were, finally, reintroduced.

5.2. *Organisation and financing of the health system*

Each Autonomous Community has a *Servicio de Salud* (Health Service), which is the administrative management structure integrating all the structures and services of the Community, the municipal governments and all other intra-Community territorial administrations[176].

Spain, like many European countries, experienced an increase in health spending in the 1990s and then a significant decrease from 2010. Spanish health expenditure is within the average European expenditure as measured by the WHO in its statistics compiled from data extracted by country[177]. When analysing the composition of expenditures, it can be

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[174] Mention should be made here of Law No. 33 of 2011, the General Law on Public Health, which extended health care to all residents of the nation-state and to all those for whom care was not yet enshrined in law.

[175] Due to the difficulties resulting from the economic crisis, the right of access to healthcare services for irregular foreigners was limited to emergency services only, while EU citizens who had lost their jobs could only access services by taking out private insurance policies. The Constitutional Court, in its judgment no. 139 of 2016, confirmed the legitimacy of the provisions of Decree-Law No. 16 of 2012 that excluded irregular foreigners from access to healthcare services. On this, see L. Melica, *Il sistema sanitario spagnolo e la tutela della salute degli immigrati: spunti di riflessione*, in Rivista AIC, 2017, no. 4.

[176] See B. Acerete, A. Stafford and P. Stapleton, *Spanish healthcare public private partnerships: The "Alzira model"*, in Critical Perspectives on Accounting, 2011, no. 22, p. 536; G. Lopez-Casasnovas, J. Costa-Font and I. Plana, *Diversity and regional inequalities in the Spanish system of health care services*, in Health Economics, 2005, no. 14, pp. 221-235; A. Rodrıguez-Alvarez, D. Roibas-Alonso e A. Wall, *The response of decentralized health services to demand uncertainty and the role of political parties in the Spanish public health system*, in Journal of Productivity Analysis, 2013, n. 40, pp. 357-365; R.B. Saltman, *Decentralization, re-centralization and future European health policy*, in European Journal of Public Health, 2008, no. 18, pp. 104-106; K. Vrangboek, *Key factors in assessing decentralization and recentralization in health systems*, in *Decentralization in health care: Strategies and outcomes*, by R.B. Saltman, V. Bankauskaite and K. Vrangboek, London, Open University Press/McGraw-Hill Education, 2007.

[177] See Health System Financing Profile by country, *Spain*, WHO, 2018, available at

observed that the share of expenditure from public sources represents 71.1% of the total; this percentage has undergone drastic cuts in the years from 1995 to 2005 (from 72.2% to 70.6%) and in the period from 2010 to 2015 (from 74.4% to 71.1%).

In turn, private expenditure has increased in terms of share of total health expenditures. About one-fifth of costs are covered by *out-of-pocket expenditure*[178], while voluntary supplementary insurance, which co-pays for cost-sharing or private health expenditure, is very low but not negligible. With regard to the degree of user contribution, the Spanish health service has never been fully funded, except for pensioners who are covered by social security. Hospitalisation, outpatient treatment, laboratory tests and diagnostic imaging are covered at 100%, while for medicines, citizens have to pay a percentage of the cost (with certain categories of people exempted, most significantly those with certain diseases, the disabled and the elderly).

Service provision and financing in Spain

The health financing system has undergone a number of transformations. In 1976, the health system was predominantly financed through workers' social contributions. With the entry into force of Law No. 37 of 1988 *Presupuestos Generales del Estado* (PGE), there was a shift towards financing based mainly on general taxation. A second source of funding is mutual funds, a remnant of the pre-1986 era, which have been steadily decreasing ever since. Thus, public funding, as in all Beveridge systems, clearly prevails over private funding.

Service provision is organised on two levels: primary care and specialised care. The public health system is structured into Health Areas, established by the general law, which are responsible for the management of Health Centres and their services. Each Health Area, which is defined by the Autonomous Communities on the basis of geographical, socio-economic and demographic criteria, has a catchment area of between 200,000 and 250,000 inhabitants and is linked to at least one general hospital. In each Health Area, health delivery occurs through two main types of facilities: one for primary care and the other for specialist care (outpatient clinics and hospitals). In some regions, facilities that integrate primary and specialist care have been created. The larger hospitals are found in the main cities and act as referral centres for more specialised procedures

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http://apps.who.int/nha/database/Country_Profile/Index/en.

178 Out-of-pocket expenditure amounted to 23.6% of health expenditure in 2017. The largest share of health care expenditure relates to the prescription of drugs, dental and optical care. See European Observatory on Health Systems and Policies, *Spain*. *Health system review. Health systems in transition*, 2018, pp. 44 ff.

(cardiovascular, neurological, transplantation surgery).

Registration with a general practitioner (GP) is compulsory and access to secondary care is by prescription from a GP (gate-keeping function required except for urgent care). Primary care is organised in a manner very particular to Spain and differently than in other European countries: the primary care facilities are public (in Valencia and Catalonia some services are performed by affiliated structures), multidisciplinary (the same facility is home to GPs, family paediatricians, medical specialists) and connected to medical laboratories. The non-profit sector plays an important role in occupational accidents and diseases. The role of the private sector is growing, but remains marginal. Traditionally, the public system has contracted out 15-20% of specialist care to private (not-for-profit and for-profit) hospitals. This outsourcing includes diagnostics and outpatient surgery as a response to the problem of managing waiting lists.

5.3. *Actors and locations of decision-making processes*

Competence in health matters is shared between the central state (Ministry of Health) and the Autonomous Communities (Health Departments)[179]. Each Autonomous Community has a health department, a minister responsible for policies and a health service for the provision of health services[180]. Consequently, health planning is carried out on two levels: the strategic plan is a national competence (Ministry of Health), while the regional level produces a strategic and an operational plan. The operational plan provides for the management of the service network and the coordination of healthcare provision.

The Spanish system is characterised by a specific tension between the need to guarantee homogeneous healthcare services and a contextual call for local specificity in the allocation of the relevant legislative and administrative functions[181]. This need for a balance between respect for the

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[179] While the central level is in charge of ensuring a common framework to guarantee equity, cohesion and quality standards, the regional level deals with regional legislation, insurance, service planning, management and service delivery. Finally, local authorities (provinces and municipalities) are responsible for public hygiene and the management of residual issues.

[180] M. León Alonso, *La protección constitucional de la salud*, Madrid, La Rozas, 2010; E. Griglio, *Unità e decentramento nella tutela della salute in Spagna,* in Sistemi costituzionali, diritto alla salute e organizzazione sanitaria. Spunti e materiali per l'analisi comparata, by R. Balduzzi, Bologna, Il Mulino, 2009; J.G. Peman, *Asistencia sanitaria y Sistema Nacional de Salud: estudios jurídicos*, Granada, Comares, 2005.

[181] In the Spanish system, the division of competences between the central State and the Autonomous Communities in the field of health is provided for in Article 149 of the Constitution and can be reconstructed by virtue of the criteria established by the 2003 Law

principle of equity of access to treatment throughout the national territory[182] and the guarantee of local specificities is reflected in the coordination function extended to the Health System Territorial Council by the 1986 Organic Law. Like the State-Regions Conference in Italy, the Council is responsible for coordinating health policy between the central and regional levels. The Council does not have executive power, but has an advisory power to promote cooperation and exchange of information between different levels of government. In the Spanish context, the balance in the health sector has been achieved through coordination mechanisms and sharing of health policies, thanks to agreements reached by a technical panel of experts (which can be considered equivalent to the Italian State-Regions Conference) charged with defining the basic level of services to be guaranteed, to be followed by additional interventions by the Autonomous Communities.

Decision-making processes in Spain

The Quality and Cohesion Act of 2003 established a number of bodies such as the Quality Agency, the National Institute for Health Information and the National Observatory for the Health System, and assigned a key role to the Inter-territorial Council. This Council (*Consejo*) is composed of representatives of central and regional levels, and within it a Council committee is composed of representatives from civil society organisations. The ways in which the Council intervenes are manifold, precisely because the tasks it is called upon to carry out are many and varied: the *Consejo* can express itself through non-binding opinions and recommendations, it can gather information, it can present reports intended in part to stimulate legislative activity, and it can and must express itself in a binding manner where required by law. One of the main functions carried out by the Council is the drafting of the Service Charter (section. 8, Law No. 16/2003), containing the basic levels of health services that must be guaranteed equally throughout the national territory, or the identification of the maximum time limits for waiting lists (section 25.1 of the law (cf. Peman, *La nueva configuración del Sistema Nacional de Salud tras la Ley de Cohesión*

on the Cohesion and Quality of the *Sistema Nacional de Salud*. The law lays down the fundamental principles, such as the principle of universality and equity of access to services on the national territory, which must be guaranteed throughout the country. Once the levels set by the State are ensured, the Autonomous Communities have the option of providing and guaranteeing additional levels of assistance. The process of defining guaranteed benefits is an interesting example of cooperation between the central level and local authorities.

[182] According to Article 4.c of Law 16 of 2003, all Spanish citizens are entitled to receive health care as set out in the basket of services under conditions of equality throughout the national territory.

y Calidad (Ley 16/2003, de 28 de mayo), in Revista Vasca de Administración Pública, 2005, no. 71, pp. 191 ff.)).

With regard to the involvement of local authorities and local communities, municipalities and provinces participate in decision-making processes concerning public health and cooperate in the provision of services and the management of residual services. The participation of civil society is promoted through the advisory committee of the Inter-territorial Council in accordance with section 67 of Law No. 16/2003. According to paragraph 2 of that section, this committee is composed of six representatives of state administrations, six representatives of the Autonomous Communities, four representatives of the local administrations, and an additional eight representatives of business organisations and eight representatives of trade unions. The committee has advisory and propositional powers and its purpose is to provide an effective vector for societal involvement in the health service. The committee draws up opinions on the content and formulation of draft laws concerning the basket of services, financing and pharmaceutical expenditure. Other opinions are requested in the process of formulating national health plans, on draft laws concerning patients' rights and duties and the basis of human resources policies. Through this committee, the Council obtains the opinions of social actors such as representatives of the business world and trade unions, although citizens' and patients' associations are completely absent (cf. J.G. Peman, *Asistencia sanitaria y Sistema Nacional de Salud*, cit., p. 209; M. Vaquer Caballeria, *La coordinación y el Consejo Interterritorial del Sistema Nacional de Salud*, cit., p. 134). The main function it seems to perform is to ensure that any conflicts that may arise in health care decisions are resolved within a multifunctional administrative body.

5.4. *Resource allocation and prioritisation*

As previously mentioned, the Spanish health system is based on the guarantee of the principles of universality and equity of access to the guaranteed services. In the health services organised on this basis, the definition of the relationship between resources and priorities intersects, as in the Spanish case, with the question of the identification of the essential levels of services and their implementation in the context of a system built on the two main decision-making platforms of national and regional planning.

In order to understand how the determination of the essential content of benefits takes place in the Spanish system, it is necessary to outline the relevant legal framework. Law No. 16 of 28 May 2003 on the cohesion and quality of the National Health Service *(Ley No 16 del 2003, de cohesión y*

calidad del Sistema Nacional de Salud) establishes the nomenclature of the services of this system.

Section 8 of Law No. 16 of 2003 provides that the guaranteed health services are established within a Charter of common services on the content of which, on the basis of section 20 of the said law, the central government and regional governments must reach an agreement in the context of the decision-making sessions of the Inter-territorial Council, taking into consideration the parameters of effectiveness, efficiency, effectiveness, safety, therapeutic utility, the existing care alternatives, the protection of the most fragile groups, social needs, economic and organizational impact. Law No. 16 of 2003 was implemented through the provisions contained in Royal Decree No. 1030 of 2006[183], which establishes not only the nomenclature of common services of the National Health System but also the procedure for its revision *(Real Decreto No 1030 del 2006 por el que se establece la cartera de servicios comunes del Sistema Nacional de Salud y el procedimiento para su actualización*). This royal decree abrogated and replaced Royal Decree No. 63 of 1995 and provided for a list of services - ranging from prevention, health promotion, primary care and pharmaceutical assistance up to urgent, outpatient, hospital and rehabilitative care - that, on the basis of the principle of equality and adopted in Federal or Regional States as an expression of territorial cohesion, must be guaranteed on the whole national territory[184].

In addition to the positive list of services guaranteed by the system, the negative list of non-guaranteed services[185] contributes to composing the content common to health services across the national territory to which the Autonomous Communities must adhere in preparing the organisation of the regional health systems. To this list, they may add, if sufficient resources are available, additional services and facilities, through complementary service charters. The criteria used to identify the guaranteed services are those laid down in section 5 of Royal Decree No. 1030 of 2006[186] which refers, as noted, to the parameters of safety, efficacy,

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[183] Royal Decree No. 1030 of 2006 has been amended several times over the years, on the basis of Article 7 (entitled *Actualización de la cartera de servicios comunes*), by order of the Ministry of Health following agreement in the Inter-territorial Council. See Orden SAS Nos 1904/2009, 1466/2010, Orden SPI 573/2011, Orden SSI Nos 1640/2012, 1329/2014, 2065/201, 1356/2015.

[184] On the types of guaranteed health services see M. Leon Alonso, *La protección constitucional de la salud*, Madrid, La Rozas, 2010, pp. 497 ff.

[185] For example, cosmetic surgery if there is no clinical justification for nasal septum surgery (Annex III Art. 5 of the Royal Decree), or orthodontic treatment (Annex II Art. 9 of the Royal Decree).

[186] Article 5 of the decree entitled "*Criterios y requisite*" provides for the following: "*1. Para la definición, detalle y actualización de la cartera de servicios comunes se tendrá en cuenta la*

effectiveness, therapeutic usefulness and to the capacity of the technology to introduce an innovative improvement in the healthcare scenario, taking into account the technologies and evidence already available.

Additionally, Article 7 of Royal Decree No. 1030/2006 defines the procedure for amending the Service Charter in a way that ensures, from a substantive point of view, the adequacy of its content with respect to both

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seguridad, eficacia, eficiencia, efectividad y utilidad terapéuticas de las técnicas, tecnologías y procedimientos, así como las ventajas y alternativas asistenciales, el cuidado de grupos menos protegidos o de riesgo y las necesidades sociales, y su impacto económico y organizativo, basándose en los criterios y requisitos establecidos en los apartados siguientes. 2. Previamente a su inclusión en la cartera, las técnicas, tecnologías o procedimientos que para su realización precisen utilizar un medicamento, producto sanitario, producto dietético u otro tipo de producto, resulta imprescindible que: a) Los medicamentos estén autorizados para su comercialización de acuerdo con la legislación vigente, y se utilicen conforme a las especificaciones de su ficha técnica autorizada. b) Los productos sanitarios, incluidos los implantes y los reactivos para diagnóstico "in vitro", cuenten con el marcado CE para la indicación de que se trate, así como los restantes requisitos que establece el Real Decreto 414/1996, de 1 de marzo, por el que se regulan los productos sanitarios, y demás normativa de aplicación. c) Los productos dietéticos hayan recibido resolución favorable de la autoridad competente como alimentos dietéticos destinados a usos médicos especiales, de acuerdo con lo establecido en el apartado 4 del artículo 10 del Real Decreto 2685/1976, de 16 de octubre, por el que se aprueba la Reglamentación Técnico-Sanitaria para la Elaboración, Circulación y Comercio de Preparados Alimenticios para Regímenes Dietéticos y/o Especiales. d) Otros productos sometidos a regulación específica cumplan la respectiva normativa vigente que les sea de aplicación. 3. Para ser incluidos como parte de la cartera de servicios comunes del Sistema Nacional de Salud, las técnicas, tecnologías o procedimientos deberán reunir todos los requisitos siguientes: a) Contribuir de forma eficaz a la prevención, al diagnóstico o al tratamiento de enfermedades, a la conservación o mejora de la esperanza de vida, al autovalimiento o a la eliminación o disminución del dolor y el sufrimiento. b) Aportar una mejora, en términos de seguridad, eficacia, efectividad, eficiencia o utilidad demostrada, respecto a otras alternativas facilitadas actualmente. c) Cumplir las exigencias que establezca la legislación vigente en el caso de que incluyan la utilización de medicamentos, productos sanitarios u otros productos. 4. No se incluirán en la cartera de servicios comunes: a) Aquellas técnicas, tecnologías o procedimientos: 1. Cuya contribución eficaz a la prevención, diagnóstico, tratamiento, rehabilitación o curación de las enfermedades, conservación o mejora de la esperanza de vida, autonomía y eliminación o disminución del dolor y el sufrimiento no esté suficientemente probada. 2. Que se encuentren en fase de investigación clínica, salvo los autorizados para uso compasivo. 3. Que no guarden relación con enfermedad, accidente o malformación congénita. 4. Que tengan como finalidad meras actividades de ocio, descanso, confort, deporte o mejora estética o cosmética, uso de aguas, balnearios o centros residenciales u otras similares. b) La realización de reconocimientos y exámenes o pruebas biológicas voluntariamente solicitadas o realizadas por interés de terceros. 5. La exclusión de una técnica, tecnología o procedimiento incluido en la cartera de servicios comunes se llevará a cabo cuando concurra alguna de las circunstancias siguientes: a) Evidenciarse su falta de eficacia, efectividad o eficiencia, o que el balance entre beneficio y riesgo sea significativamente desfavorable. b) Haber perdido su interés sanitario como consecuencia del desarrollo tecnológico y científico o no haber demostrado su utilidad sanitaria. c) Dejar de cumplir los requisitos establecidos por la legislación vigente."

the temporal and scientific context, and, from a procedural point of view, compliance with the obligation for cooperation between levels of government. With regard to the modification of the content of the charter, section 21 of Law No. 16 of 2003 affirms the principle according to which the Service Charter can be updated by means of a regulatory source, in cases where a new health technology or a medical device is submitted to the evaluation of the Ministry of Health, which refers, for evaluation issues, to the network of agencies for the evaluation of health technologies, which was formally established by Royal Decree-Law No. 16 of 2012[187]. The initiative for the updating of the Service Charter, based on Art. 8 of the Royal Decree, lies with the health administrations of the Autonomous Communities or the Ministry of Health through the Inter-territorial Council. The proposal that includes a new technology or device must be accompanied by a report on technical and economic aspects with an in-depth analysis of the impact of the admission of the new technology. The proposal is considered by the Performance and Financing Committee, which reports to the Inter-territorial Council, which then has the task of reaching a consensus and agreement on the proposal to be forwarded to the Ministry. Ultimately, the Ministry may or may not approve it.

6. Germany

6.1 The underlying philosophy and its evolution

Although no explicit reference to the right to health is found in the Basic Law of the Federal Republic of Germany (*Grundgesetz*, GG), it is a central element of the German welfare system and the protection of this right is an obligation not only for the *Länder*, which have exclusive competence in this matter, but also for the Federal State, as clarified by the case law of the Federal Constitutional Court (*Bundesverfassungsgericht*). In fact, that institution has filled the constitutional gap by providing a derivation of the right to health from art. 2, para. 2 (right to life and physical integrity) and art. 1, para. 1 of the GG (principle of human dignity), as well as by closely linking its protection to the existence of the welfare state (art. 20, para. 1, and 28, para. 1, GG) and, therefore, to the functioning of the German state itself[188].

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[187] The Network coordinates the activities of seven regional homologous entities (operating in Andalusia, Aragon, Basque Country, Canary Islands, Catalonia, Galicia and Madrid) and the Charles III Institute of Health.

[188] See the pronouncements cited in G. Cerrina Feroni, *Il sistema sanitario tedesco alla prova della immigrazione*, in Rivista AIC, 2018, n. 2, pp. 6-7.

Since its origins, the German model has been based on a system of compulsory social insurance[189] (*Sozialversicherung*), organised on the basis of the contributory principle and aimed at protecting workers from the fundamental risks of life (illness, accidents at work, old age, unemployment and the ability to care for one's self)[190]. This makes the German health care system (*Gesundheitswesen*) deeply connected to the other welfare sectors and gives it a mixed character, "presenting at times the features of a health care system, at times those of a social security system, at times those of an occupational health and safety system."[191] Taken together, all these measures contribute to the concrete definition and implementation of the basic principle of the welfare state. As is well known, the German welfare system originated as a result of the social policies introduced at the end of the 19th century by the first chancellor of the Second Reich, Otto von Bismarck, and has long been the prevailing model in Europe. Today, it is known as the "Bismarck model" and found primarily in central European countries[192], but it has also often been associated with the concept of an employment system[193] or employment-meritocratic system[194] because of the link it establishes between the role of an individual in the labour market and their access to health services. The criterion on the basis of which the benefits are granted is neither the citizenship nor the need situation of the beneficiary, but their employment status[195].

In light of the relations generated between the State, the family and the market, this model of care has also been described as a

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189 Article 74, para. 1(12) of the *Grundgesetz* defines social insurance as "a community of solidarity of a compulsory nature with the function of protecting against the major risks of life."

190 These correspond, in the current German welfare system, to the three pillars of public health *(gesetzliche Krankenversicherung*), occupational accident insurance *(gesetzliche Unfallversicherung*) and social security *(gesetzliche Rentenversicherung*). This has been the case since the 1880s, with more recent additions concerning unemployment (*Arbeitslosenversicherung,* 1927) and long-term care and social services (*Pflegeverischerung,* 1994).

191 L. Cristanelli, *Il riparto costituzionale delle competenze legislative nel sistema sanitario tedesco*, in Sistemi costituzionali, diritto alla salute e organizzazione sanitaria, edited by R. Balduzzi, Bologna, Il Mulino, 2009, pp. 125-155, spec. p. 133.

192 M. Ferrera, *Le politiche sociali. L'Italia in prospettiva comparata*, cit.

193 M. Ferrera, *Modelli di solidarietà. Politiche e riforme sociali nelle democrazie*, cit. The author considers the system's characteristic feature to be the fragmentation of public solidarity according to occupational characteristics, which gives rise to a plurality of communities at risk, uninsured because they have no employment status.

194 R.M. Titmuss, *Social policy*: *An introduction*, London, Hyman, 1974.

195 This is pointed out by G. Esping-Andersen, *Welfare States without work: the impasse of labour shedding and familism in continental European social policy*, in Welfare States in transition, edited by G. Esping-Andersen, London, Sage, 1996, pp. 66-87, spec. p. 67.

conservative-corporative welfare regime[196]. In Germany, a central role in the protection of the individual is played by intermediate social bodies (first and foremost, families and professional groups) and State intervention is only subsidiary. This has positive effects in terms of empowerment of the individual, as well as the recognition of a much greater decision-making power than in other health care systems, in favour of both professionals and their trade associations and workers' unions. The former are directly involved in the management and organisation of the services; the latter jointly exercise control over the contributions paid by workers to their respective membership funds by way of insurance premiums[197]. By adopting a corporative and subsidiary logic, the German system accepts that risk conditions are distributed differently within the population and concludes that the level of protection must be allowed to vary according to social class, reflecting the status attained by the individual[198]. This makes solidarity and risk-sharing, which are an expression of any social policy, more restricted and particularistic[199].

In Germany, however, there are instruments to offset the potential inequities arising from such a configuration of the welfare model. On the one hand, the State's limited and subsidiary role extends to the setting of minimum standards to be applied to private contracts governing the provision of healthcare services, concluded between patients, healthcare facilities/professionals and the insurance funds with which the former are registered. On the other hand, a set of welfare policies supports the insurance system, offering even those excluded from the labour market a minimum level of protection[200]. This guarantees a higher level of

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196 G. Esping-Andersen, *The three worlds of welfare capitalism*, cit.

197 F.C.J. Stevens and J. Van der Zee, *Health system organization models (including targets and goals for health systems)*, in G. Carrin (ed.), Health systems policy, finance, and organization, Amsterdam, Elsevier, 2009, pp. 247-256, esp. p. 251.

198 G. Esping-Andersen, *Welfare States without work*: *The impasse of labour shedding and familism in continental European social policy*, cit. p. 67.

199 On the equity issues raised by this configuration, see for example M. Grunow and R. Nuscheler, *Public and private health insurance in Germany*: *The ignored risk selection problem*, in Health Economics, 2014, no. 23, pp. 670-687 and C. Schwierz, A. Wubker and B.A. Kuchinke, *Discrimination in waiting times by insurance type and financial soundness of German acute care hospitals*, in the European Journal of Health Economics, vol. 12, 2011, no. 5, pp. 405-416.

200 State subsidies are provided to ensure that children and the poor are also covered. In fact, even those who need medical care but do not have adequate means (due to insufficient income or assets) are entitled to public insurance. On the other hand, those who would have to opt for a private fund but for whom payment of the basic tariff would lead to indigence are entitled to half the contribution set for access to the GKV. Finally, if this is not sufficient, other pillars of the social insurance system will take over (unemployment policies or social services). For policyholders of private health insurance funds, on the other hand, the

redistribution of wealth than that pursued by liberal welfare regimes and makes it possible to consider the German model (especially before the 2007 reform that, as we will see, strengthened competition between the funds) as a substantially universalistic system[201].

At the same time, the configuration of the model through health insurance funds implies the need for lower public spending compared to the social-democratic universalist models. Health expenditure is, in fact, financed primarily through the contributions paid directly by workers to the health insurance fund to which they belong. Thus, unlike in the models characterised by the use of general taxation, in Germany the resources to be allocated to health services are in fact separated from all other public revenues and the funds are protected from being diverted to other expenditure sectors. At the same time, however, the financial capacity of the various funds depends on the level of contributions paid and the number of their members, which in turn influence the sustainability of their management. This is one of the reasons why, since the end of the 1990s, the public debate has focused on the financing of public health insurance, and many of the most recent reforms have resulted in a progressive and steady containment of its costs.

The main reforms in Germany

There are three phases that can be identified in the evolution of the German health care system: 1) from the birth of compulsory social insurance in the 19th century to the end of the Second World War; 2) from 1945 to national reunification; and 3) from 1990 to the present (see European Observatory on Health and Policies, *Germany*: *Health System Review*, in Health Systems in Transition, vol. 16, 2014, no. 2, pp. 21 ff.).

1) In the first phase, health insurance funds sprang up in the various occupational sectors, first spontaneously, then under the obligation imposed by the law on health insurance for workers of 15 June 1883. A uniform regulation of insurance systems, after the creation of the further pillars of social security and occupational health and safety policies, was dictated by a law of 1911 (the *Reichsversicherungsordnung* or "Social Security Act"). This act would remain in force in the health sector until 1988, but upon its approval it provoked a conflict between doctors and health insurance funds that was channelled into constructive negotiation by the Federal Government and ultimately gave rise to today's system of shared self-government between the associations representing the health insurance funds and the doctors. Neither the institutional transition from the German Empire to the Weimar Republic nor the national-socialist regime

coverage of benefits for dependent family members is guaranteed directly by the policyholder, through the payment of additional contributions.

[201] See G. Cerrina Feroni, *Il sistema sanitario tedesco alla prova della immigrazione*, cit.

fundamentally changed the essential organisational features of the resulting system. However, in Third Reich Germany, the influence of the professional associations increased further, while the influence of the health insurance funds was reduced through decisive decision-making and organisational centralisation, which was accompanied by the exclusion of Jews and minorities from both the provision of and access to health services (*ibid*., pp. 30-31).

2) The second phase saw a diversification of the way health care was managed, with the introduction in the GDR of a socialist-style system that maintained an insurance status in name only. This system, which was in fact highly centralised, entered a phase of crisis in the 1970s due to a lack of resources, personnel and technology (*ibid*., pp. 34-36). Meanwhile, in the Federal Republic, the insurance system already in place in the Weimar Republic underwent sweeping reforms that extended compulsory health insurance beyond the borders of the Federal Republic of Germany and introducing the dual system of hospital financing, which divided responsibility between the *Länder* (for investments) and the health insurance funds (for operating costs). Total public expenditure rose sharply until a law on health cost containment in 1977 linked the level of expenditure to contributions to the public insurance system in order to ensure the stability of the system.

3) The aim of cost containment and the increase in efficiency through competition between funds, between health care facilities and between operators in the sector also characterise the third and most recent phase of development of the German health care system. This started with the enormous task of updating medical facilities and upgrading in-service training in half of the country and extending the social insurance model in force in West Germany to the entire population (see European Observatory on Health and Policies, *Germany*: *Health System Review*, in "Health Systems in Transition, vol. 6, 2004, no. 9, pp. 186-187). Since then, cost containment has been pursued mainly through the imposition of expenditure ceilings and budget constraints on providers, but the introduction of the DRG method in the remuneration of services provided by the hospital and outpatient sector has also produced savings. The limitation of pharmaceutical expenditure, in particular, has been a battleground both at political level and between the health insurance funds and the manufacturers (which have a significant weight in the German economy). Starting in 2006, it has also passed through a system of economic incentives known as the *bonus-malus rule*, which imposes penalties and allocates resources to the regional associations of doctors according to the consideration given to the cost-effectiveness of medicines in their prescription policy (the Act to Improve Efficiency in Pharmaceutical Care of 2006). In line with the preference for rationalisation of the system over the rationalisation of services, starting in the nineties a reduction in the number of hospital beds and outpatient clinics coupled with a limitation on the acquisition of high-cost technological equipment has been underway, but few treatments have been excluded from the basket of services covered by the public insurance system (*ibid*., pp. 187-188). However, private cost-sharing has increased significantly and its negative effect on the overall equity of the system has been countered by wider exemption schemes for the chronically ill, children and the poor. The aim of fostering competition between health insurers has been pursued in several ways: on the one hand, by recognising the freedom of choice between insurers for the majority of the population and introducing a risk compensation scheme between

them in order to redistribute contributions taking into account the disparities in expenditure and income of the members (Health Care Structure Act, 1993); on the other hand, by modifying the latter several times to reduce the high contribution levels recorded in former East Germany (Act to Equalize the Law in Statutory Health Insurance, 1999) and to better contrast risk selection by funds (Act to Reform the Risk Structure Compensation Scheme in Statutory Health Insurance, 2001).

In 2007 and 2011, two major reforms addressed the sustainability of the public insurance financing system (for a detailed overview of the measures, see European Observatory on Health and Policies, *Germany*: *Health System Review* (2014), cit., pp. 247-252). The first law (Act to Strengthen Competition in SHI, 2007), in force since 2009 and expressly aimed at reinforcing competition among the funds of the GKV, made the obligation to have health insurance universal, committed private insurers to offering a basic rate for services equivalent to those guaranteed by public insurance, prevented insurance funds from setting the level of contributions themselves and shifted the power to set these contributions to the level of the Federal Government; it also created a central mechanism for collecting and reallocating contributions between funds (*Gesundheitsfonds*), which partially replaced the risk compensation scheme's function of neutralizing differences in financing due to variations in income among members (D. Gopffarth and K.-D. Henke, *The German Central Health Fund. Recent Developments in Health Care Financing in Germany*, in Health Policy, 2013, n. 109, pp. 246-252). The 2011 health care reform, on the other hand, removed the power of the federal government to set the contribution rate annually, establishing it in the *Sozialgesetzbuch* (SGB), or German Social Code, at a fixed level independent of future increases in service costs. Following the reform of January 2015, that is 14.6 % of the insured person's income, 7.3 % of which is borne by the employer and the rest by the employee *(Gesetz zur Weiterentwicklung der Finanzstruktur und der Qualität in der gesetzlichen Krankenversicherung,* 2015). The distribution of resources among the funds via the Gesundheitsfonds had already made it necessary for the funds to raise additional resources to meet the costs of the health services provided to their members and to avoid bankruptcy. Many health insurance funds (*Krankenkassen*) now require employees to pay additional premiums, setting their own amounts to compete with other funds. In 2011, the federal legislator abolished the 1% of income limit set by previous legislation for such premiums, but also ensured the protection of the lowest paid workers from an excessive financial burden of contributions through a social adjustment mechanism with resources from general taxation.

6.2 Organisation and financing of the health system

Germany is the only country in Europe with a dual insurance system. Within the limits of the compulsory health insurance established by the 2009 law (which is incumbent on all residents in Germany, citizens and foreigners with a residence permit, who are not indigent), the choice can fall on the public insurance system *(Gesetzliche Krankenversicherung*, GKV)

or on the private insurance sector *(Private Krankenversicherung*, PKV)[202]. Currently, public health insurance coverage stands at around 85% of the population (about 70 million people)[203], while 11% rely on the private sector, with a separate insurance scheme reserved for the military and the police (who represent the remaining 4% of the population). In addition, for the payment of additional insurance premiums, the private sector also provides those who have opted for public insurance with the possibility of obtaining coverage for services excluded from the GKV, including certain dental services for adults.

The choice between the different insurance funds is free[204] and the health insurance funds (*Krankenkassen*) compete by diversifying rates and additional services offered, as well as by setting higher or lower supplementary premiums, to be paid to the fund together with the federally fixed contribution of about 15% of the applicant's income. Health insurance funds in the public sector (GKV) are not-for-profit public law bodies with administrative autonomy. These are mandated to pursue social policy objectives such as family equalisation, that is, free coverage for other members of the insured person's family, according to the principle of efficient resource management[205]. Through their associations, the health insurance funds plan, negotiate and purchase services for their patients from hospitals and contracted doctors.

Total health expenditure represents 11.4% of German GDP. Of this, public expenditures represent 76.7%, but only about 5% is financed through the general taxation system; the bulk is drawn from the monthly contributions paid by members of health insurance funds[206]. In fact, the cost of the benefits falling under the coverage offered by the GKV (in the case of public insurance) or by the specific contract stipulated with the user of the services (in the case of membership of a private fund) is borne by the health insurance fund to which the insured person is affiliated, but the necessary resources come from the insurance premiums paid monthly by

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[202] The public health insurance scheme is compulsory for the majority of workers, but the self-employed and those who have declared an income above a certain threshold for at least three consecutive years are free to choose whether or not to participate in it. In this respect, however, the German system is atypical in comparison with other countries, which generally entrust the management of health care to a compulsory public insurer. Civil servants, on the other hand, are required to have private insurance.

[203] European Observatory on Health and Policies, *Germany*: *Health System Review* (2014), cit., p. 17.

[204] Health Care Structure Act (*Gesundheitsstrukturgesetz*), 1993.

[205] L. Cristanelli, *Il riparto costituzionale delle competenze legislative nel sistema sanitario tedesco*, cit., pp. 136-137.

[206] C. Normand and S. Thomas, *Health care financing and the health system*, in Health systems policy, finance, and organization, edited by G. Carrin, K. Buse, K. Heggenhougen and S. Quah, Oxford, Elsevier, 2008.

workers and, if they are employed, from the employer contribution. In this way, the risk of the individual's illness is spread within the community of caregivers, in an application of the solidarity principle. While contributions for GKV members are set at federal level and in proportion to the insured person's income, premiums paid by private fund members are set independently and linked to age, gender, health status and the benefits claimed by the insured. Health insurance is therefore more expensive for some groups (such as the elderly, people with serious illnesses and women). However, since 2007, private funds have also been required by law to offer a standard rate, established exclusively on the basis of indicators such as gender and age, and to provide the same services covered by the GKV.

The provision and financing of services in Germany

Outpatient medical care is provided by general practitioners and specialist doctors (by referral from the GP or by direct access, but subject to payment of the relevant co-payment). The professionals in question may be civil servants or self-employed. However, access to the services provided by the latter is only covered by public insurance if the doctors are affiliated with the GKV.

Hospital care is provided in public hospitals, contract hospitals and private clinics. This last category is not available to the publicly insured excepting those who have taken out supplementary private insurance. Hospital services are provided on an outpatient or inpatient basis; in the event of hospitalisation, public policyholders only have to bear the additional daily costs, up to a maximum of 28 days per year, or the costs of treatment exceeding the standard level. In order to keep costs down, the general practitioner or specialist issuing the referral is required to indicate the two nearest hospitals that are suitable for providing the prescribed treatment; if the user then chooses another facility, any additional costs will be charged to the patient.

Emergency care, which is also subject to co-payment, can be provided through the general practitioner (or an on-call physician), through direct access to the emergency room, or in the most serious cases through the emergency services and an ambulance.

The typical financing system of the model has both advantages and drawbacks. On the one hand, it is often considered preferable because, in contrast to what happens in models characterised by the use of general taxation, in Germany the resources to be allocated to health benefits are in fact separated from all the others (known in this case as *earmarked income taxes*, partly linked to the income of the worker and partly linked to the employees hired by the employer). This secures the contributions against the diversion of these funds to other expenditure areas. On the other hand, under this mechanism the financial capacity of the various funds ultimately depends on the level of contributions paid and the number of their insured, which influences the sustainability of their management. For this reason, the public system is characterised by an additional solidarity mechanism between the funds across the whole federal territory. Established in 1993, the

structural risk equalisation system financed by general taxation (*Risikostrukturausgleichssystem*) is designed to rebalance the finances of all public funds in Germany and aims to eliminate the imbalances caused by socio-economic variables and differences in the morbidity of their insured.

Moreover, the fact that in Germany the payment of insurance contributions involves both employees and employers means that the increase in premiums has traditionally been seen as a problem for international competitiveness. This helps to explain the federal legislator's insistence on intervening in their regulation, even to the extent of setting a standard level of contribution in the SGB. Following the aforementioned reform of January 2015, this is equal to 14.6% of the member's income, with 7.3% borne by the employer and the rest by the employee.

The level of cost-sharing is linked to income and can further vary on the basis of the health insurance fund to which one belongs and the optional rates chosen. Among these, some set a threshold for the insured's contribution to treatments and medicines (*Selbstbehalttarif*), while others grant economic advantages to those insured who go first to the general practitioner rather than to hospitals, so that the former can act as gatekeeper or to those who participate in a treatment program for the chronically ill (*Disease Management Program*). In the case of public health insurance funds, for some specific services the co-payment is payable only by those over 18 years of age (e.g., co-payment for outpatient medical expenses, *Praxisgebühr*), while for prescription drugs there are numerous exemptions (children up to 12 years of age, young people with developmental disorders, people undergoing standard treatment due to a serious illness, i.e., generic drugs). In the case of private insurance, insured persons are generally required to advance all kinds of expenses (outpatient, hospital, pharmaceutical), which will then be reimbursed, in full or in part.

However, there is an annual cap on individual health expenditure (for co-payments and additional costs) equal to 2% of gross annual income. After exceeding the threshold, the individual will be able to apply for a waiver card from their health insurance company. In the case of a chronic illness (for taxpayers or dependent family members), the ceiling for additional expenses is 1% of income.

Children under the age of 18 are exempt from most additional charges and co-payments, as are de facto asylum seekers and refugees in the first four years of their stay. Additionally, regular preventive and early diagnosis examinations are paid for by the public insurance system and are exempt from co-payments, as are generic medicines, medicines for children under 12 years of age, medicines for young people with developmental disorders and treatments required for serious illnesses (e.g., heart attacks).

There are also services that are not covered by GKV at all (including homeopathic treatments, medicines such as appetite suppressants or anti-impotence drugs, and vaccinations for travel purposes). Those who have to make frequent use of these always have the option to take out a private supplementary insurance policy to cover them. Finally, treatment offered under GKV is not covered outside the country (except for outpatient treatment in EU member countries, or in countries with which specific agreements have been signed). Patients hospitalised abroad must apply for authorisation from their health insurance fund before treatment starts.

6.3 Actors and locations of decision-making processes

Even though the Federal Government - the Federal Assembly (*Bundestag*) and the Federal Council (*Bundesrat*) - played an increasing role in the reform process of the health care system in the 1980s, in Germany the decision-making processes affecting the health care system are still characterised by a high level of decentralisation and autonomy[207]. At the federal level of government, the main actors are the Federal Assembly, the Federal Council and the Federal Ministry of Health (*Bundesministerium für Gesundheit*), which is organised into 6 departments and supported by numerous ad hoc committees, central government agencies and the Advisory Council for the Evaluation of Developments in the Health System (*Sachverständigenrat zur Begutachtung der Entwicklung im Gesundheitswesen*). In particular, the central government agencies share with the Ministry the functions of supervising the various healthcare sectors, providing information to the population and the scientific community and supervising private health insurance funds[208].

However, responsibility for health care lies primarily with the 16 *Länder* (federal states) that make up the country, which are responsible (under Article 74 of the Basic Law) for exercising a shared legislative competence[209] in many matters related to health care (first and foremost, social insurance). Therefore, legislative initiative normally only comes from the *Länder*, unless the *Bund* has already enacted legislation in order to guarantee equivalent living conditions in the territory of the Federal Republic or to ensure legal or economic unity in the general interest of the State. The public health insurance system, for example, is regulated by the Federal Code of Social Legislation *(Sozialgesetzbuch*, SGB). Notwithstanding the potential fragmentation resulting from this institutional set-up, the tendency towards homogeneity of the regulations produced by the individual *Länder* is ensured by the functioning of the German model of

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[207] On the other hand, the federal level of government retains administrative powers and financial responsibility for unemployment, old age and disability insurance schemes.

[208] The most important of these are: the Federal Institute for Drugs and Medical Devices (*Bundesinstitut für Arzneimittel und Medizinprodukte*), which is responsible for the authorisation of drugs and their safety; the Federal Financial Supervisory Authority (*Bundesanstalt für Finanzdienstleistungsaufsicht*), which supervises private insurers; the Federal Insurance Authority (*Bundesversicherungsamt*), which supervises public insurers, manages the *Gesundheitsfonds* and the risk compensation mechanism.

[209] Furthermore, for everything that is not expressly mentioned in Art. 74, the initiative lies with the states and the power to enforce both state and federal legislation is always reserved to them (hence the German model of *administrative* or *executive federalism*).

cooperative federalism and thus by the coordination carried out in the permanent conferences (*Ständige Konferenzen)* between the ministers of the federated states[210]. However, none of them has a specific Ministry of Health, and the competences for health overlap more with those for labour and social services, family and youth protection, environmental protection or consumer protection.

In concrete terms, the GKV is not managed directly at these levels of government, however; this management is entrusted to a corporatist administrative council consisting of, on the side of the providers, the regional and federal associations of doctors and dentists affiliated with the GKV and, on the side of the payers, the health insurance companies and their federal association. Since 2004, the representatives of these autonomous and compulsory affiliated institutions have been sitting on the Single Federal Committee (*Gemeinsamer Bundesausschuss*, GB-A) together with those of the Federation of German Hospitals. In accordance with the principle of subsidiarity, the Single Federal Committee administers the health insurance scheme directly, under the supervision of the federal and state authorities. Therefore, in Germany all levels of government participate to some extent in the decision-making processes concerning health[211].

Decision-making processes in Germany

One of the characteristic features of the German system is the sharing of certain policy choices between the *Länder*, the federal government and civil society organisations, which represent the interests of the providers and medical staff as well as third party payers, i.e., the health insurance funds (see European Observatory on Health and Policies, *Germany*: *Health System Review* (2014), cit., pp. 61-63). As far as the providers are concerned, in each federal state (*Bundesland)* there is at least one association of doctors and dentists accredited with the GKV (a total of 17 associations on the federal territory). These in turn are represented in the respective federal associations (*Kassenärztliche Bundesvereinigung*), which are responsible for defending the interests of their members in negotiations with the central government level. As for the more than 2000 hospitals in Germany, they are represented by private law entities. The most important trade association is undoubtedly the Federation of German Hospitals, which has two representatives sitting on the Single Federal Committee. As far as health insurance funds are concerned, however, since 2009 the decision-making powers previously vested in the state associations have been centralised in a federal association (*GKV-*

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210 L. Cristanelli, *Il riparto costituzionale delle competenze legislative nel sistema sanitario tedesco*, cit., pp. 128-130.

211 V. Paris, M. Devaux and L. Wei, *Health systems institutional characteristics*: *A survey of 29 OECD countries*, OECD Health Working Papers, 2010, no. 50, pp. 67-70.

Spitzenverband) that is responsible for negotiating both contracts and remuneration schemes for outpatient and hospital services on a collective level. It has five representatives on the Single Federal Committee.

It is precisely the involvement of civil society through the GB-A that qualifies the German insurance system in corporatist (or self-governing) terms. It is responsible for major decisions, such as the distribution of available funds between the various types of care (primary, outpatient, hospital), the definition of the basket of services included in the GKV and the evaluation of innovative diagnostic and therapeutic methods.

Additionally, on the basis of the powers granted to it by the SGB, the committee can issue guidelines (*Richtlinien*) in almost all areas of care, for example with regard to the level of service coverage. According to the procedure, after their approval the guidelines are communicated to the Federal Minister of Health, who has two months to raise formal objections; failing that, they then become legally binding for all actors in the GKV. However, health insurance funds, their members, doctors and pharmaceutical companies can still challenge them in a social court (*Sozialgericht*). In Germany, there is a separate judicial system for disputes involving any of the branches of social insurance, consisting of 69 local social courts, 14 national courts and the Federal Social Court in Kassel. For example, patients can sue health insurance companies for not covering a service, or medical device companies can file a complaint about the exclusion of their product from the list of outpatient medical services covered by the GKV. Pharmaceutical companies file a great many actions to complain about inadequate reference pricing or the inclusion of their preparation as a non-prescription medicine. Notwithstanding its fundamental importance, as there are no internal appeal procedures against the decisions of the GB-A, the lengthy timeframe for adjudication has prompted pharmaceutical companies to call for the creation of an independent ombudsman to resolve such disputes (K. Kieslich, *Social values and health priority setting in Germany*, in Journal of Health Organization and Management, vol. 26, 2012, no. 3, pp. 374-383, esp. p. 376).

6.4 Resource allocation and prioritisation

In Germany, health resources are allocated through complex, multilevel processes. At the highest level and as in most OECD countries, it is the legislative body (the Federal Parliament) that decides on the total amount of revenue to be collected and allocated to the financing of the public insurance system, as well as on the level of user contributions[212]. The federal level of government is responsible for determining the total health budget and allocating the available resources between the member states of the federation (Federal Government) and for allocating the available resources between the different areas of care (Single Federal Committee). The *Länder*, in turn, finance the construction of new hospitals, while the

[212] This is what Book V of the *Sozialgesetzbuch* states as of 2009.

maintenance of the existing ones is the responsibility of the health insurance funds, as well as of the hospitals themselves (which will therefore also bear the costs through the rates charged to users). The purchase and financing of new high-cost equipment is also the responsibility of the individual providers concerned, after the 1997 GKV reform abolished the state committees for the control of the regional distribution of high-cost equipment and for the negotiation of their joint use[213]. On the other hand, the local level of government is involved in identifying priorities, through the establishment of specific public health goals, subject to GB-A monitoring and mostly defined in terms of outcome (e.g., reducing breast cancer mortality by 20%)[214]. Although the achievement of these target outcomes is monitored, there are no mechanisms for assigning responsibility in the event of the failure to achieve them. Lastly, health insurance funds are responsible for financing outpatient (primary and specialist) and hospital care.

The specific German allocation strategy can be assessed by analysing the definition of the services and treatments included in the guaranteed basket of services, the use of the HTA[215] approach and the way in which health objectives are identified[216]. The particular decision-making

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[213] The State Committees were created in 1989, whereas as early as 1982 the Hospital Costs Containment Act had made the purchase of high-cost equipment conditional on hospital planning (European Observatory on Health and Policies, *Germany: Health System Review* (2014), cit., pp. 93-94).

[214] V. Paris, M. Devaux and L. Wei, *Health systems institutional characteristics: a survey of 29 OECD countries*, cit., pp. 81-82. In fact, it is stressed that this activity is one of the possible forms of "prioritisation" of investments in health.

[215] "The HTA emerged some 40 years ago [in the 1970s], in response to the uncontrolled spread of expensive health technologies, as a multidisciplinary assessment process, the intention of which was to establish itself as a decisional support tool for the allocation of economic resources. The HTA is concerned with assessing the medical, economic, organisational, social and ethical aspects of the introduction or implementation of health technologies or interventions, taking into account all aspects that may be affected by the technology under study, but also all aspects that may influence its use and its results. The focus of the HTA is on the clinical effects, safety, technical performance and effectiveness, costs and cost-effectiveness, and the organisational, ethical, social and cultural repercussions of different technologies for health care. Among the countries that have used this approach are, first and foremost, the United Kingdom, with the experience of NICE, as well as Sweden (through the Swedish National Committee for Technology Assessment) and Germany (see Health Equality Europe, *Understanding heath technology assessment*, ed. by G. La Torre, A. Monteduro and F. Kheiraoui, Milan, Prex SpA, 2009, esp. pp. 7 and 12-13). Currently, in Germany, the HTA is mainly used to establish and update the list of services and treatments covered by the GKV" (F. Fricke and H.P. Dauben, *Health technology assessment: A perspective from Germany*, in Value in Health, vol. 12, 2009, no. 2, pp. S20-S27, esp. p. S26).

[216] The competition of all these activities for the purpose of "prioritising" interventions is noted by V. Paris, M. Devaux and L. Wei, *Health systems institutional characteristics: a survey*

autonomy and trust enjoyed by both the local government authorities and the various components of the corporate system in fact characterise the priority-setting process in the German context as very unusual, and some authors even represent it as an impediment to the functioning of the system[217].

Health policy objectives are defined both at federal level and by individual *Länder*[218]. At the federal level, Book V of the SGB defines the general purpose of the GKV as maintaining, restoring or improving the health of the insured persons as members of a community of solidarity (*Solidargemeinschaft*)[219]. Care must be provided which is commensurate with the health needs of the users, in accordance with the latest generally recognised medical knowledge and in a uniform manner throughout the federal territory[220]. The principle of solidarity is the main guiding principle, but the principle of co-responsibility of the persons concerned must also be taken into account. They are required to contribute to maintaining, restoring or improving their state of health by adopting a correct lifestyle, complying with basic preventive measures and actively participating in medical and rehabilitative treatment, both to prevent the onset of illnesses and disabilities and to overcome their consequences[221]. Lastly, Art. 12 of the SGB-V also adds the principle of efficiency (*Wirtschaftlichkeitsgebot*), according to which the services covered by the GKV must always be adequate, appropriate and economically advantageous and must not exceed the extent of what is necessary; beyond this level, the public insurance does not cover additional costs (e.g., the use of particular materials or services such as gold fillings at the dentist's, or single room or the involvement of the head physician at the hospital). At the state level, each of the *Länder* then develops specific health objectives or identifies priority areas for action on the basis of the national health policy. However, it is not only the content of these policies that changes across the federal territory, but also their structure and the means used to achieve their objectives[222]. In order to coordinate federal and national strategies and to jointly address new health challenges and risks in the country, an initiative of the *Länder* and the federal government in 2000 initiated a process to

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of 29 OECD countries, cit., p. 75.

217 K. Kieslich, *Social values and health priority setting in Germany*, in Journal of Health Organization and Management, vol. 26, 2012, no. 3, p. 381.

218 European Observatory on Health and Policies, *Germany: Health System Review* (2014), cit., p. 263.

219 SGB-V, § 1.

220 SGB-V, § 70.

221 SGB-V, § 1.

222 European Observatory on Health and Policies, *Germany: Health System Review* (2014), cit., p. 264.

define and periodically update eight common objectives[223].

Within the system of shared self-government typical of the asymmetric model, in the German system the body in charge of making "prioritisation" choices is, once again, the GB-A. It is not only responsible for monitoring the health objectives identified by the municipalities, but also for defining the basket of services covered by the public health insurance and for evaluating the quality and the efficiency of the services[224]. To this end, since 2004 the Committee has been assisted by the Institute for Quality and Efficiency in Health Care (*Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen*, IQWIG). This technical and advisory body is tasked with preparing, at the request of the GB-A itself or the Minister of Health, and submitting reports to the committee based on the HTA method, for the evaluation of the benefits of the various existing medical interventions (*benefit assessment*) and the additional benefits of innovative ones or newly introduced pharmaceutical products in relation to existing ones[225]. Its analyses allow the Single Federal Committee to make decisions on the inclusion or exclusion of therapeutic products and drug treatments from the guaranteed benefits basket, based on independent assessments of available medical evidence[226]. The federal law stipulates that the IQWIG shall refer to the most up-to-date, internationally recognised standards of Evidence-Based Medicine (EBM) and health economics in its work and that it shall evaluate test results according to their relevance to patients[227].

As for the decision-making process leading to the definition of the level of coverage of outpatient and inpatient services, both presuppose the existence of a federal law dictating the regulatory framework. For outpatient treatment only, however, approval of the treatment is also required directly by the Federal Committee, based on the findings of special

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[223] The project has its own website: https*://gesundheitsziele.de.*

[224] P.C. Smith et al., *Leadership and governance in seven developed health systems*, cit., pp. 37-49, esp. p. 42.

[225] K. Kieslich, *Social values and health priority setting in Germany*, cit., pp. 376-377.

[226] In Germany, the identification of the benefits to be granted to GKV members has a particular nature, since the definition of the basket is carried out by drawing up the Single Federal Committee of negative lists of excluded treatments only. While for medical procedures the negative list approach is also applied in countries like Switzerland and the United Kingdom, Germany is the only country to use it also for the identification of drugs reimbursed by the public system (see V. Paris, M. Devaux and L. Wei, *Health systems institutional characteristics*: *A survey of 29 OECD countries*, cit., p. 77).

[227] Institute documents (quoted in K. Kieslich, *Social values and health priority setting in Germany*, cit., p. 377) make it clear that: "The decisive criteria are outcomes that are important for patients. It is not enough for a drug to simply alter the results of a lab test. It should enable people to live longer, reduce their symptoms or complications, or improve their quality of life."

evaluation committees[228]. For hospital services, on the other hand, the approval of the decision to exclude treatment by the Federal Committee is the responsibility of the Federal Minister of Health[229].

Formally, the criteria used to identify services include both diagnostic and therapeutic appropriateness as well as convenience/efficiency (for inpatient and outpatient care services), while the requirement of adequacy (which applies to the hospital context in addition to the other contexts) is replaced for outpatient care with that of medical necessity[230]. However, elements such as making the cost-benefit analysis of new pharmaceutical products conditional on the prior finding of their innovative and superior benefit compared to existing therapeutic alternatives, suggest that the clinical effectiveness requirement takes precedence over the cost requirement[231]. Lastly, although there is no formal document in Germany comparable to NICE's Social Value Principles in Great Britain, value judgements of a social nature are not entirely alien to the "prioritisation" choices of German institutions either. For example, the "efficiency frontier" method, which is used to express the cost-benefit ratio of medical interventions and thus judge which of these represent the best investment of the scarce resources available, implicitly indicates that the system pays particular attention to the principle of solidarity. The fact that the method provides for the comparison only of the treatments indicated for the same pathology testifies to the intention to guarantee treatment equally on the basis of individual health needs, without access being restricted even on the basis of the greater or lesser severity of the illness[232].

The focus on guaranteeing the best possible quality of care for all insured persons is also found elsewhere at institutional level, with the establishment of the Institute for Quality Improvement and Research in the Health Sector (*Institut für Angewandte Qualitätsförderung und Forschung im Gesundheitswesen*, AQUA). Since 1995, the Institute has been assessing the performance of individual service providers on the basis of data on 27 performance indicators that hospitals themselves are required to provide

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228 The definition of the basket of outpatient services in Germany is implicit and is based on the establishment of a national list of fixed price limits for the reimbursement of general practitioners by health insurance funds (for public health insurance funds, the list is called EBM and the inclusion of new methods of diagnosis or therapy is subject to the approval of the GB-A; for private health insurance funds, the list is called GOÄ and the decision is taken by the German Medical Association).

229 *Ibid*, tables 2 and 3.

230 J. Schreyögg *et al*., *Defining the "Health Benefit Basket" in nine European countries*, in European Journal of Health Economics, 2005, No 6, suppl. 1, pp. 2-10, esp. p. 7.

231 K. Kieslich, *Social values and health priority setting in Germany*, cit., pp. 378-379.

232 *Ibid*, pp. 379-380.

to the public in their biennial quality reports[233]. Since 2014, it has also been joined by the Institute for Quality Assurance and Transparency in Health Care (*Institut fur Qualitätssicherung und Trasparenz im Gesundheitswesen,* IQTIG), which assesses the quality of services across sectors. This development seems to bode well for a further enhancement of *outcome-related* financing techniques of service providers (first and foremost, hospitals)[234] in the future.

Since the 2000s, a debate has developed in Germany on the setting of priorities in health care. Primarily limited to scholars and professionals in the field, this debate has led neither to a widespread involvement of public opinion nor to the assumption of explicit political choices on the allocation and prioritisation plan. In two different reports, in 2000 and 2007 respectively, the Central Ethics Committee of the German Medical Association (*Zentrale Ethikkommission bei der Bundesärztekammer*, ZEKO) called for reflection on the subject, foreshadowing the deterioration of the financial situation of compulsory insurance due to the combined factors of demographic ageing and the principle of solidarity, which places the burden of benefits paid to pensioners on ever smaller cohorts of workers[235]. The initiative was followed by appeals and contributions from other institutions and the scientific community, but the criteria and guidelines discussed were not selected and fixed by policy in any legislative act[236].

The definition of priorities in Germany therefore remains an implicit and non-transparent process, guided by the principle of efficiency that the aforementioned Article 12 of the SGB places at the basis of the identification of the benefits reimbursed by the compulsory public insurance system[237]. As we have seen, in order for the GKV to cover the cost of the services, this article prescribes that they must be *Ausreichend, Zweckmässig, Wirtschaftlich,* and *Notwendig:* "adequate, appropriate, economically advantageous (*Wirtschaftlich*) and must not exceed what is

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[233] P.C. Smith et al., *Leadership and governance in seven developed health systems*, cit. 43.

[234] European Observatory on Health and Policies, *Germany: Health System Review* (2014), cit., p. 77.

[235] See in particular ZEKO, *Priorisierung medizinischer Leistungen im System der Gesetzlichen Krankenversicherung (GKV)*, 2007, available at https://www.zentrale-ethikkommission.de/fileadmin/user_upload/downloads/pdf-Ordner/Zeko/LangfassungPriori- sierung.pdf, pp. 1-3.

[236] For a review, see T. Meyer and H. Raspe, *Priorisierung im Gesundheitswesen*. *Eine Diskussion nimmt Fahrt auf*, in Zeitschrift für Evidenz, Fortbildung und Qualität im Gesundheitswesen, vol. 103, 2009, no. 2, pp. 73-74.

[237] F.S. Oduncu, *Priority-setting, rationing and cost-effectiveness in the German health care system*, in Medicine, Health Care and Philosophy, vol. 16, 2013, pp. 327-339, esp. pp. 336-338.

necessary"[238]. By virtue of these principles, treatments that lead to sufficiently positive outcomes in terms of life expectancy and quality of life (adequacy), are neither superfluous nor unnecessary (appropriateness) and represent the most cost-effective option available for each case (economically advantageous) are included in the German compulsory insurance system. Therefore, the German prioritisation system is ultimately based on the internationally recognised criteria of evidence-based effectiveness and clinical benefit[239].

In 2007, the ZEKO had proposed a more articulated prioritisation framework[240] which, if developed at political level, would have led to the identification of five different priority levels, three of which would have been based on the main criteria of medical necessity (*Medizinische Bedürftigkeit*; according to the seriousness of the danger of illness and the urgency of the intervention), adequacy and proven clinical benefit (*Nachgewiesener Nutzen und Zweckmäßigkeit*; according to the dictates of EBM), as well as cost-benefit effectiveness (*Kosten-Nutzen-Effektivität*). Moreover, according to ZEKO, only in the event of a level playing field on the basis of the first three criteria could the choice then be based on the waiting time and, in the event of a further level playing field, on lottery-based resource allocation mechanisms. Some authors have argued that one of the reasons why priorities have not been made explicit as in the Scandinavian countries can be found in the high level of involvement of the legal system in the management of healthcare in Germany[241]. In particular, the jurisprudential orientation which followed the ruling of December 6, 2005 (referred to in the literature as the St. Nicholas judgment)[242], in which the Federal Constitutional Court affirmed the obligation of the State to protect life and physical integrity when designing the benefit system taking into account the specific conditions of the patient in the case of life-threatening illnesses, and declared the unconstitutionality of the exclusion of reimbursement from the GKV of treatments for illnesses for which there are no conventional medical treatment methods, has been the subject of criticism. Only a few months after this ruling, the Central Ethics Committee of the medical association likewise expressed its concern about this proposal, and its hope that "legislators and jurisprudence will not take this decision as an opportunity to regularly accept methods of dubious

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[238] SGB-V, § 12.

[239] Thus F.S. Oduncu, *Priority-setting, rationing and cost-effectiveness in the German health care system*, cit., p. 336.

[240] ZEKO, *Priorisierung medizinischer Leistungen im System der Gesetzlichen Krankenversicherung (GKV)*, cit., pp. 22-26.

[241] J. Carlsson, *Geht auch weniger? Stand der Diskussion in Schweden*, in Zeitschrift für Evidenz, Fortbildung und Qualität im Gesundheitswesen, vol. 107, 2013, no. 2, pp. 140-147.

[242] BVerfG BvR 347/98; NJW 2006, 891.

effectiveness"[243].

7. Switzerland

7.1 The underlying philosophy and its evolution

The Swiss Confederation's health system is the most expensive of the OECD European countries, but also one of the most satisfying to its citizens and users. The Swiss healthcare system is based on a private insurance model, in which competition among insurers (more than 80 existing health insurance funds[244]) and among service providers is regulated and tempered to varying degrees by federal legislation on social security[245].

First and foremost, insured persons enjoy a wide freedom of choice when it comes to choosing their service providers and health insurer, including the possibility of changing their chosen private insurer (up to twice a year). With the exception of some public hospitals, which are owned by the cantons, providers are also of a predominantly private nature. However, in order to limit the demand for and free supply of services, the law provides for some mechanisms of cost conditioning and selection of applications for access to services. On the one hand, the law stipulates that no insurance plan can guarantee complete protection against all health costs and provides that some are always excluded (out-of-pocket expenses); on the other hand, the Swiss system is characterised by a high rate of co-participation of the insured in health expenditure, in the form of both insurance premiums and out-of-pocket expenses, partly to discourage recourse to unnecessary medical services and to contain the costs of health care.

The insurers, who compete with each other, offer differentiated premiums and services, but they are subject to the scrutiny of the federal authorities, particularly with regard to the soundness of their finances.

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[243] ZEKO, *Priorisierung medizinischer Leistungen im System der Gesetzlichen Krankenversicherung (GKV)*, cit., pp. 8-9.

[244] These are non-profit legal persons under private or public law that are recognised by the Federal Department of Home Affairs, or private insurance companies that are authorised to do so on the basis of statutory provisions.

[245] In the landscape of the Italian constitutional doctrine on the Swiss system of health insurance, it is worth mentioning in particular the contribution of G. Grasso, *Diversificazione ed uniformità di un modello sanitario federale: il caso della Svizzera*, in Sistemi costituzionali, diritto alla salute e organizzazione sanitaria, edited by R. Balduzzi, Bologna, Il Mulino, 2009, pp. 189-246.

Some solidarity-inspired corrections prevent risk selection by insurers from depriving the weakest, such as the elderly, the chronically ill or the disabled, of their health cover. This is because whatever the condition of the person applying, health insurance funds cannot refuse applications for insurance for basic benefits and must guarantee everyone a minimum level of services set by federal law. Finally, the solidarity-based inspiration of the system is reflected in the principle of compulsory health insurance. In fact, following the entry into force of the new federal law on health insurance (the Health Insurance Act), the Federal Council decided to introduce a new law on health insurance. In 1994, the Swiss health system reached an essentially universal level of coverage: every person living in Switzerland is required to take out health insurance within three months of taking up residence or being born in Switzerland (Art. 3 KVG) and it is up to the cantons to ensure that this obligation is met (Art. 6 KVG). If there are people who do not have the means to take out an insurance plan, they will have access to public subsidies to cover the insurance premium and thus have access to basic healthcare services.

The model resulting from this combination of elements – the free market, on the one hand, and the constraints imposed by the legislator on the other – is mostly associated with the approach that governs the French and German systems: a social security system of Bismarckian inspiration[246]. It is aimed at achieving the benefits offered by the economic efficiency of the system, promised by the mechanisms of the free market, but to some extent also aimed at achieving equity in access to care[247], an objective that is typical of systems that do not limit themselves to recognising a regulatory role for the State but entrust it with the preparation and provision of the service. It is also sometimes described as a "pluralist"[248] or "consumer-driven" health care system[249].

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[246] According to the taxonomy of G. Esping-Andersen, *The three worlds of welfare capitalism*, cit., the Swiss system is associated with conservative-corporatist welfare regimes, such as France and Germany. The continuity with continental insurance systems is also underlined by M. Ferrera, *Modelli di solidarietà. Politiche e riforme sociali nelle democrazie*, cit. and more recently by F.C.J. Stevens and J. van der Zee, *Health system organisation models (including targets and goals for health systems)*, in International Encyclopedia of Public Health, 2008, pp. 247-256, esp. p. 251.

[247] As regards the residual inequities, which derive mainly from the fragmentation of competences in the field of health, see G. Grasso, *Diversificazione ed uniformità di un modello sanitario federale: il caso della Svizzera*, cit., spec. pp. 189-192 and L. Crivelli and P. Salari, *The inequity of the Swiss health care system financing from a federal State perspective*, in International Journal for Equity in Health, 13, 2014, no. 17, pp. 1-13.

[248] Group de travail "Rationnement", *Le rationnement au sein du système de santé suisse : analyse et recommandations*, Bâle, Académie Suisse des Sciences Médicales, 2007, p. 40.

[249] R.E. Herzlinger and R. Parsa-Parsi, *Consumer-driven health care: Lessons from Switzerland*, in Journal of American Medical Association, 292, 2004, no. 10, pp. 1213-1220.

The main reforms in Switzerland

The first federal law on health insurance in Switzerland dates back to 1911 (*Loi fédérale sur l'assurance maladie*, LAMa, 13 June 1911). It limited itself to dictating minimum conditions so that health insurance funds could be recognised and receive financial aid from the Federation, but did not establish a real system of social health insurance. In fact, the insurance remained optional at the federal level and only a few cantons made it compulsory for their entire population or for the lower income brackets. Additionally, the strong autonomy that the law left to the health insurance funds and the fact that each of them ended up representing a distinct risk community meant that both the basket of reimbursable services and the insurance premiums to be paid by the insured varied significantly, being fixed in direct proportion to the age of the person requesting access to the services of the fund.

The system was, however, profoundly innovated by the Federal Law on Health Insurance of 1994, known as the LAMal, which came into force on 1 January 1996 (*Loi fédérale sur l'assurance-maladie*, 18 March 1994). First and foremost, it aimed to strengthen solidarity between insured persons, for example, by introducing capitated insurance premiums unrelated to the age of the insured persons, the principle of free choice of insurers and providers and the broad freedom of transfer between health insurance funds, as well as a mechanism for offsetting risks between insurers. However, it also aimed to contain health costs by reducing demand (by increasing user participation in the costs of health services and encouraging the establishment of private health insurance schemes) and limiting supply (by planning hospital services and increasing cantonal participation in the financing of hospital facilities), as well as to fill the gaps in the basket of services, guaranteeing high-quality health care for all residents. The aim of improving the quality and efficiency of the health sector has also been behind the most important changes made in recent decades (for a more complete examination of the reforms that have taken place since the entry into force of the LAMal, see the book by G. Frésard-Fellay, B. Kahil-Wolff and S. Perrenoud, *Droit suisse de la sécurité sociale*, vol. II, Berne, Stämpfli, 2015 and the document from the Federal Office of Public Health (OFSP), *Informations générales concernant la loi fédérale sur l'assurance maladie*, April 2012, available at www.bag.admin.ch, as well as OECD, *Reviews of health systems*: *Switzerland*, Paris, OECD Publishing, 2011, esp. pp. 115-136). They concerned the design of an integrated care network known as "managed care" or *réseaux de soins coordonné* and the system of financing hospitals.

The former is a special insurance contract which has existed since 1994, whereby the insurer and the insured agree to limit their freedom of choice of providers to a list predetermined by the health fund on the basis of the most economical nature of their services (Art. 41(4) of the LAMal). In this case, the objective of reducing overall costs has long been pursued by means of organisational measures aimed at promoting and reinforcing the coordination and

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For a contrasting view, see instead Kieke G.H. Okma and L. Crivelli, *Swiss and Dutch "consumer-driven health care": Ideal model or reality?* in Health Policy, 2013, no. 109, pp. 105-112.

collaboration between service providers organised in integrated care networks, on the basis of a specific optional insurance plan. This provides, among other things, for the general practitioner to act as gatekeeper concerning treatment requests from the insured, for the corresponding generics of the prescribed drugs to be subject to reimbursement by the health insurance where possible, and for internal guidelines to be drawn up at all levels of service provision. Attempts in 2012 to make such a scheme mandatory for all policyholders, however, failed (see below).

On the other hand, the decision of the federal legislator in December 2007 to adopt a new system for billing hospital services represented a real change in the philosophy of the system (L. Crivelli, *I DRG nel contesto internazionale: quali lezioni per la Svizzera?* in Rivista per le Medical Humanities, 2012, n. 21, pp. 16-20, esp. pp. 17 ff). This was part of a more comprehensive reform of hospital financing and care provided by the *établissements médicaux-sociaux* and by the home care organisations (on the 2007 reform see the extensive contribution of M. Mader, *Financement des hôpitaux et des soins: éléments importants des révisions LAMal, marge de manoeuvre des cantons et rôle de la liberté économique*, in Jusletter, 16 August 2010, pp. 87-124 and G. Longchamp, *La planification hospitalière cantonale selon la LAMal*, in L'hôpital entre droit, politique et économie(s), edited by O. Guillod, Berne, Weblaw, 2015, pp. 85- 106).

Thus, since 2012 Switzerland has, albeit somewhat later than the majority of European countries, also embraced the classification system known as DRG, constructing its own Swiss DRGs on the German model (see the contributions in monographic issues no. 21 of 2012 of *Rivista per le Medical Humanities* and no. 3 of 2015 of the *Sécurité sociale* journal of the Département fédérale de l'Interieur) and abandoning the traditional method of paying for health care services, i.e., "payment on the spot" based on set fees for outpatient services performed in a hospital or physician's office.

The current model is characterised by the classification of patients by diagnosis. According to this model, also known as "case payment", the reimbursed price of the service is defined upstream of the treatment process itself ("prospective payment") and by the attention to the result of health treatment, which is why this is also referred to as "activity-based payment", "payment by result" or "payment for performance." The latter is in line with the objective of containing health insurance costs, as it creates an obligation for institutions to carry out prudent cost management, allowing them to retain any profits arising from the cost of a treatment that is lower than that assumed as a reference for each homogeneous group of patients. However, the DRG model also entails risks, which the doctrine does not neglect to emphasise, especially in terms of the appropriateness of treatment, more specifically through *cream skimming* ("encouraging/discouraging the care of patients whose expected costs are lower/higher than their associated reimbursement"), *up-coding* ("determining an upward adjustment in the coding of the severity of diagnoses… encouraging more intensive care of certain patients" in order to increase severity as defined in DRG and thus the associated reimbursement, or "encouraging a change in treatment approach (choosing inpatient rather than outpatient care)"); and "leading to a transfer of costs to other actors in the system," for example through the inappropriate practice of early discharge (L. Crivelli, *I DRG nel contesto internazionale: quali lezioni per la Svizzera*, cit., p. 19).

Lastly, there have also been interventions to strengthen the position of insured persons and the social nature of the insurance system, such as the one that, as of January 2012, prevented health insurance funds from suspending the reimbursement of benefits for non-paid premiums or cost-sharing contributions by insured persons (art. 64a LAMal, as amended by the Modification of the Federal Law on Health Insurance of 19 March 2010).

7.2. Organisation and financing of the health system

The right to health is governed by the Federal Constitution and the provisions of the individual cantonal constitutions. One of the great innovations of the Federal Constitution, amended on 18 April 1999, is the introduction of health protection as a social objective in Chapter 3 ("Social Objectives") of Title II of the Constitution ("Fundamental Rights, Civic Rights and Fundamental Objectives")[250] which is primarily balanced by the availability of the necessary resources for this purpose.[251] This is the main reason why the Federal Constitution is so important for the protection of health. On the basis of the principles of subsidiarity[252] and duty of

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[250] The Swiss system suffers from the dichotomy between the social right and the fundamental right to health, which can also be found in many other countries. Health is understood as a right to freedom, i.e., as a guarantee of a sphere of protection from possible State or private interference and as a guarantee of the many choices that can be made in this area (ranging from consent to treatment to freedom of choice of doctor and therapies), and as a social objective aimed at guaranteeing a series of positive interventions in the areas of care, prevention and rehabilitation. See G. Steffen, *Droit aux soins et rationnement. Approche d'une définition des soins nécessaires*, Berne, Stämpfli Editions, 2002, pp. 83 ff.; G. Steffen, *Le droit aux soins. Pourquoi un droit aux soins? Quel droit? Quels soins? Pour qui?* in Droit aux soins, 13ème Health Law Day edited by O. Guillod, D. Sprumont and B. Despland, Zürich, Weblaw, 2007, pp. 42 ff. Part of the Swiss doctrine underscores the nature of a right to benefits, therefore enforceable in a pre-judicial way, of the right to health as the right to the care necessary to guarantee human dignity, cf. D. Sprumont, *Le droit aux soins dans les bouleversements actuels du secteur de la santé*, Bulletin Université Neuchâtel, 1999, pp. 39-43; G. Steffen, *Droit aux soins et rationnement: approche d'une définition des soins nécessaires*, cit., pp. 83 ff.

[251] The social objective is specified in Art. 41(1) of the Constitution, whereas the need to balance it against available resources is laid down in Article 41(3), where it reads: "They [the Confederation and the Cantons] shall endeavour to achieve these social objectives within the scope of their constitutional powers and the resources available to them"; while paragraph 4 reads: "Social objectives do not give rise to claims for direct state benefits."

[252] See Articles 5a and 43a of the Constitution, introduced following the popular vote on 28 November 2004. The latter stipulates, for the purposes of allocating powers, that "The Confederation only undertakes tasks that the Cantons are unable to perform or which require uniform regulation by the Confederation."

cooperation[253], the Swiss constitutional provisions contained in Articles 3, 42 and 43 provide for the sharing of the exercise of those competences that are not expressly attributed to the Confederation[254]. As far as health protection is concerned, the Federal Constitution provides, in art. 41(1)(b), that "The Confederation and the Cantons shall, as a complement to personal responsibility and private initiative, endeavour to ensure that... every person has access to the health care that they require"; and the following paragraph 2 states that "The Confederation and Cantons shall endeavour to ensure that every person is protected against the economic consequences of old-age, invalidity, illness, accident, unemployment, maternity, being orphaned and being widowed.".

On the basis of the need for uniform regulation Articles 118[255] and 118b, 119, 119a, 120[256] of the Constitution provide that certain powers are specifically assigned to the Confederation. Where there is no specific federal power, regulatory competence is exercised on the basis of the general competence clause[257] by the individual cantons. The sharing of competence in health (which is subject to the Confederation's power of pre-emption, the limit of which lies in the principle of subsidiarity[258]) has led to the existence of 26 health systems[259], some of which are unconnected, and

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253 Article 44 of the Federal Constitution.

254 The aforementioned provisions establish a general competence of the cantons (art. 3 and art. 43) in matters not assigned by the Constitution to the competence of the Confederation and in matters that do not require unitary regulation (art. 42). On the "complex" distribution of competences in the Swiss system, see G. Grasso, *Diversificazione ed uniformità di un modello sanitario federale: il caso della Svizzera*, cit. pp. 196 ff.

255 "The Confederation shall, within the limits of its powers, take measures for the protection of health. It shall legislate on: a. the use of foodstuffs as well as therapeutic products, narcotics, organisms, chemicals and items that may be dangerous to health; b. the combating of communicable, widespread or particularly dangerous human and animal diseases; c. protection against ionising radiation."

256 These are regulations on sensitive and ethically controversial topics: research on human subjects, reproductive medicine and genetic engineering in the human sphere, transplantation medicine, genetic engineering in the non-human sphere. As a result of the gradual transfer of powers to the federal government, a series of laws were passed at federal level in the first decade of the 2000s in the areas mentioned above: Law on Medically Assisted Procreation (2001), Transplantation Law (2007), Law on Human Gene Analysis (2007), Law on Biomedical Research (2014). In 2007, the Law on Medical Professions was also passed.

257 This is the clause included in Article 3 of the Federal Constitution.

258 On the primacy of federal law, see Article 49 of the Constitution.

259 The cantons' competences in the provision and financing of health services, including regulations on hospital and outpatient organisation and planning, have therefore developed within the scope left by federal law. In almost all cantons, a cantonal health law and regulations have been drawn up to govern the application of federal health law. Each canton has the power to decide independently on the planning of health care facilities (especially

to the existence of 26 cantonal ministries but no federal Ministry of Health[260]. This general fragmentation of health policies is further evidenced by the absence of federal health planning for the whole of Switzerland except in particular sectors[261] or for specific health programmes[262].

With respect to the significant diversification of the cantonal approaches in this field, the main unifying instrument in the Swiss system is a regulatory cluster consisting of the Federal Law on Health Insurance (LAMal[263]), the Federal Act on the General Part of Social Insurance Law (LPGA)[264] and a number of implementing ordinances, such as the Health Insurance Ordinance (OAMal)[265] and the Ordinance on Benefits in the Compulsory Health Insurance System (OPAS)[266].

The LAMal, in particular, which has been the subject of numerous reforms over the years, has had the objective (alongside regulating social insurance against illness by providing for compulsory health care insurance and optional daily allowance insurance[267]) of reinforcing the principles of

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hospitals and homes for the elderly), which competences to delegate to the municipalities and how to provide training for professionals. The organisational autonomy granted to the cantons has led to a marked diversity, both in the provision of health services and in the methods and levels of financing, which has led to significant problems of social and territorial equity. See La *gouvernance des politiques suisses de santé*, edited by S. Rossini, Lausanne, Réalités sociales, 2014, pp. 29 ff.

260 See Observatory on Health Systems and Policies, *Switzerland*. *Health system review*, 2015, p. 26; G. Martinico, *Dov'è il Ministro federale della sanità? La Svizzera e il Welfare decentrato*, in La tutela multilivello dei diritti sociali, edited by E. Balboni, Naples, Jovene, 2009, pp. 795-814. Federal health functions are exercised by the Federal Office of Health.

261 In the area of health promotion and combating addiction, mention should be made of the 2008-2012 National Tobacco Programme, aimed at reducing the impact of smoking on the health of the population and extended by the Federal Council until 2016, and the National Alcohol Programme, 2008-2012, also extended until 2016. These programmes have also more recently been incorporated into the framework for action established by the Santé 2020 programme.

262 One example is the federal health strategy known as Santé2020 and the one adopted by the Federal Council on 6 December 2019, known as Santé2030.

263 The LAMal law of 18 March 1994 came into force on 1 March 1994. It repealed the Federal Law of 13 June 1911 on Health Insurance (LAMa), partially amended in 1964, which together with the Federal Law of 20 March 1981 on Accident Insurance and the Federal Law of 19 June 1992 on Military Insurance, constituted the basic laws on the matter before the entry into force of the LAMal.

264 *Loi fédérale sur la partie générale du droit des assurances sociales*, 6 October 2000.

265 The *Ordonnance sur l'assurance-maladie* was passed on 27 June 1995 and, like the LAMal, has been amended several times over the years, most recently by the ordinance of 14 November 2015, in force since 1 January 2016.

266 *Ordonnance du DFI sur les prestations dans l'assurance obligatoire des soins en cas de maladie*, 20 September 1995.

267 On the Swiss insurance system see Kieke G.H. Okma and L. Crivelli, *Swiss and Dutch "consumer-driven health care": Ideal model or reality?*, cit., pp. 105-112; G. Frésard-Fellay, B.

the market and the competitive dimension in the field of health, by increasing the freedom of choice of insurance services and making providers responsible for the quality of care[268]. The law makes it compulsory for all persons domiciled in Switzerland to take out health insurance within three months of taking up residence or being born in Switzerland, providing freedom in the choice of the insurer among those dictated by law[269]. Insurance costs are independent of the diversity of individual risk and income (*single premium*)[270] but are set by each insurer on the basis of the health costs incurred and foreseeable in the territorial scope of each canton.

Article 61 of the LAMal stipulates that the amount of insurance premiums must be approved by the Federal Council after the cantons have expressed their views on the tariffs. In relation to the need to guarantee access to care for less well-off citizens, for reasons of economic and social solidarity, articles 64 and 65 of the LAMal give the cantons the power to impose reductions in insurance premiums for young people and insured persons whose income does not allow them to pay the high premiums charged by insurance companies, including cross-border workers (and their family members) residing in one of the countries of the European Union[271]. These reductions, which are intended to guarantee equal access to services, are compensated by subsidies that the Confederation grants up to a limit of 7.5% of the gross costs of compulsory health insurance, which the Federal Council divides up into quotas for the cantons on the basis of the criteria of resident population and the number of cross-border workers[272].

Compulsory insurance covers the set cost of services based on their verified effectiveness, the appropriateness and cost-effectiveness of the services provided in the form of a third-party guarantor (reimbursement of the patient for outpatient services is paid by the insurer) or a third-party

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Kahil-Wolff and S. Perrenoud, *Droit suisse de la sécurité sociale*, vol. II, Berne, Stämpfli, 2015.

[268] See S. Moresi-Izzo, V. Bankauskaite and C.A. Gericke, *The effect of market reforms and new public management mechanisms on the Swiss health care system*, in International Journal of Health Planning and Management, 2010, no. 25, pp. 368-385.

[269] See Art. 3, para. 1 of the LAMal and Art. 1 of the OAMal.

[270] On the principle of solidarity underlying the single premium, see A. Froidevaux, *Amélioration de la compensation des risques*, in Sécurité Sociale CHSS, 2014, no. 3, pp. 155 ff.; A. Müller and T. Schoch, *Redistribution dans l'assurance obligatoire des soins: étude de microsimulation*, in Sécurité Sociale CHSS, 2014, no. 3, pp. 180 ff.

[271] For insured persons up to the age of 18, there is no deductible and the maximum percentage rate to be payed is halved. See Art. 65, para. 1 and 1-bis and art. 65a of the LAMal, as well as S. Bonfiglio, *Sistemi sanitari alla prova dell'immigrazione: il caso svizzero*, in Rivista AIC, 2017, no. 3, pp. 7 ff.

[272] See Article 66 of the LAMal.

payer (billing to the insurance company for hospital services)[273].

Health insurance is the basic infrastructure of the health system and is built on a number of mutually dependent health insurance funds. To access the services, people living in Switzerland must be registered with a health insurance fund and pay a monthly premium. The health insurance fund covers a range of benefits set at federal level, while insurance premiums are set at regional level by each insurer. This has led to significant premium variability in each region and canton.

A constant trend in the Swiss system is that, alongside the acknowledged high quality of care, costs are rising steadily, which is reflected in higher insurance premiums for individuals[274].

The need to rationalise costs stems from the fact that Switzerland, with a health expenditure of 12.1% of gross domestic product, has the second most expensive health care system of all OECD countries after the United States, and the most expensive of the European countries. Government health expenditure accounts for 64% of total health expenditure, while out-of-pocket expenditure accounts for 28% of total health expenditure[275].

The health system is financed through a mix of resources from different sources: public resources, resources from compulsory health insurance, general social insurance[276], complementary health insurance[277], private and out-of-pocket[278] contributions, and other private sources. Public health expenditure is composed of contributions that the Confederation, the cantons and the local authorities collect through the taxation system and allocate in two ways. On the one hand, some resources are allocated directly to specific services such as hospitalisation, home care, primary care

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[273] See Article 42 of the LAMal. In 2004 a uniform tariff schedule, TARMED, was introduced to replace the 26 existing cantonal tariffs, which significantly reduced the scope for negotiation between cantonal associations of insurers and providers.

[274] Insurance costs have grown significantly over time, see J. Indermitte and S. Otto, *Financement des prestations de santé: le souhaitable et le possible*, in Sécurité Sociale, 2015, no. 1, p. 11.

[275] See OECD, *Health policy in Switzerland*, 2017, available at https://www.oec.d.org/els/health-systems/Health-Policy-in-Switzerland-July-2017.pdf.

[276] Social insurance is provided, as in other systems, to insure people against the risks of old age, disability and accidents. In some cases, the social security system contributes to the financing of health services such as rehabilitation in case of disability and health care costs arising from treatment of occupational and non-occupational diseases of workers.

[277] Supplementary insurance is based on a premium related to a specific risk (for individual contracts) or related to categories of risks (for group contracts). Generally, they cover some health services or additional options for hospital stays not included in the basket of reimbursable services.

[278] Cost-sharing costs include the deductible and the above-mentioned 10% rate and services that are not included in the basket of services, such as dental care, residential care, and over-the-counter drugs.

- mostly covered by cantonal resources - and other interventions such as prevention and health promotion. On the other, indirect financing resources are allocated to groups of people with a medium-low income who do not have the means to pay for compulsory insurance, covered jointly by the Confederation and the cantons[279].

The provision and financing of services in Switzerland

In terms of services, the most important responsibilities exercised by the individual cantons in the health sector concern the planning and provision of health services in inpatient and outpatient settings.

With regard to hospital planning, the cantons exercise their competence within the scope allowed by the federal laws on the subject, i.e., the LAMal law, the OAMal and OPAS ordinances. These have provided the fundamental principles to unify the system, leaving to the cantons the competence to implement and organise the system according to those principles and objectives.

Art. 39 of the LAMal law establishes the conditions under which hospitals are authorised to carry out their activities on the basis of a series of decrees issued by the individual cantons, which periodically establish the list of hospital institutions authorised to operate. The conditions laid down in Article 39 of the LAMal are cost-effectiveness, quality and intercantonal coordination. Public hospitals (cantonal or communal owned), which represent the largest share, or private hospitals, which fall under cantonal planning, are authorised to operate as service providers and, therefore, according to the mechanisms of the LAMal, can access public reimbursements and/or financing. Hospital financing has been regulated by the LAMal since the revision of the law approved on 21 December 2007, which with regard to the DRG part of the reform came into force on 1 January 2012. All the requirements of cantonal planning for the recognition of service providers also apply to semi-hospital care providers and nursing homes that provide treatment, medical care and rehabilitation for long-term patients.

Inclusion in cantonal planning on the basis of Article 41 of the LAMal means that the patient is required to go to the institutions, hospitals or nursing homes located in the canton in which he/she is domiciled. If the patient wishes to go outside the canton of reference, he or she must refer to institutions included in a special list in which the canton of reference indicates the external institutions with which it has established agreements. This leads to limited competition between insurers within the boundaries of each canton.

The cantonal competence in hospital planning and organisation entails one risk stemming from the proximity of hospital services to the needs of the population: an inefficient use of resources for the hospital sector. Health care services, especially in locations that are close to neighbouring cantons, may be subject to duplication, and hospitals may be distributed irrationally across the federal territory without taking into account the overall characteristics of a wider area but simply with a

[279] See Articles 65-66a of the LAMal and 106-106e of the OAMal.

view to meeting the clinical needs of the cantonal population. The lack of coordination in hospital planning has led to a surge in health costs, given the particular morphology of Switzerland and the great differences in size and population between the cantons. A solution to these risks, even if only a partial one, lies in intercantonal agreements and specifically intercantonal hospital planning (see below). It should be noted, however, that this would only be a partial solution because the cantons find it hard to downsize hospital supply, close down hospitals and upgrade those in operation, since these initiatives are generally perceived more as a reduction of citizens' rights than as an attempt to ensure a more efficient use of resources. This perception has traditionally had a negative impact at the ballot box.

In addition to hospital care, another area in which the cantons have played a decisive role is outpatient care. These services are provided in two ways: the first concerns care provided by doctors, physiotherapists, nurses, speech therapists and dieticians, who often work on a freelance basis or in the outpatient units of public and private hospitals. The second concerns care provided by the outpatient units of public and private hospitals and by organisations providing integrated care in network systems. The cantons generally have the power to grant and revoke the authorisation to practise in almost all health professions and to approve university training programmes; even the opening hours of pharmacies and the operation of private health analysis laboratories are subject to this cantonal authority. This general competence has been addressed by the entry into force of a regulation (the "medical needs clause"), which has modified the ordinary system of the LAMal in order to contain the health costs due to a significant increase in the number of providers in the outpatient sector since the early years of the new millennium. In 2013, the Federal Chambers reintroduced Article 55 of the LAMal, which was originally introduced in 2001, regarding the strategic management of the number of authorisations. The Federal Council ensured its application by means of an ordinance of July 2013, extending its validity until 30 June 2021 (Ordinance limiting the number of service providers authorised to perform at the expense of compulsory health care insurance (OLNF) of 3 July 2013, the validity of which was extended until 30 June 2021 by the Ordinance of 15 May 2019). As a result, officially the cantons no longer have the power to authorise competent supplementary service providers, pursuant to Article 36 of the LAMal, to practise at the expense of compulsory insurance. As provided for in the legislation, the same discipline applies to doctors practising in institutions within the meaning of Article 36a LAMal or, by decision of the cantons, in the outpatient sector of hospitals within the meaning of Article 39 LAMal.

The maximum number of service providers authorised to practise, on the basis of the planned breakdown by geographical area and fields of specialisation, is set out in Annex 1 to the Ordinance of 3 July 2013. They correspond to the resources actually available in the outpatient sector and are based on the registers of Santésuisse (the association that brings together the representatives of health insurance funds) that list authorised service providers. However, if a canton considers that there is a need to do so for all or for certain specialty areas, it may decide, by virtue of Article 55(4) and Article 3(a) of the Ordinance, to lift the restrictions for these categories of services or specialties, which will then no longer be subject to the limitation. The canton can base its decisions on the density of health coverage on its own territory, on the one hand, and on the density of health

coverage in the other cantons, in the seven large regions (Lake Geneva Region, Mittelland, Northwestern Switzerland, Zurich, Eastern Switzerland, Central Switzerland, Ticino) or in the whole of Switzerland, on the basis of Annex 2 to the OLNF Ordinance. However, cantons that have opted for a restriction on authorisations remain free to authorise new providers if the number of service providers falls below the limits indicated in Annex 1 (possible reasons: closing of practice, moving house, retirement or death). In this case, the cantons may proceed with new authorisations within the limits set out in Annex 1 of the OLNF; these limits cannot be exceeded.

A constant trend in the Swiss system is, as mentioned, the gradual increase in costs, which has an impact on the increase in insurance premiums for individuals. In order to contain this growth, some types of insurance schemes have also been introduced to regulate the supply and demand side of service provision. Besides the compulsory social health insurance, voluntary supplementary insurances provide managed care coverage schemes. The legal basis for the managed care scheme is provided by Article 41, para. 4 and 62, para. 1 and 3, of the LAMal.

The draft revision of the LAMal aimed at introducing this scheme into the LAMal and making it compulsory was clearly rejected in the popular referendum on 17 May 2012 (76% voted against amending the LAMal; decisive considerations regarded the loss of freedom of choice of doctor and the financial penalties for not participating in the programme). The stated aim of the managed care contractual scheme, which was introduced in 1994 and has seen a sharp increase since 2004, was to contain insurance costs and increase competition among insurance providers. The managed care scheme, which is still optional, offers a reduction in the insurance premium in return for limiting the freedom to choose a doctor. According to this scheme, a doctor or a group of doctors act as gatekeepers, filtering non-urgent clinical needs and deciding the type of health trajectory to be followed together with the patient.

Within this insurance framework, a number of variants have developed which accentuate one or more features of the managed care contract. Under the General practitioner and Health Maintenance Organisation scheme, the insured person undertakes, in the event of illness, to first consult a recognised general practitioner or a group practice (HMO centre). The health network is responsible for the management of a certain financial budget, which is remitted by capitation based on the number of people enrolled in the programme. The financial responsibility of health professionals provides an incentive not to request examinations and not to prescribe treatment that is not strictly necessary. Under the Telmed scheme, the insured, in the event of health problems, undertakes to always call a medical advice centre by telephone, where competent professionals provide information and advice and, if necessary, direct the user to a doctor, hospital or therapist. Also with a view to the establishment of service networks, the preferred provider plan scheme has been drawn up, which provides for an agreement between a health insurance company and a network of professionals to whom the user can turn in return for a reduction in the insurance premium.

7.3. Actors and locations of decision-making processes

The federal structure of Switzerland consists of three decision-making levels: the Confederation, the cantons and the municipalities[280]; it also includes the involvement of a variety of public and private actors in decision-making and organisational processes, such as institutions, professional associations, representatives of relevant interests in various sectors.

The Swiss health care system is characterised by considerable organisational complexity, resulting from a number of factors, including a marked fragmentation in the federalist distribution of competences between levels of government; a significant diversification among the 26 cantonal organisational arrangements, which are characterised by specific features and small territorial dimensions; and the difficulty of pursuing health care reforms as a result of increased federalism and direct democracy[281].

Health decision-making processes have given priority to the need to increase the quality of mediation and negotiation between the various parties mainly through two actions: first, by enabling the widest possible involvement of stakeholders in health decisions through the instruments of direct democracy, legislative initiatives and referenda at both federal and cantonal levels, and the instruments of consultation and involvement of stakeholders, special interest representatives and experts; and secondly, by establishing and supporting the coordination of health policies between the main decision-makers in the health sector, i.e., the cantons.

The positive effects of the system thus envisaged include, from the point of view of the decision-making processes, the proximity of the decisions with reference to the location of the recipient of the decision, a targeted approach to the specific needs of the population according to local diversification, and the definition of strategic solutions for specific problems. However, at the same time, some critical issues have emerged which appear just as relevant, consisting of difficulties in the management of such complex health care governance and problems in the construction

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280 With regard to the distribution of competences, as we have already seen the federal government and the cantons play a fundamental role in the health sector, while the competences of municipalities are limited to the sectors of public hygiene, home care and social assistance. See G. Kocher, *Confédération, cantons et communes : partage des compétences et des taches*, in Système de santé suisse 2010-2012. Survol de la situation actuelle, edited by G. Kocher and W. Oggier, Berne, Editions Hans Huber, 2011, pp. 115 ff.

281 The characteristics of the system, the orientation towards competition and the market, and the plurality of actors involved pose a problem in terms of system coherence; see S. Rossini, R. Crivelli, I. Bolgiani, A. Clausen, D. Prélaz and F. Scalici, *Allocation des ressources et cohérence du système suisse de santé*, Lausanne, HES, Juillet 2012, pp. 24 ff; S. Rossini (ed.), *La gouvernance des politiques suisse de la santé*, Lausanne, Réalités sociales, 2014, *passim*.

of a health care policy that is truly coherent[282].

It is precisely the instruments of direct democracy, legislative initiative and referendums, through which Swiss citizens have had their say on a wide range of health policy issues[283], that highlight some of the most significant vagaries in the Swiss health system.

The last thirty years have seen a large number of important popular votes at federal level in the health sector (around twenty legislative initiatives and a dozen optional referendums) in three main areas: health insurance, perinatology (termination of pregnancy, medically assisted procreation) and policies concerning narcotic drugs[284]. The number and outcomes of the referendums make clear how difficult it is to manage a complex and multi-polar health governance system like Switzerland's.

While direct democracy instruments at federal and cantonal level (referendums and legislative initiatives) are limited, it must be noted that they are also very effective formal instruments of community participation[285]. Private stakeholders are systematically involved in decision-making processes that affect them through institutionalised

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[282] Cf. on this point I. Bolgiani and L. Crivelli, *Planification des équipements hospitaliers coûteux : un regard économico-politique*, in L'hôpital entre droit, politique et économie(s), 21ème Journée de droit de la santé, edited by O. Guillod, Berne, 2015, pp. 130-131

[283] Provisions about legislative initiatives and referendums are found in Articles 139 and 141, respectively, of the Federal Constitution. Since 1980, the use of referendums and legislative initiatives has grown exponentially, reaching 86 optional referendums and 125 legislative initiatives. Cf. O. Guillod, *Conflits entre la participation citoyenne et la politique gouvernementale de santé dans l'élaboration des normes*, in Les grands conflits en droit de la santé, edited by C. Régis, L. Khoury and R. Kouri, Montréal, 2016, pp. 63-92.

[284] For illustrative purposes, the following is a list of the most recent public votes on the cited matters. On 14 June 2015, a constitutional initiative was held to authorise the development of more than three embryos obtained through medically assisted procreation and to allow pre-implantation diagnosis (Yes prevailed); on 28 September 2014, a constitutional initiative was held to amend the compulsory health insurance system, in an attempt to replace the dozens of existing private health insurance funds with a single public health insurance fund (No prevailed); on 18 May 2014, a constitutional initiative was held to strengthen basic medical services and encourage family medicine (Yes prevailed); on 9 February 2014, there was a constitutional initiative to exclude the termination of pregnancy from the list of services covered by compulsory insurance (No prevailed); on 23 September 2012, there was a constitutional initiative to protect the population from the risks of passive smoke (No prevailed); on 17 June 2012, there was a referendum against the amendment to the federal law on health insurance, which introduces facilitations to set up service networks, or "managed care" (result of law amendment rejected). On this point, see O. Guillod, *Droit de la santé : quelques développements récent*, in L'hôpital entre droit, politique et économie(s), cit., pp. 10 ff.

[285] It should be recalled that the Federal Council's Santé2020 strategy called for increased public involvement and participation of patient associations in health care decision-making processes. Patient associations are organised at federal, cantonal and municipal level.

participation mechanisms at political level (consultative procedures)[286], through lobbying in parliament[287] and the representation of the interests of civil society and expert knowledge in the relevant health-related consultative bodies. In the latter case, decision-making processes concerning the setting of priorities characterised by what some privileged witnesses regard as a "slipping" trend in favour of the federal level[288], the representation of interests rooted in civil society has been substantially accompanied by the expression of expert competences within the federal health administration.

Decision-making processes in Switzerland

The Office Fédéral de Santé Publique (OFSP) and the Institut Fédéral des Produits Thérapeutiques (SWISSMEDIC) operate within the framework of the Federal Administration for Public Health and Therapeutic Products. In the OFSP, three commissions - the Federal Commission for General Services and Principles, the Federal Drugs Commission and the Federal Commission for Medical Tests and Devices - play a key advisory role to the Federal Office of Health in drawing up the list of services, drugs and medical devices subject to reimbursement, representing the most important issues through a multidisciplinary composition. The multidisciplinary composition of representatives of social bodies and expert knowledge is governed by Article 37(*c)*, (*e*) and (*f)* of the OAMal and the *Ordonnance sur l'assurance-maladie*.

In each of these commissions, with membership ranging from 15 to 18 members, the interests of insurance policy holders are represented by two members along with those of insurers, while expert knowledge, both clinical and pharmaceutical, tends to be expressed by half of the commission members. The main criticism against the system concerns the opacity of the processes leading up to the adoption of an opinion and the fact that representatives of "powerful" interests, such as those of the pharmaceutical industry, and expert knowledge are over-represented compared to representatives of patients' associations and civil society in general.

The OFSP, organised into the aforementioned consultative commissions, is part of the central federal administration, while SWISSMEDIC, the federal body responsible for the marketing authorisation of pharmaceuticals, is an autonomous administrative unit with the status of a legal entity under public law. SWISSMEDIC

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[286] See on this point the *Loi fédérale sur la procédure de consultation* of 18 March 2005, which regulates the consultation procedure for interested parties in Articles 4 and 7.

[287] Cf. P. Sciarini, *Eppure si muove*: *The changing nature of the Swiss consensus democracy*, in Journal of European Public Policy, 2013, esp. pp. 116-120, where it is pointed out that the relevance of interest groups and experts in the pre-parliamentary consultation phase is decreasing in favour of political parties acting in the parliamentary phase.

[288] *Le rationnement au sein du système de santé suisse : analyse et recommandations*, Rédigé par le Groupe de travail "Rationnement" sur mandat du Groupe de pilotage du projet "La médecine en Suisse demain", July 2007, p. 40.

began its activities on 1 January 2012 with the entry into force of the Federal Act on Therapeutic Products.

SWISSMEDIC is made up of a board in charge of managing the institute, whose president is appointed by the Federal Council and whose function is to ensure the proper exercise of the institute's functions as well as the implementation of strategies in the field of therapeutic products, and a number of technical-scientific commissions which draw up preliminary draft opinions. The body's independence is strengthened by rules on the appointment of its members, the duration of their mandate and the possibility of their revocation only on significant grounds. Once appointed by the Federal Council, the members of SWISSMEDIC's Board of Directors, Executive Board or Audit Board may only be dismissed for important reasons (cf. Art. 71 of the LPTh).

Given their role in assessing the safety and efficacy of medicines, scientific and technical committees play a key role. Article 68.5 of the Therapeutic Products Act of 15 December 2000 states that "Il [L'institut] peut instituer des commissions consultatives et mandater des experts", while Article 10 of the *Ordonnance sur l'organisation de Swissmedic* of 28 September 2001 specifies that the *commissions consultatives sont instituées par décision du conseil de l'Institut*. The institute's two standing committees are the Committee on Human Medicinal Products and the Committee on Veterinary Medicinal Products. The committees are made up of eight and seven members, respectively (ordinary members, extraordinary members and consultants), specialised in internal medicine, pharmacology, anatomopathology (for the Human Medicines Commission) and veterinary medicine. They are appointed by the Institute Board (*Conseil*) for a period of four years (cf. the *Swissmedic Regulation* approved by the Institute Board on 9 May 2014 and in force since 1 June 2014).

The requirement underlying the operation of the two committees, which make decisions by simple majority, is to ensure that expert knowledge on medicines, both clinical and veterinary, is taken into account[289]. Again, as with the committees operating in the context of the OSFP, a dense and dominant presence of clinical and pharmaceutical expert knowledge can be observed, with an almost total absence of representatives of the interests of civil society.

With regard to the second aspect concerning the development of health-related decision-making processes, the Swiss system presents a unique form of cooperation: inter-cantonal conventions. It should be noted that, although there are numerous constitutional provisions[290] concerning forms of coordination between the Confederation and the cantons, vertical cooperation (between the Confederation and the cantons) is not envisaged,

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[289] See Article 7 of Swissmedic's Rules of Procedure entitled "Taking decisions", which stipulates that decisions may be taken in the presence of at least four persons engaged in clinical activity and one person engaged in pre-clinical activity from among the ordinary members of the Committee for Human Medicinal Products, and at least three persons engaged in clinical activity and one person engaged in pre-clinical activity for the Committee for Veterinary Medicinal Products.

[290] See Articles 44, 45, 48, 55, 147, 186 of the Federal Constitution.

while horizontal cooperation (between different cantons) is intensive[291] but has never been systematically formalised[292]. Intercantonal cooperation in health matters has a long tradition in Switzerland[293]. It was envisaged in 1919 with the creation of the Swiss Conference of Cantonal Health Directors[294], was subsequently developed at federal level and since the 1970s has also expanded at regional level[295]. Conventionally regulated intercantonal cooperation is fairly frequent. On the basis of Article 48(1) of the Federal Constitution, the cantons may conclude agreements among themselves and set up joint organisations and institutions for the common purposes laid down in the agreements they have signed. The two main instruments of horizontal cooperation are the *conferences*, through which the members of the executive bodies of the cantons meet and exchange

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[291] D. Bochsler, *Neighbours or friends? When Swiss cantonal governments co-operate with each other*, in Regional & Federal Studies, 2009, no. 3, 349-370; N. Bolleyer, *Consociationalism and intergovernmental relations*. *Linking internal and external power-sharing in the Swiss federal polity*, in Swiss Political Science Review, 2006, no. 3, pp. 1-34; N. Bolleyer, *Intergovernmental arrangements in Spanish and Swiss federalism*: *The impact of power-concentrating and power-sharing executives on intergovernmental institutionalization*, in Regional and Federal Studies, 2006, no. 4, pp. 385-408.

[292] S. Rossini, R. Crivelli, I. Bolgiani, A. Clausen, D. Prélaz and F. Scalici, *Allocation des ressources et cohérence du système suisse de santé*, cit., pp. 24.

[293] W. Achtermann and C. Berset, *Les politiques suisses de santé potentiel pour une politique nationale*, Office fédéral de la santé publique (OFSP), 2006, pp. 71 ff.

[294] This conference, which was established in 1919, brings together the cantonal managers in the health sector in a political coordination body called, since 2004, the Swiss Conference of Cantonal Ministers of Health (GDK) (previously known as the "Swiss Conference of Cantonal Ministers of Health"). The aim of the conference is to promote intercantonal cooperation, as well as cooperation with the federal government and important organisations in the health sector. Representatives of federal offices and the Principality of Liechtenstein attend the meetings of the GDK as permanent guests. As a rule, two Plenary Assemblies and nine Steering Committee meetings are held each year. See the Presentation on the GDK website: http://www.gdkcds.ch/fileadmin/docs/public/gdk/gdk/gdk_home_gdkin9_i.pdf.

[295] Since 1978, the Conference has had a permanent Central Secretariat based in Bern. The Conference and its Central Secretariat are legally and financially supported by the cantons. The decisions taken by the Conference are not binding on its members or the cantons, but are mere recommendations. The Conference also plays an important role as a discussion forum for medical directors and is a privileged interlocutor for federal bodies and numerous national associations and institutions. Its main tasks include taking position on and coordinating efforts in the field of health insurance as well as the financing of care services, health service planning with the focus on hospitals and in particular on highly specialised medicine, health promotion and prevention as well as the development of information systems. In cooperation with the federal government, the Conference has started taking measures to promote health information technology (eHealth), basic medicine, palliative care and mental health. The Conference works closely with the national umbrella organisation for health professionals OdASanté to promote the training and recruitment of staff in the health sector.

information, and the *concordats*, which are the concretely operational agreements on matters of intercantonal cooperation[296].

Intercantonal planning for highly specialised medicine in Switzerland

An important area of intercantonal cooperation in hospital planning, in addition to cooperation dictated by linguistic and geographical considerations, was the promotion of highly technically advanced university hospitals. Intercantonal planning in the field of highly specialised medicine was envisaged not only to guarantee the quality of interventions (mainly because of the issue regarding the volume of activity in highly specialised medicine), but above all to rationalise costs in a sector characterised by very high technological and professional intensity. To this end, Article 39, para. 2-bis of the LAMal states the following: "*Dans le domaine de la médecine hautement spécialisée, les cantons sont tenus d'établir conjointement une planification pour l'ensemble de la Suisse. Si les cantons n'effectuent pas cette tâche à temps, le Conseil fédéral détermine quels hôpitaux figurent pour quelles prestations sur les listes cantonales.*"

Planning highly specialised health services is therefore a cantonal competence, over which the Confederation can exercise an alternative (subsidiary) power. On this basis, the cantons drew up the *Intercantonal Convention on Highly Specialised Medicine* (CIMHS), which came into force on 1 January 2009 and by which they delegated the competence to define and plan activities in the field of highly specialised medicine to an intercantonal *college* (decision-making body or board), which corresponds to the decision-making body of the CIMHS. Article 1 of the Convention adopts a broad notion of highly specialised medicine, characterised by "*rareté de l'intervention, par un fort potentiel d'innovation, par un investissement humain ou technique élevé et/ou par des méthodes de traitement complexes et surtout par des frais élevés de traitement, y compris de diagnostic.*" Article 4 of the Convention sets out the scientific criteria for inclusion in the list of conventional services: "*la qualité des prestations, la disponibilité de personnel et d'équipes qualifiés, la disponibilité des disciplines de soutien, l'économicité et le potentiel de*

[296] Intercantonal conventions are contracts under public law concluded between two or more cantons on matters falling within cantonal competence. To date, there are approximately 800 intercantonal conferences on matters falling within the jurisdiction of the cantons. Intercantonal Conferences have no formal legal basis and their activities are regulated by agreements. The Conference at federal level consists of the Intercantonal Conference of Health Directors and Managers and the administrative apparatus of the conference secretariat. The conference at regional level consists of four conferences: *Conference Romande* of Health and Social Affairs founded in 1981, Conference of Northwestern Switzerland founded in 1980, Conference of Health Directors of Eastern Switzerland and the Principality of Liechtenstein founded in 1974, Conference of Central Switzerland of Health and Social Affairs founded in 1974. According to the federalist logic, the four conferences are part of the Intercantonal Conference of Health Directors and Managers. Regional conferences of health directors deal with priority issues such as the standardisation of clinical practice (in this area, variability between areas is a significant problem), training and further education of health professionals outside universities.

développement."

The CIMHS stipulates that for highly specialised medical services, it is the decision-making body, and not the cantonal governments, that draws up an intercantonal list of highly specialised medical hospitals. The Convention's Board is elected by the members of the Conference of Cantonal Health Directors and Managers. The Board consists of five members from cantons with university hospitals and five members from other cantons, at least two of whom have an interregional function. In addition to the GDK members, the Federal Office of Public Health, the Conference of Universities and Santésuisse may also delegate a representative. The tasks of this body are: the development of the strategy for highly specialised medicine; the planning of highly specialised medicine activities; and the monitoring of the implementation of the planning and its results.

This body bases its decisions on the proposals of the scientific body, a panel of Swiss and foreign experts, made up of 12 doctors specialising in different disciplines. The most important function of the Convention Board is to decide on the services to be included in the conventional list of services, which has a prevailing force over the provisions of the cantonal list of services. Since it began its activity, the Board has made decisions in many areas of competence, such as: organ transplantation, stem cell transplantation in adults and newborns, proton therapy, hearing organ implants, treatment of severe burns in adults and newborns, treatment of severe injuries, complex treatment of critical cerebral vascular problems, neurosurgery, primary (genetic) immunodeficiencies, tracheal surgery, liver surgery and transplantation, diagnosis and treatment of congenital metabolic problems, intensive care for premature babies, paediatric oncology, complex visceral surgery.

In these areas, the Board, supported by the committee of experts, determined which Swiss hospitals were best placed to provide services requiring a very high level of technological capability on the basis of conventional criteria.

7.4. Resource allocation and prioritisation

In Switzerland, there has been a lively debate on priority setting. However, the attention paid to the subject, which is concentrated in a period that spans essentially from the end of the 1990s to the present day[297], has been fluctuating in the wake of the ups and downs of interest shown by the mass media in the face of individual cases of refusal of treatment that is too expensive. Examples include the *Novo Seven* case, in 1999, in which the health authorities of Bâle-Ville had refused to provide a

[297] Among the first contributions of legal doctrine are those by S. Raducszweit, *Il razionamento delle prestazioni sanitarie*, Thesis work, University of Geneva, 1997 and among the first official documents on the subject is the report of the Conseil d'État Vaudois, *Rapport au Grand Conseil sur le postulat Paul-Arthur Treyvaud demandant de clarifier les principes de la distribution généralisée des soins et de la lutte contre le rationnement des soins ainsi que d'étudier l'opportunité de légiférer dans la matière*, in Bullettin des Déances du Grand Conseil du Canton de Vaud, 2001, no. 56, pp. 6618-6673.

high-cost anti-haemorrhagic drug (50,000 CHF per day, for a minimum of 6 days of treatment)[298] to a 70-year-old man, and the ruling by the Federal Court, in 2010, refusing to allow the health insurance company to pay for an expensive medicine for a rare disease (Pompe disease)[299].

In addition, this debate partly overlapped with another concerning the *rationnement des soins*, a term that could be translated as "rationing of care" but which is unfortunately not unequivocally defined in the legal[300], economic and medical literature that flourished in that period, nor in the institutional documents that addressed it[301]. The Federal Commission on the Benefits and Principles of Health Insurance has defined *rationnement des soins* rather broadly, specifying that the process of choice on the basis of priorities in which it consists can take place either explicitly or implicitly, since it is a question of "*un processus de choix, fondé sur des priorités parmi des services, des pratiques et des prestations efficaces et utiles, demandées ou considérées comme nécessaires par le patients ou les consommateurs d'une part, et par les fournisseurs de soins d'autre part. Un tel processus influence la prescription et la consommation de soins et donc l'accès au système de soins*[302]."

Definitions provided by independent scientific bodies, such as the Swiss Academy of Medical Sciences[303] and the Dialogue Éthique

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[298] B. Baertschi, *Le prix de la santé et le coût des soins : rationnement, santé publique et justice*, in "Médecine et Hygiène", vol. 57, 1999, no. 2263, pp. 1464-1466.

[299] This is the *Myozyme* case, which is mentioned in the section on resource allocation and prioritisation below in subsection 7.3.2.

[300] This is underscored by O. Guillod, *La perspective juridique*, in Groupe de travail "Rationnement", *Le rationnement au sein du système de santé suisse : analyse et recommandations*, Bâle, Académie Suisse des Sciences Médicales, 2007, pp. 29-31. The author lists, among problematic factors for the legal analysis of the topic, the widespread, asystematic and legally hard to grasp nature of rationing and the absence of legislative texts (with the notable exception of transplant legislation) and, at least until the decision of the Federal Court in the Myozyme case in 2010, the lack of any specific jurisprudence on the subject.

[301] In addition to the aforementioned report commissioned by the Swiss Academy of Medical Sciences and those of other independent organisations, there is also a document by the Federal Commission for Health Insurance Benefits and Principles (CFPP), which is part of the OFSP, as well as two studies commissioned by the OFSP (all of which can also be found on the OFSP website www.bag.admin.ch) and a number of parliamentary questions and answers from the Conseil Fédéral (available at http://www.parlament.ch/i/dokumentation/curia- vista/Pages/default.aspx).

[302] It should be recalled that implicit rationing occurs either when priorities have not been explicitly decided or defined and their identification is therefore left to the discretion of a doctor or other health professional, who either decides alone or at least decisively influences the provision of treatment, or because of a lack of transparency in the allocation of resources.

[303] For the Working Group "Rationnement", *Le rationnement au sein du système de sanitaire*

foundation[304], also point in the same direction. When used at institutional level, therefore, the concept of *rationing of care* largely overlaps with that of *priority setting*, as understood in the Scandinavian countries and in Great Britain.

The doctrine, on the other hand, tends to include in the *rationnement des soins* exclusively decisions based on objective criteria that are prefixed and identified through democratic procedures[305]. This implies a distinction both from the allocation of resources (which logically precedes and determines it, by virtue of the effective limitation of resources or the choice of setting a binding limit to the health budget), and from the setting of priorities (a more ambiguous term because it refers to both the macro and micro levels of decision-making, where it is often used to indicate timely decisions made in urgent situations), and the refusal of treatment in individual cases (which is a natural and necessary consequence of any rationing, but does not presuppose it, since it may otherwise result from a doctor's assessment of the inappropriateness of a treatment, regardless of any consideration of the availability of the organisational and financial means necessary for its implementation).

In any case, the concept is clearly distinguished from rationalisation. In fact, while rationing implies a reduced provision of services that are by definition effective and beneficial for the patient's health, rationalisation processes are aimed at improving the effectiveness of the health system in terms of organisation or its level of coverage, as well as reducing its costs, often involving the elimination or reduction in the provision of ineffective or unnecessary services.

Regarding the existence of some form of rationing in the Swiss health

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suisse : analyse et recommandations, cit., pp. 9-12, rationing is instead "*tout mécanisme implicite ou explicite qui prive une personne d'une prestation utile lors de sa prise en charge médicale.*" The explicit aim here is to adopt the least normative definition possible, excluding both polemical definitions of rationing, which immediately ascribe a negative value judgement to the concept itself, and distinctive ones, which delimit its boundaries, e.g., distinguish between conscious and systematic choices (explicit r.) and indirect choices linked to individual cases (implicit r.).

304 According to Group de travail interdisciplinaire et indépendant, *Manifeste pour une répartition équitable des ressources dans le domaine de la santé publique*, Zurich, Dialogue éthique, 13 January 1999, rationing of care occurs "*dans une situation critique, il est renoncé - dans le présent et éventuellement à l'avenir - à des prestations médicales et à des remèdes pourtant utiles et appropriés*."

305 This is how G. Steffen defines rationing. Steffen is the author of the most complete work in French-language legal literature on the subject (G. Steffen, *Droit aux soins et rationnement*, cit.). After reviewing the main definitions that existed up to then (pp. 244-249), Steffen wrote: "*Le rationnement est une décision, justifiée par le manque de ressources, de ne pas attribuer certains soins à certaines personnes, alors que ceux-là seraient nécessaires d'un point de vue purement médical; la décision est basée sur des critères objectifs, fixés à l'avance et respectant les règles de notre démocratie*."

insurance system, following the uproar raised by the Myozime case the Federal Council denied both the desirability of introducing some form of explicit rationing[306] (to which it states that it prefers the path, albeit one strewn with obstacles[307], of rationalisation) and the possibility of deducing the existence of implicit rationing from existing regional disparities in access to care[308]. Independent studies and literature, on the other hand, have found some examples of selection of beneficiaries by health professionals on a case-by-case basis and in the absence of clear and predetermined criteria (or "bedside rationing")[309]. The fact that the LAMal does not refer in any way to the concept of rationing, nor does it provide for limitations in access to the health system according to the characteristics of the beneficiary, does not prevent an implicit rationing of care[310]. This is what is likely to happen, for example, as a result of the new fixed rate system of remuneration for hospital services in the absence of a clear

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306 "*Le Conseil fédéral s'est toujours prononcé contre les rationnements dans le domaine de la santé. Il estime, par contre, qu'il faut exploiter le potentiel de rationalisation de toutes les mesures du domaine de la santé*" (Réponse du Conseil fédéral du 6.6.2011 à l'Interpellation no. 11.3306, par Gutzwiller Felix, *Une limite de coûts de 100 000 francs pour les thérapies médicales?*).

307 The institutional complexity of the Swiss system brings the decision-making bodies in which decisions on the size and nature of health care allocations are made closer to the population, complicating any attempt to rationalise by eliminating care facilities (see Group de travail "Rationnement", *Le rationnement au sein du système de santé suisse: analyse et recommandations*, cit., p. 40).

308 CFPP, *Prise de position sur la question du "rationnement" dans le système de soins en Suisse*, Berne, 2006, available at www.bag.admin.ch, point 11.

309 Group de travail "Rationnement", *Le rationnement au sein du système de santé suisse: analyse et recommandations*, cit., pp. 90-95, highlights that, even if these facts are rarely serious and mostly hidden or not very visible, both because of the high level of general welfare and because of institutional factors such as the solidarity nature of the insurance system and the federal structure, Switzerland has problems of equity and unfair rationing practices. The elderly, those living on the margins of society and those suffering from a disability or chronic illness are usually the ones who are most negatively impacted by these issues.

310 A study known as RICH (Rationing in Nursing CH) (M. Schubert, B. Schaffert-Witvliet, T. Glass and S. De Geest, *Effects of Rationing in Nursing Care in Switzerland on Patients' and Nurses' Outcomes*, Basel, Institute of Nursing Science, 2004), showed that, besides being influenced by the limited material resources of a nursing facility (in this case, a hospital), implicit rationing is also linked to the quality of the working and professional environment of the medical team. This is emphasised first and foremost by the Federal Commission for Principles and Performance in its position paper on the studies commissioned by the same commission in 2001 (CFPP, *Prise de position sur la question du "rationnement" dans le système de soins en Suisse*, Berne, 2006, available at www.bag.admin.ch), as well as J. de Haller, *Droit aux soins: Rationnement des soins dans l'assurance-maladie?* in Droit aux soins. 13ème Health Law Day edited by O. Guillod, D. Sprumont and B. Despland, cit., pp. 65-69, esp. p. 67.

definition of the requirement of appropriateness of care and agreed criteria for defining priorities in the provision of services[311]. The potentially discriminatory nature of rationing and the shortcomings of implicit rationing in terms of transparency and accountability have for years been the subject of criticism and appeals by the scientific community, which has so far called in vain for the establishment of well-defined and mandatory health objectives as part of a genuine national health policy.

Some studies have gone to great lengths to assess the compatibility of the criteria most commonly used in the international practice of explicit rationing (in some cases dictated by medical considerations, in others by economic or procedural considerations) with the relevant provisions of the Federal Constitution and, in particular, with Article 8, which prohibits any discrimination on the basis of personal or social factors[312].

As the doctrine points out, since the logic of rationing collides a priori with that of the constitutional guarantee of equity of treatment, it must be based on relevant criteria of distinction, backed up by a legal basis and complying with the conditions laid down in Article 36 of the Federal Constitution (i.e., be justified by a public interest and respect both the principle of proportionality and the essence or intangible core of fundamental rights)[313]. According to this analysis, if, in the future, explicit and predetermined rationing criteria were to be established - based on personal and social factors, such as age, lifestyle or wealth situation - they would pose significant legal problems. It would then be advisable to entrust rationing to medical personnel with gatekeeping functions, or to reduce the range of services included in the list of guaranteed services, or to favour the criterion of quality of life[314].

However, leaving aside for the moment such *de jure condendo* considerations, it can be noted that the only case in which federal

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311 The economic incentive to reduce costs generated by DRGs can lead to the overshadowing of the objectives of quality and appropriateness of care contained in art. 32 of the LAMal: thus D. Cauzza, *Dagli APDRG agli SwissDRG: le implicazioni per l'Ente Ospedaliero Cantonale*, in Rivista per le Medical Humanities, 2012, no. 21, pp. 13-15.

312 The reference is mainly to the monograph by G. Steffen, *Droit aux soins et rationnement*, cit., pp. 265-328.

313 O. Guillod, *La perspective juridique*, in Groupe de travail "Rationnement", *Le rationnement au sein du système de santé suisse: analyse et recommandations*, cit., pp. 29-31, esp. p. 30.

314 G. Steffen, *Droit aux soins et rationnement*, cit., pp. 313-314. However, aware of the limitations of quantitative methodologies such as the QALY used to implement this criterion, the author (pp. 320-326) proposes a new criterion, which is referred to as the "weighted quality of life" criterion; this corrects the quantitative element by taking into account the patient's subjective assessment of his or her own quality of life: "*l'idée est qu'il est nécessaire d'introduire un élément d'appréciation subjective du patient, qui est le seul vraiment habilité à juger de sa propre qualité de vie, pour éviter de tomber dans un piège qui n'accorderait des soins de qualité qu'à ceux qui sont jeunes et beaux et qui peuvent le rester.*"

legislation directly addresses the problem of rationing, anchoring it to explicit and predefined criteria, is provided by the Federal Act on Organ Transplantation[315]. Sections 17 and 18 of the Act reiterate the applicability of the principle of non-discrimination in this field as well and provide some criteria for determining priority in the allocation of organs available for transplantation. These include criteria of a purely technical nature, such as the urgency of the transplant and its expected effectiveness (which implies the need to also take into account the age and nature of the pathology from which the patient suffers[316]), but also concerns of equity, such as the attempt to ensure that even patients with less urgent physiological conditions - and therefore with a necessarily longer wait time - have an equal chance of receiving the available organs (Art. 18(1)(b)). 1c and 2).

Lastly, in Switzerland one area in which there is currently room for the development of some form of explicit rationing – which, in fact, already exists to some extent – pertains to decisions on inclusion in or exclusion from the basket of services. The centralisation of powers at federal level in this field opens the way to the establishment of uniform decision-making criteria applicable throughout the country[317].

7.4.1. *The basket of services and the evaluation of their appropriateness, cost-effectiveness and efficiency*

The LAMal defines the statutory "basket of services" in Articles 24 to 31 and clarifies its compulsory and exhaustive nature (Art. 34 LAMal)[318]. Its content (i.e., the benefits actually covered by compulsory sickness insurance) is, however, determined by the OPAS of 29 September 1995, while all the services excluded may be included in the plans of the various supplementary insurances[319]. The list contains not only medical services, but also drugs, therapies, diagnostic services and medical devices. Specific

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315 *Loi fédérale sur la transplantation d'organes de tissus et de cellules*, 8 October 2004.

316 V. Junod and J.B. Wasserfallen, *Rationnement des soins: le TF joue enfin cartes sur table. Commentaire de l'ATF 136 V 395*, in Jusletter, 29 August 2011, pp. 223-244, esp. p. 225.

317 Group de travail "Rationnement", *Le rationnement au sein du système de santé suisse: analyse et recommandations*, cit., p. 40.

318 On this subject, see in particular the works of: G. Frésard-Fellay, B. Kahil-Wolff and S. Perrenoud, *Droit suisse de la sécurité sociale*, cit., pp. 187-232; S. Schneider, *Evolution du catalogue des prestations dans la LAMal*, in Droit aux soins. 13ème Health Law Day edited by O. Guillod, D. Sprumont and B. Despland, cit., pp. 65-70; G. Longchamp, *Conditions et étendue du droit aux prestations de l'assurance-maladie sociale*, Lausanne, Institut de Recherche sur le droit de la Responsabilité civile et des Assurances, 2004; and G. Steffen, *Droit aux soins et rationnement*, cit., pp. 135-158.

319 The OPAS also provides for a list of benefits not covered or covered with certain restrictions by compulsory insurance.

positive lists are, however, established for the latter (*liste des moyens et appareils*, LIMA), as well as for medicines (*liste de spécialités*, LS)[320] and diagnostic services (*liste des analyses*, LA), on the basis of a procedure at federal level (in particular by the OFSP at the Ministry of the Interior), which provides for the consultation of expert commissions. These are composed of representatives of service providers, insurers and insured persons[321].

Positive lists have price ceilings which in most cases are unlikely to be reached and which, in the case of medical devices, also act as upper limits for reimbursement (the option for a more expensive product places the excess cost directly on the patient). In fact, the AOS (*Assurance obligatoire de soins* or mandatory health care insurance) provides that the patient is the direct debtor of the invoices for the services used, but that he or she is entitled to reimbursement for all the services guaranteed by the health insurance fund to which he or she belongs, once the applicable cost-sharing quota has been determined[322]. In principle, only services provided on the national territory are covered, but exceptions may be made if the treatment cannot be obtained in Switzerland, if it is urgently necessary to use other health systems during a stay abroad and if there are special agreements with border areas.

Article 32 of the LAMal states that all compulsory insurance benefits must be adequate, effective and affordable. The three criteria (also known as "*principe EAE*") are cumulative, and translate respectively into:

- its ability to produce the effect sought in the specific case *(adéquation*);
- its ability to produce a general effect *(efficacité*);
- its presenting an appropriate cost-benefit ratio *(economicité*).

The imposition of a legal constraint on the cost-effectiveness of the service, in particular, demonstrates the willingness of the legal system to take into account the issue of limited resources for medical treatment. In this way, the legislator distances itself from the idea that every life is sacred and by nature places itself, *et pereat mundi*, above any other requirement[323].

The LAMal also makes it clear that efficacy must be demonstrated through scientific methods and that, even after its inclusion in the list of services, the individual treatment's compliance with the criteria must be

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320 The list of reimbursable drugs is organised by manufacturer and names the different pharmaceutical products individually, whereas the list of medical devices only designates them generically.

321 Their composition is regulated by the Ordinance of 27 June 1995 on Health Insurance (OAMal).

322 This system is also called the "third-party guarantor system".

323 V. Brulhart, *L'économicité en matière d'assurance*, in Haftung und Versicherung Have/Responsabilité et assurance REAS, 2014, no. 4, pp. 376-387, esp. p. 385.

regularly verified.

After the assessment carried out by the Department of the Interior or the Federal Office for Public Health when the service is entered in the relevant list (pursuant to Articles 33 and 52 of the LAMal), the effectiveness, cost-effectiveness and appropriateness of the services are entrusted to the providers themselves (in particular by general practitioners), by the insurers and, with regard to the provision of a specific service, by the courts[324]. Indeed, while providers have a legal obligation to limit services to what is required by the interests of the insured party and the purpose of the treatment[325], insurers may refuse to accept measures that are ineffective, inappropriate or do not meet economic criteria[326]. The law provides for various types of sanctions against providers who do not comply with this criterion or who do not provide services of sufficient quality, ranging from a warning to temporary or permanent exclusion from the social health insurance scheme, as well as total or partial reimbursement of the fee in the event of inappropriate services[327].

7.4.2. *Federal case law on rationing*

The most interesting cases that the jurisprudence has addressed over the years in the field of treatment rationing have arisen precisely from claims for reimbursement by insured persons with regard to drugs and services that the health insurance funds refused to pay for, i.e., that were excluded from the positive federal lists or included therein but for the treatment of pathologies other than the one for which they were used in the case in question ("off-label" use of a drug).

This case law has given rise to both general principles, applicable to the particular review carried out by the courts whenever they interpret the federal ordinances consisting of the various baskets of services, and concrete rules, which direct the health insurance funds in favour of or against the reimbursement of a benefit.

From a general point of view, when assessing the lists drawn up by the

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[324] For example, the costs and services of hospitals and nursing homes are monitored through the recently introduced obligation to adopt analytical accounting and to record services for statistical purposes. Thanks to the reform of hospital financing, the Federal Council is now able to carry out nationwide comparisons between hospitals, particularly with regard to costs and the quality of medical results (Art. 49 LAMal). Moreover, insurers are also subject to cost-effectiveness control, especially with regard to the costs of their administrative management. See G. Frésard-Fellay, B. Kahil-Wolff and S. Perrenoud, *Droit suisse de la sécurité sociale*, cit., pp. 188-189.

[325] Art. 56, par. 1, LAMal.

[326] Art. 34 LAMal.

[327] Art. 59 LAMal.

Department of the Interior or the OFSP, the judge must neither encroach on the discretion reserved for these bodies (not least because of the technical nature of the assessments of the advisory commissions that contribute to their drafting) nor use an analogical argument to fill this alleged gap and extend the objective scope of the basket of services[328]. For example, in a case in which a woman with fertility problems (Ms M.) complained about the exclusion of artificial insemination practices by means of in vitro fertilisation from the basket (by virtue of its inclusion in the negative list annexed to the basket of benefits), the federal judge ruled in favour of the health insurance fund opposing their reimbursement, pointing out that the judicial authority may not substitute its judgement for that of the competent authority in order to decide on the reimbursability of such treatment, unless the latter had exceeded the legislator's powers or violated the Constitution[329].

The most famous case, which was also the first to explicitly address the issue of rationing, is known as the Myozyme case and stems from a ruling by the Federal Court on 23 November 2010[330]. This decision, which has had long-lasting resonance in the media and in scientific literature, addresses the condition of 70-year-old Ms F., who had been diagnosed with the adult form of a rare, neurodegenerative and fatal disease: Pompe disease. After receiving reimbursement from her health insurance company for a six-month treatment with the drug Myozyme, which does not cure but alleviates the symptoms of her illness, Ms F. was refused further treatment under the social health insurance scheme because of the uneconomical nature of the treatment (its annual cost amounting to more than CHF 500,000). Myozyme was excluded from OFSP's *liste des specialités,* so the Court had to review whether it could be charged to social sickness insurance on the basis of a case-law exception[331]. To this end, the Court took into account not only the seriousness of the illness and the absence of recognised and reimbursed therapeutic alternatives – aspects which were not at issue in the case at hand – but also the nature of the therapeutic benefit expected from the service and its economic viability. On the basis of this analysis and by reforming the decision of first instance, the Federal

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328 ATF 130 V 532, co. 3-4 and ATF 125 V 21, co. 6a.

329 ATF, Order 9C835/2011 of 1 October 2012.

330 ATF 136 V 395.

331 The criteria developed for this purpose by case law were subsequently transposed into the new Articles 71a and 71b of the OAMal (following the amendment approved on 1 March 2011), which are not applicable to the present case. In particular, it is now Article 71b of the OAMal that addresses the assumption of the costs of a medicine not found on the *liste des specialités*. On the modification of the OAMal see L. Magistrini, *Remboursement de médicaments par l'assurance obligatoire des soins : commentaire des nouveaux arts. 71 and 71b OAMal*, in Jusletter, 30 January 2012, pp. 95-104.

Court ultimately endorsed the health insurance company's argument, denying Ms F.'s right to be treated by the AOS on the grounds of its excessive cost and the not sufficiently high nature of the expected clinical benefit.

The argumentation followed by the Court is peculiar. The Court seems to have taken on the role of legislator, taking into consideration the outcome of its decision not only on the individual case under examination, but in general on all those insured and, therefore, on the general sustainability of the precedent for the health insurance funds.

In considering the cost-effectiveness of the treatment, the Court also drew from comparisons with other health systems what appeared to some to be a kind of absolute limit to the reimbursement of a drug, using the QALY method and indicating as reasonable a threshold of less than CHF 100,000 per year of life gained. The decision to use this method was criticised by many and has given rise to numerous parliamentary questions and statements by the Federal Council, which ultimately denied that the CHF 100,000 threshold has any absolute significance, stating that the specific assessment of the circumstances of each case must always prevail[332]. Criticism was also expressed in the doctrine, for the acritical and dangerous application of the QALY method[333] and for the choice of basing the decision on it instead of relying on internationally and traditionally recognised rights (in particular the combined provisions of Articles 8, 10 and 12 of the Federal Constitution)[334].

Lastly, it should be noted that, as a result of the aforementioned ruling, since 2011 the drug Myozyme has been included in the list of specialities reimbursed by the health insurance funds with very stringent restrictions (duration of treatment limited to 12 months; need for specific qualification by the doctor who wants to evaluate the start of treatment; written confirmation by the doctor of the costs to be borne by the insurer; strict evaluation of the success of the treatment before authorising a new cycle) and this at a price almost 50% lower than it once was. On the basis of these considerations, the Federal Court, called to decide on a case in which a health insurer had refused to reimburse the treatment, stated that once a drug has been included in the *liste des specialités*, health insurers can only question its efficacy to a very limited extent and that "…if the limitations

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332 Conseil Fédérale, *Réponse du 6.6.2011 au postulat Humbel (Interpellation 11.3154 du 16.3.2011)*, available at http://www.parlament.ch/i/dokumentation/curia-vista/Pages/default.aspx.

333 V. Junod and J.-B. Wasserfallen, *Rationnement des soins : le TF joue enfin cartes sur table. Commentaire de l'ATF 136 V 395*, in Jusletter, 29 August 2011, pp. 223-244, esp. p. 243.

334 Thus O. Guillod, *Un appel au pouvoir politique*, in Bioethica Forum, vol. 4, 2011, no. 3, pp. 92-93, especially p. 93, in a monographic issue of the journal entirely dedicated to the judgment and to which the reader is referred for further bibliographical references.

are respected, there is no room for an examination of cost-effectiveness in a concrete case", rejecting the complaint of the health insurance fund[335].

8. France

8.1. The underlying philosophy and its evolution

In France, paragraph 11 of the *Préambule* of the French Constitution of 27 October 1946 states that the Nation:

> *garantit à tous, notamment à l'enfant, à la mère et aux vieux travailleurs, la protection de la santé. Tout être humain qui, en raison de son âge, de son état physique ou mental, de la situation économique, se trouve dans l'incapacité de travailler a le droit d'obtenir de la collectivité des moyens convenables d'existence*[336].

In a well-known decision of the 1990s, the *Conseil Constitutionnel* stated that "*il incombe, tant au législateur qu'au Gouvernement, conformément à leurs compétences respectives, de déterminer, dans le respect des principes proclamés par le onzième alinéa du Préambule, les modalités de leur mise en oeuvre*"[337]. In this constitutional case law, too, health protection takes on the form of an objective that the legislator must pursue by balancing the various existing requirements, among which the limited availability of economic resources emerges strongly[338]. A normative definition is provided by the *Code de la santé publique* (CSP), which proclaims (art. L. 1110-1) the right to health as a fundamental right of the system, sanctioning the obligation of its implementation "*par tous moyens disponibles au bénéfice de toute personne*" and ensuring "*la continuité des soins et la meilleure sécurité sanitaire possible*". This provision is relevant at least in relation to some basic aspects: the CSP, in fact, defines the right to

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[335] ATF 142 V 478. of 16 September 2016, co. 6.4.

[336] See J.M. Forges, *Droit de la santé*, Paris, Presses Universitaires De France, 1997, *passim*; Haut conseil de la santé publique, *Les inégalités sociales de santé: sortir de la fatalité*, Paris, Documentation Française, 2010, *passim*.

[337] Conseil constitutionnel, Décision no 93-325 DC du 13 août 1993, 125. See also Décision no. 89-269 DC du 22 janvier 1990, Cons. no. 26.

[338] On this subject, see Judgment No 97-393 of 1997 on the constitutionality of the *loi de finance de la sécurité sociale pour 1998*. The *Conseil Constitutionnel* held that it was for the legislator to reconcile the different requirements of financial balance with the objective of protecting individual and public health. The need for a balance between health protection and the availability of resources is reiterated in the subsequent case law of the Constitutional Council; see Décision no. 2004-504 DC of 12 August 2004; Décision no. 2010-620 DC of 16 December 2010. See V. Federico, *I sistemi sanitari alla prova dell'immigrazione. La Francia*, in Rivista AIC, 2018, no. 1, pp. 10-11.

the protection of health as a fundamental right in direct connection with the principle of equality, specifying the obligation of the health authorities to "*garantir l'égal accès de chaque personne aux soins nécessités par son état de santé*". As is evident, the constitutional reference to health protection, implemented within the CSP, places health protection in close connection with the system of social security that was established by the ordinance of 4 October 1945.

In 2002, the Law on Patients' Rights and Quality of Care (Law 303 of 4 March 2002) strengthens the individual rights (equity of access, informed consent, privacy, respect for dignity) and collective rights (health democracy and participation) of patients[339] and provides, on the one hand, for continuous training for professionals and some tools to evaluate professional practices and, on the other, the terms of compensation in case of damages suffered by patients.

In 2009, a health care reform radically changed the governance of the French health system. The *Loi hôpital, patients, santé et territoires*, approved by Law No. 2009-879 of 21 July 2009, merged several regional institutions and created unified regional health agencies that act as the real drivers of the system[340]. What emerged from the reform was the need to strengthen the regional system through the rationalisation of the health bodies and institutes that existed in each of the 26 regions, including the establishment of a regional insurance fund body and the creation of a regional health conference (and the resulting creation of a regional hospital agency, which was later transformed).

In 2012, the Ministry of Health launched a *Stratégie nationale de santé* that led to the 2015 health reform aimed at reducing health inequalities by strengthening preventive and territorial care.

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[339] J.-P. Domin, *La democratie sanitaire participe-t-elle à la construction d'un consommateur de soins ?* in Journal d'Economie Medicale, 2006, nos. 7-8, pp. 427-438.

[340] In general, see D. Benamouzig and J. Besancon, *Administrer un monde incertain : les nouvelles bureaucraties techniques. Le cas des agences sanitaires en France*, in Sociologie du Travail, 2005, no. 5, pp. 301-322; A. Valette and J.L.Denis, *Analyse de l'action des Agences Régionales de l'Hospitalisation: vers une transformation de la gouvernance publique?* in Sciences Sociales et Santé, 2003, No 3, pp. 5-27. The regional health agencies have been operational since 1 April 2010 and have been established by merging a number of institutions and operational bodies at regional level: the regional hospital agency, the regional union of insurance funds, the regional directorate of health and social affairs, the departmental directorate of health and social affairs (which corresponds at regional level to the ministerial directorate of health and social affairs), the regional public health group, the regional health unit. See M. Brunn, K. Berg Brigham, K. Chevreul and C. Hernández-Quevedo, *The impact of the crisis on the health system and health in France*, in A. Maresso, P. Mladovsky, S. Thomson, A. Sagan, M. Karanikolos, E. Richardson, J. Cylus, T. Evetovits, M. Jowett, J. Figueras and H. Kluge, Economic crisis, health systems and health in Europe, European Observatory on Health Systems and Policy, Copenhagen, 2015, pp. 75 ff.

8.2. Organisation and financing of the health system

In the European landscape, the French health system represents a profoundly mixed system characterised by an insurance approach that, with a view to universality and equity, covers the entire French population through a plurality of schemes[341]. The recipients of the system are those insured under the various existing insurance schemes. However, since 1 January 2000, Law No. 641 of 27 July 1999 (CMU - *Couverture maladie universelle*), which was replaced in 2016 by *Protection universelle maladie* (PUMA), has provided for universal health coverage that also protects the poor[342]. For irregular residents and transitory foreigners, the *aide médicale d'état* (AME) covers access to initial examinations, hospitalisation and test prescriptions.

Since its establishment, the financing of the health service has been organised through the statutory insurance scheme, which is compulsory for all residents and provides for the partial or total reimbursement, depending on the case, of the services guaranteed by the system[343]. This

[341] The statutory health insurance is composed of three general schemes which are divided according to the beneficiaries: the general scheme (*Caisse nationale d'assurance maladie des travailleurs salariés*) – which covers 87% of the population and the beneficiaries of which are employees in commerce and industry and their families, and CMU beneficiaries; the agriculture scheme (*Mutualité sociale agricole*) – for workers in the agricultural sector and their families; and the scheme for freelancers (*régime social des independents*). Other specific insurance schemes exist for specific categories (e.g., miners, railway workers, etc.) or on a geographical basis (Alsace historically has had insurance schemes offering more extensive health cover). Funds are also structured at local level: there are 105 local funds (101 *caisses primaires d'assurance mal*adie) and 16 regional funds (*caisses régionales d'assurance maladie*).

[342] On 1 January 2016 the *loi de financement de la securité sociale pour 2016*, no. 2015-1702 of 21 December 2015, introduced the PUMA, to replace the CMU, which allows for broader conditions of coverage of health expenses. However, the CMU-C (*Couverture maladie universelle complementaire*) remains in force. Decree no. 2017-240 of 24 February 2017 on the control of the conditions for benefiting from universal sickness protection clarifies in Article 1 that regularity of residence is a *conditio sine qua non* for benefiting from the PUMA.

[343] In France, non-hospital healthcare services, with the exception of emergency services, are provided on a direct payment basis. Patients are then reimbursed by *Assurance maladie*, with the exception of persons covered by CMU and AME. The system is financed on the basis of general taxation and the insurance system, which in turn is financed by contributions from employers and employees. Long-term care for the elderly and disabled is financed through a fund (fund for independence) established in 2004. The linkage of funding between the health system and labour contributions has created a problem of resources for health care in some phases of economic stagnation due to the resulting unemployment. This is why some general taxation resources are also dedicated to the health system. See C. Weill, *Health care technology in France*, in Health Policy, 1994, no. 30, pp. 123-163.

insurance scheme pertains to three-quarters of all health expenditures, leaving the remainder to out-of-pocket expenditure or possible coverage by private insurance scheme[344]. Private insurance is, in fact, contracted on a voluntary basis and is supplementary in nature[345]. The French health system exhibits good performance[346] and the country's health expenditure is in the medium to high range in the European context. Health expenditure accounts for 11.3% of gross domestic product. 83.41% of health expenditure is covered by public funds, with 9.4% covered by out-of-pocket expenditure and the remainder by other expenditures[347]. Total pharmaceutical expenditure amounts to 15.2% of health expenditure and 1.8% of gross domestic product[348].

The most significant exemptions relate to certain diseases, people with disabilities, people on particularly low incomes, beneficiaries of social support, pregnant women and victims of occupational accidents.

The provision and financing of services in France

The French social security system represents a middle ground between the Bismarckian and Beveridgian models in that it combines the insurance system with strong state intervention. In fact, it is a complex system of co-management of the healthcare organisation by the insurance system and the State, characterised by a high level of freedom of choice, both for patients (freedom to choose the cover structure and the doctor) and for professionals (freedom to choose the context in which to work). The French system can be contrasted with the systems in the UK and Spain in that it is characterised by a centralisation of competences in health matters and by a decentralisation of the most important operational functions.

The organisation of the French health system has been shaped by a series of reforms that have influenced its institutional dynamics. The most significant reforms have been the following: the Juppé Reform of 1996, which was approved by Constitutional Act No 96-138 of 22 February 1996, followed by the Ordinance no. 96-344, which defines the respective responsibilities of the State and the insurance system; Ordinance No. 96-345, concerning the control of expenditure on care provided by professionals; Ordinance No. 96-346 of 24 April 1996, concerning the reform of the insurance system; Ordinance No. 96-346 of 24 April 1996,

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344 European Observatory on Health Systems and Policies, *France. Health system review*, 2015.

345 On supplementary insurance see B. Saliba and B. Ventelou, *Complementary health insurance in France. Who pays? Why? Who will suffer from public disengagement?* in Health Policy, 2007, no. 81, pp. 166-182.

346 On the French position in international rankings see J. Apple, *Which is the best health system in the world?* in British Medical Journal, 2011, no. 7826.

347 WHO, *Health System Financing Profile by country, France*, 2018, available on the WHO website at http://apps.who.int/nha/database/Country_Profile/Index/en.

348 These data on pharmaceutical expenditure are extracted from the OECD report (2020), *Health spending* (indicator).

concerning the reform of public and private hospitals and the creation of regional agencies, the 2004 health reform approved by Law No. 2004-810 of 13 August 2004 and the 2009 reform. The 2004 reform established the Alert Commission, which has the task of informing Parliament, the insurance industry and the Government whenever health expenditure exceeds a certain threshold. In that event, the social security directorate (Direction de la sécurité sociale) of the Ministry of Health is called upon to take measures to reduce the expenditure, such as increasing the contributions to health expenditures on medicines or specialised consultations, etc.

These reforms laid the foundations for parliamentary control over the health care system and the allocation of resources, in the search for a specification of the institutional roles of the State and the insurance system, and in the attempt to strengthen the regional role in health care. They also introduced the annual legislation on the financing of the social security system, which makes it possible to estimate the expenses to be borne by the system, establish a ceiling for total health expenditure and approve the policy directives established by the Government. Since 1996, the Parliament annually approves a law on the financing of social security proposed by the Government and based on the reports of the Court of Auditors (*Cours des comptes*), which is an independent body called to supervise the appropriate use of public resources, the High Council for the Future of Health Care (*Haut conseil pour l'avenir de l'assurance maladie*), the High Council of Public Health (*Haut conseil de la santé publique*) and the National Health Conference (*Conference nationale de santé*). The annual law sets a ceiling for national insurance expenditure for the following year, approves a report on policy trends in the health and social security sector, and presents new forecasts.

8.3. Decision-making actors and locations

It can be said that the regulation of health matters is placed mainly with the State and the public health insurance system, whereas the administration of health is in the hands of the Ministry of Social Affairs and Health, which is structured in nine directorates[349]. The process of policy formulation is basically driven by the Ministry of Health, which sets the policy agenda together with the Ministry of Economy and Finance when defining the annual social security financing law. The actors of the insurance system are involved in the decision-making process when they are called upon by the Ministry of Health to define a five-year pact that provides for the objectives, management and governance of the insurance system *(Convention d'objéctifs et de gestion*, COG)[350].

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[349] The directorates responsible for the health sector are the following: *Direction générale de la santé*; *Direction générale de l'offre de soins*; *Direction de la sécurité sociale*; *Direction générale de la cohésion sociale*; *Direction des finances, des achats et des services*; *Direction de la recherche, des études, de l'évaluation et des statistiques*; *Direction des ressources humaines*.

[350] Under the COG, the main objectives are: to enhance risk management; to strengthen and diversify the provision of quality services to policyholders; to ensure more targeted

Since 2009, with the approval and entry into force of the Law on Hospitals, Patients, Health and Territory, the administration of health and social affairs is governed at regional level through regional health agencies (Agences régionales de santé, ARS). These are responsible for health care planning, delivery and financing of services at regional and departmental level. They represent the State locally, but retain their autonomy. The coordination and mediation functions between the State and the regional health agencies are carried out by the National Council for the Governance of Regional Health Agencies.

Decision-making processes in France

The ARS, set up in 2010 and charged with health policy responsibilities previously exercised by the (now dissolved) Regional Health Insurance Funds, define the broad strategic lines within a Regional Strategic Health Plan (PSRS) on the basis of locally identified needs. Planning, as we have seen, is based on negotiations between representatives of the providers (hospitals and professionals), the insurance system and the State (represented by the Minister of Health and the Minister of the Economy). The ARS is an autonomous body and its director, appointed by the Minister of Health, has extensive financial management and planning capacities in the sectors where the agency has regulatory powers (hospital sector, social health sector for elderly and disabled people, outpatient sector). On a regional scale, the ARS are therefore responsible for defining the broad strategic lines within a PSRS. On this basis, after consultation with the *Conférence Régionale de Solidarité et d'Autonomie* (CRSA), composed of bodies with tasks in public health (associations, health professionals, local authorities), they define programmes and mechanisms in each region.

Two other structures play a crucial role in cooperation with the Regional Agencies: Commissions made up of representatives of local governments have an advisory competence towards regional health agencies; General Councils at departmental level are involved in the planning of health and social care services for the elderly and disabled. The following social and health services are entrusted to General Councils at departmental level: (*i*) health and social care institutions and services for the elderly and persons with disabilities; (*ii*) financial support for low-income or vulnerable groups, including the financing of home care and long-term care; (*iii*) protection of children through mother and child health centres; (*iv*) disease prevention and (*v*) public health and hygiene.

8.4. Resource allocation and prioritisation

prevention; to improve insurance efficiency. Generally, the decision-making processes between the relevant actors are based on tripartite negotiation between the representatives of the insurance scheme, the representatives of the providers, the regional and ministerial representatives. The result of these negotiations translates into draft decrees that are submitted to Parliament for approval.

The health system in France is essentially a centralised system in which regional de-concentration has been in place since 1996 (Juppé reform). The competences in the field of health are divided between the central level (Parliament, Government and Ministry of Health and Social Affairs), the insurance sector, the regional level and, to a lesser extent, the local authorities.

The Ministry of Health has an extensive competence in allocating the available resources among the various health areas, based on thresholds set by the Parliament within the *Objectif National des dépenses d'assurance maladie*, in approving the agreements between the insurance sector and the trade unions representing professionals working as freelancers, in setting the prices of specific medical procedures and medicines based on the proposal of the commissions of the High Health Authority, in setting safety standards in hospitals, and in setting priorities for national programmes[351]. The functions carried out by the Ministry are supported firstly by the Interministerial Economic Commission for Health Products (*Commission Économique des Produits de Santé*, CEPS), which determines the price of drugs and medical devices and controls health expenditure trends, and secondly by the High Health Authority (*Haute Autorité de Santé* - HAS). The latter has gained prominence in recent years and has inherited multiple functions from different agencies: from accreditation and audit activities, to the promotion of appropriateness among health professionals, to the monitoring of health information. Among all these activities, so far HAS's technology assessment has mainly resulted in updating the positive list of services covered by the compulsory insurance system.

Since the Juppé reform, Parliament has been responsible for approving, along with the social security budget, an annual budget for health insurance expenditure *(Objectif National des dépenses d'assurance maladie*), within which resources are distributed between the three macro sectors of outpatient, hospital and socio-medical care. Since 2004, the health care reform law and the health care law that have been passed have strengthened the role of Parliament in setting priorities, deciding on resource allocation and the rational management of the insurance system. The Parliament has also acquired an enhanced monitoring function, which

[351] The Government prepares a report attached to a draft law specifying the objectives and main action plans it intends to put in place and which form part of the five-year health plan. The Government report proposes an analysis of the population's health problems and the factors likely to affect them through the analyses carried out by the High Council of Public Health, which is responsible for identifying the instruments aimed at improving the population's state of health (Art. L1411-2 CSP). In the preparation of the bill establishing health objectives, the Government consults the National Health Conference, which is responsible for drawing up a report, after consulting the regional health conferences, addressed to the Minister of Health concerning the extent to which the rights of users of health services are being respected (art. L1411-3 CSP).

is carried out by the Alert Commission, set up in 2004 (*Comité d'alerte sur le respect de l'objectif national de dépenses d'assurance maladie*). Its function consists in taking action in the event that the deficit in the social security sector reaches a certain threshold, in order to push the decision-makers of the system to adopt suitable measures to contain the expenses exceeding this threshold[352].

In order to implement health policies at regional level, the State does not communicate directly with the regional agencies, but has to transmit the acts to the ARS National Steering Council (*Conseil national de pilotage des agences régionales de santé*), which performs a vertical coordination function between the central and the regional levels[353], while the horizontal coordination between the various regional agencies is implemented through the Regional Conference of Health and Autonomies (*Conférence régionale de la santé et de l'autonomie*)[354].

Since the economic crisis of 1974, cost containment has been considered a priority objective of French health policy; this, however, has not been spared from spirited criticism over the years by specific actors of the health system[355]. The achievement of the objective of controlling health expenditure and rationalising the resources used has been pursued through multiple measures that have confirmed its central nature within French health policy. The goal is finding a balance between protecting the rights of the individual and the interests of the community, balancing the principles of solidarity and the economic sustainability of the system. The constant preoccupation of the French system with reducing health expenditure has also led to a rationalisation of the consumerist tendency in health, which affects both the behaviour of patients (health demand side) and professionals (health supply side). This was made possible by a variety of measures, including the establishment of care pathways coordinated by the *médecin traitant*, a figure whose functions are similar to those of the general practitioner. These pathways are financially incentivised - but not imposed by law, given that the principle of free choice in health matters is

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352 The procedure was activated for the first time in 2007. See M. Steffen, *The French health care system*: *Liberal universalism*, cit., p. 373.

353On the composition and functions of this Council, see L1433-1 ff. CSP. Its composition (representatives of central organisations and centrally organised health insurance funds) and its steering functions towards the ARS further highlight the top-down dynamic of French health care.

354 On the nature and composition of this advisory body, see Art. L1432-4 CSP.

355 This cost-containment objective was strongly opposed by the medical associations. Measures to contain health expenditure were accompanied by an attempt to standardise the conduct of doctors, which was followed by penalties for non-compliance with expenditure rationalisation guidelines. These sanctions were declared unlawful by the French Council of State. On this see M. Steffen, *The French health care system*: *Liberal universalism*, cit.

fundamental in the French system - because the 2004 reform provides for the request to the patient of an increased contribution to the health system in the event of non-adherence to the coordinated treatment pathways[356]. Other instruments aimed at empowering the user have been the establishment of the *carnet de santé*, a register in which all the services and prescriptions the patient has accumulated are recorded, and the provision of cost-sharing (the *ticket modérateur)*[357]. In order to contain the costs of treatment, the co-payment has been increased for those treatments that demonstrate a relative effectiveness, thus pushing part of the system towards complementary private insurance[358]. The rationalisation of costs has also extended to the conduct of health professionals. In 2005, the action programme *Maîtrise médicalisée des dépenses de santé* was established to promote the reduction of variation in medical practice through the adoption of guidelines and the development of good practices by national health agencies (the HAS, the *Agence nationale de sécurité du médicament et des produits de santé*, the *Institut National du Cancer*). Incentives were provided in 2011 for pharmacists who promoted the purchase of drugs with a lower financial burden on insurance funds, and in 2012 for pharmacists who promoted the purchase of generic drugs[359].

As this should make clear, there have been numerous initiatives aimed at influencing the use of resources, both at the macro-level of public authorities (the role of the Ministry of Health and the role of Parliament in allocating resources) and at the micro-level for the rational use of resources by users and health professionals.

The intersection of the need for optimal resource management and the need to set priorities at system level has led to the provision of specific arrangements that the French system adopts to determine which health benefits are guaranteed and reimbursed by the social security system. Article L. 162-1-7 of the *Code de sécurité sociale* (CSS) establishes that all reimbursed services are indicated in a list drawn up (within the framework of priorities and resources established by various regulatory acts by the

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356 On this, see S. Thomson, T. Foubiser and E. Mossialos, *Health system perspectives*: *Can user charges make health care more efficient?* in British Medical Journal, 2010, No 7771, p. 488.

357 See P. Batifoulier, J.-P. Domin and M. Gadreau, *Market empowerment of the patient*: *The French experience*, in Review of Social Economy, June 2011, No 2.

358 Cf. on this aspect B. Saliba and B. Ventelou, *Complementary health insurance in France Who pays? Why? Who will suffer from public disengagement?* cit.

359 Cf. on this point M. Brunn, K.B. Brigham, K. Chevreul and C. Hernández-Quevedo, *The impact of the crisis on the health system and health in France*, in Economic crisis, health systems and health in Europe, edited by A. Maresso, P. Mladovsky, S. Thomson, A. Sagan, M. Karanikolos, E. Richardson, J. Cylus, T. Evetovits, M. Jowett, J. Figueras and H. Kluge, Copenhagen, European Observatory on Health Systems and Policy, 2015, p. 84.

Ministry[360]) by the National Union of Health Insurance Funds in conjunction with the National Union of Complementary Health Insurance Organisations. The inclusion or removal of a certain medical device, medicine or service from this list is based on the opinions of the High Health Authority[361].

In France, priorities are identified through the technical expertise provided by agencies such as the HAS and its internal committees, which have the function of providing technical and scientific support for efficient resource allocation decisions[362]. This independent scientific authority was established in 2004 to contribute to the regulation of the health system by improving its quality and efficiency[363] through the development of scientific assessments on the use of medicines, medical devices and health care procedures[364]. Economic evaluation, which was initially excluded from the assessment, was later taken into account starting in 2008. In fact, from that moment on the authority began working on developing guidelines and recommendations to be used in the economic evaluation of decisions on the

[360] Consider, for example, the aforementioned Social Security Financing Act (for its specific content, see Article 111-3 of the Social Security Code), as well as ministerial recommendations and governmental sources that implement the opinions of the High Health Authority.

[361] Prior to the establishment of the High Authority (2004), health technology assessments were conducted by a variety of bodies and organisations the functions of which were later merged into the High Health Authority. On these, cf. C. Weill, *Health care technology in France*, pp. 136 ff.

[362] The main bodies involved in prioritisation decisions are the Commission on Transparency, the Commission for the Evaluation of Medical Devices and Health Technologies, the Commission for Economic and Public Health Evaluation, the Commission on Care Strategies, and the Commission for Certification of Health Facilities. See Arts. 5123-2 ff. of the CSP.

[363] The authority was established in 2004 by Act No. 2004-810 of 13 August 2004, which amended Articles 161-37 ff. of the CSS. The authority assumes a role of scientific support to governmental decisions and the social security sector through the elaboration of recommendations and opinions concerning medical devices, clinical procedures and the organisation of services in addition to documentation concerning the procedures related to the accreditation of facilities and training for professionals. On this point, see Article 35 of Law 2004-810. The bodies of the authority are the *College* (Board) composed of eight members appointed for a period of six years, renewable once, by decree of the President of the Republic on the basis of proposals from different state institutions (two by the President of the Republic, two by the President of the Senate, two by the President of the National Assembly, two by the President of the Economic, Social and Environmental Council), and the President of the *College* elected from among the members of the *College* itself. In accordance with Art. 161-37 CSS, the authority is an independent, scientifically oriented body whose tasks relate to the procedures set out in Art. 6113-3 and 6113-4 CSP.

[364] See articles 161-71 and 162-2 CSS as amended by Decree no. 2012-1116 of 2 October 2012 on the clinical and economic tasks of the High Health Authority.

most efficient health strategies[365].

The authority, in an attempt to clarify the methods that are used in carrying out its clinical-economic evaluation, has produced a handbook explaining the use of economic evaluation criteria[366]. The principles included in the handbook are: transparency on principles and methodological choices; transparency on levels of uncertainty and robustness of results; argumentation in case of deviations from standard cases and explanation of the reasons for such deviations; and the option to reconsider decisions when new scientific evidence becomes available. On the basis of these principles the manual provides twenty methodological guidelines to be considered as a multidisciplinary approach to the evaluation of health decisions, since it refers to a plurality of criteria of a different nature (economic, clinical, epidemiological and social)[367]. The twenty guidelines contained in the Handbook, to be used for resource allocation decisions in the health sector, are grouped under several main subheadings: health-economic evaluation (guidelines 1-7); evaluation of health outcomes (8-10); evaluation of costs (11-13); decision-making models for health-economic evaluation (14-18); presentation and

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[365] A specific contribution to the definition of the relationship between scarcity of economic resources and the identification of priorities was made through the establishment in 2008 of the Specialist Commission on the Economy and Public Health. This commission consists of 33 members appointed for a period of three years among experienced health and economic professionals and representatives of users and patient associations. Its function is to provide opinions to the Ministry of Health, which is responsible for the final decisions. See the Rules of Procedure of the Economic and Public Health Evaluation Commission adopted by Decision No. 2014/40 of the High Health Authority.

[366] See on this point the Handbook approved by the *College* (Board) of the Authority in October 2011 and entitled *Choix méthodologiques pour l'évaluation économique à la HAS*.

[367] The guidelines included in the Handbook are the following: "*Recommandation 1: le choix de la méthode d'évaluation économique; Recommandation 2: le choix de la perspective; Recommandation 3: le choix de la population d'analyse; Recommandation 4: le choix des interventions à comparer; Recommandation 5: le choix de l'horizon temporel; Recommandation 6: la méthode d'actualisation; Recommandation 7: les donne mobilisées dans une évaluation économique; Recommandation 8: l'identification et la mesure des résultats; Recommandation 9: l'évaluation des résultats dans les analyses coût-efficacité; Recommandation 10: l'évaluation des résultats dans les analyses coût-utilité; Recommandation 11: l'évaluation économique repose sur l'analyse des coûts de production; Recommandation 12: l'identification, la mesure et la valorisation des coûts directs dans l'analyse de référence; Recommandation 13: l'identification, la mesure et la valorisation des coûts indirects dans une analyse complémentaire; Recommandation 14: une évaluation économique s'appuie le plus souvent sur un modèle; Recommandation 15: le choix du type de modèle et de sa structure; Recommandation 16: la définition des valeurs des paramètres du modèle; Recommandation 17: la validé du modèle; Recommandation 18: l'appréciation de la robustesse des conclusions du modèle; Recommandation 19: l'utilisation des conclusions de l'évaluation économique à des fins d'aide à la décision; Recommandation 20: la présentation de l'évaluation économique*".

interpretation of economic evaluation results (19-20)[368].

Depending on the case, the guidelines may be applied variously to different scenarios: some guidelines must be applied jointly and systematically, while others, due to their content, must be applied in a preferential manner, and still others can be used according to criteria of greater adherence to concrete cases.

The first category of guidelines, on the subject of economic health evaluation, sets out two reference criteria: cost-utility and effectiveness of the intervention. These criteria can be used either jointly or separately, depending on whether the expected effect is to assess the quality of life related to the level of health resulting from the health intervention under consideration[369]. If the expected result does not concern the patient's quality of life, the economic criterion used is cost-effectiveness and, in this case, the positive or negative result of the intervention is assessed on the basis of the metric of length of life. Specifically excluded from the Handbook is the criterion of cost-benefit analysis. The justification for this exclusion is based on the fact that, although this criterion provides an evaluation of the allocation decisions of the resources, thus allowing an evaluation of the social gradient of public expenditure, in the health sector the use of this criterion is highly debated and criticised[370].

The Ministry normally follows the indications coming from the French High Authority, but its mandatory opinions are not binding[371]. This is partly due to the fact that more emphasis is placed on the technical and higher administrative dimension of the evaluation process. Here the difference between the French and the English prioritisation process is evident. The HAS is an independent technical-scientific body, whereas NICE in the UK, although performing its functions according to the principle of independence, is part of the Ministry of Health. The HAS's opinions are mandatory but not binding, while NICE's guidance on the evaluation of health technologies is binding for the health service, CCGs and local authorities[372]. Participation in NICE decisions is very broad[373], precisely for

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368 *Annexe a*: *Synthèse des réponses de la consultation publique sur le guide méthodologique*, November 2011. This guide was subject to a review process in June 2019.

369 Cf. the first Guideline mentioned, which in essence refers, as regards the first criterion, to the QALY measure for which reference is made to the English system.

370 In the health sector, the principle of equity is considered to be a fundamental principle that would be undermined by the application of the cost-benefit criterion, which normally refers to the measurement of future benefits of the person undergoing treatment.

371 The activation of the evaluation process is the responsibility of both the National Union of Health Insurance Funds and the Ministry of Health for health-related decisions.

372 It should be kept in mind that health technology guidance, although binding, leaves room for discretion to local authorities and the CCGs called upon to implement it.

373 On the list of stakeholders entitled to participate in the appraisal process (members of

the reason of establishing their legitimacy, while participation in the evaluation processes taking place within the HAS is limited to key players.

9. Conclusions: three different allocation and prioritisation strategies in Europe

From the analysis conducted, three main allocation and prioritisation strategies emerge.

In one group of countries (Sweden and Norway), there is no list of treatments covered by the National Health Service, and decisions on cover are reserved to the doctor or the facility taking care of the patient, in consideration of, in part, the specificities of each individual case, but also of the principles established in a widely discussed and shared ethical platform.

In Great Britain (and looking further afield, in New Zealand) there is no list of treatments covered by the National Health Service and decisions on coverage are made at the local level of government, i.e., as close as possible to the user of the services, on the basis of guidelines developed at national level through a largely transparent and participatory process.

Lastly, there is a larger group of countries (and a very diverse one from an administrative perspective) that entrusts the definition of priorities to decision-making processes whose degree of clarity and public participation (as regards the actors involved, the criteria followed for the allocation and the identification of priorities, the strategies and the purposes of the decisions) does not lend itself to being distilled into explicitly defined processes[374]. These processes are designed to draw up and maintain a positive list of services guaranteed in the health system or health insurance system in question (Spain, Denmark, France, Germany and Switzerland, to which Canada could be added at the broader international level and, within Europe, Italy as well as we will see in chapter 3).

9.1. Prioritisation by health professionals on the basis of explicit and shared set of principles

Since there is no explicit list of treatments covered by the national health service in Sweden and Norway, decisions on coverage are reserved to the doctor or facility treating the patient on a case-by-case basis, based

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the Appraisal Committee, consultees, commentators, citizens through the public involvement programme, clinical and health service experts), see *Guide to the process of technology appraisal*, April 2018, pp. 7 ff.

[374] See the lexical clarifications in Chapter 1.

on consideration of the specifics of each individual case. These decisions are delimited and directed by a set of explicit, known and knowable reference principles elaborated by a national commission of experts and representatives from civil society. Those principles ensure that their balance becomes controllable by public opinion and each individual citizen-user-taxpayer, although the conflict between alternative uses of available resources cannot be excluded.

In this respect, two main phases can be distinguished. At first, the two countries entrusted commissions composed of representatives of the Parliament and relevant professional categories with the identification of a table of principles and moral values to serve as a guide for the allocation and treatment choices of professionals of the sector. In no case has the selection of priorities been left to a single principle; on the contrary, values of varying natures (medical, philosophical and economic) have been placed side by side. Then, with the emergence of concerns about the economic sustainability of health systems in the late 1990s, Sweden and Norway developed new priority-setting strategies, characterised by the use of empirical evidence and co-efficacy analysis in the selection of drugs and treatments, as well as an increased focus on transparent decision-making and public information. In this phase, the principle of cost-effectiveness was given particular relevance and is now expressed in the form of the "cost-effectiveness principle" included in the table of reference values.

Over time, each of the two Scandinavian countries has developed its own reference principles (in Sweden, human dignity, need and solidarity, treatment efficiency; in Norway, level of severity of need, clinical effectiveness of treatment, expected efficiency and usefulness of treatment). Based on these, guidelines have been drawn up according to priority at national level (mostly general and of little practical use) or local level (often more specific and advanced). Particularly well-researched in the literature are the national evidence-based guidelines produced in some specific clinical areas (such as chronic heart disease) in Sweden, which were drawn up for disease-treatment pairs on the basis of a national model, recommending consideration of the severity of the condition, and the expected benefit and efficiency of the treatment. These were intended to ensure the transparency of prioritisation by presenting the classification, its practical implications and the reasoning behind it to the public and patients.

As far as principles are concerned, the principle of human dignity generally acts as a negative threshold on prioritisation choices, preventing discrimination in access based on personal characteristics or social function, but does not provide any indication on how to prevent resource limitations from undermining the guarantee of rights. On the other hand,

the criterion of need appears to be central, which gives considerable weight to the health demand of the person who turns to healthcare facilities and directs the allocation of resources towards the areas of intervention characterised by higher levels of need (for example, life-saving treatments) or towards the needs of the most vulnerable groups and those less able to assert their rights (for example, children or the disabled). In Sweden, its prevalence over the efficiency criterion is made explicit, while in Norway the complementary nature of the three criteria has been clarified (all three must be at least partially met for a funding decision to be considered legitimate). In recent years, the criterion of efficiency has also gained ground (in Sweden, this is to be understood as a calculation in which the benefit is not expressed purely in terms of monetary value, but in terms of lives saved, accidents avoided or clinical cases registered, while in Norway it is measured in terms of QALY). The principle of usefulness and life expectancy influenced by parameters such as the age of the patient are also expressly excluded in Sweden, and the principle of autonomy/responsibility is also limited, since the patient's previous lifestyle is not relevant, whereas expectations regarding the future (e.g., transplants) sometimes are.

9.2 Negative list of inappropriate treatments and guidelines on health technology assessment

The second model that emerges from the comparison between European countries is the one developed in Great Britain, which is similar to the one adopted in New Zealand. Here, as in the Scandinavian countries, there is no positive list of treatments covered by the National Health Service, but decisions on coverage are made at local government level, i.e., at a level as close as possible to the user of the services, on the basis of guidelines drawn up at national level through a largely transparent and participatory process. In England and Wales priority setting is based on the development (centrally) and practical application (locally) of the NICE health technology assessment guidelines, and, in Scotland, on the assessment of health technology economics with evidence notes by HIS and advice statements on clinical, organisational and drug procedures by SHTG. On the basis of these guidelines, local health authorities (CCGs in England, HBs in Scotland and LHBs in Wales), sometimes assisted in England by Priorities Committees, proceed to the identification of the services to be offered and the subjective requirements to access them, mostly on the basis of economic evaluation methodologies such as the PBMA and the MCDA.

Among the various types of guidelines produced by NICE, clinical

practice guidelines (which recommend certain treatments for specific conditions while declaring others inappropriate) and health technology assessment guidelines are of particular note. The former, although formally non-binding, have in fact acquired a greater level of cogency with health professionals and local government authorities who decide on the funding of services with regard to the list of treatments deemed inappropriate. Through the latter, which are explicitly declared binding and address the use of new or existing medicines, treatments and therapies, NICE has contributed to the unification of allocative choices in the health sector and initiated an explicit rationing process in the country. They distinguish between recommended and non-recommended treatments on the basis of their cost-effectiveness and clinical effectiveness, but also on substantive social values such as justice, equity, solidarity, respect for people's autonomy and dignity, and procedural values such as transparency, independence, inclusiveness, scientific rigour, timeliness and contestability. Particular attention is paid to the transparency of the decision-making process, which is guaranteed through:

- the use of quantitatively measurable criteria relating to economic and clinical effectiveness (QALY and DALY), accompanied, where appropriate, by qualitatively measurable principles;
- the publication of Decision Protocols, which summarise the interests and values at stake in the individual concrete cases;
- the definition of reference cases that allow the contextualisation of the methods used.

The leeway left to local authorities to set priorities and the reduced mobility allowed between geographical areas across the country (access to the NHS is linked to residence, and non-residents are only guaranteed emergency care) have led to significant problems in terms of formal and substantive equality and a differentiation in access to services (the "postcode lottery"). Also for this reason, since the 1990s English case law has changed its orientation and extended its scrutiny to allocative and prioritisation decisions. Before this *revirement*, the decision in the *Child B*. case seemed to be particularly salient. Here, the judicial review was not considered to be an adequate means of assessing the reasonableness of a clinical decision, and the Court of Appeal explicitly rejected the competence to make the "difficult and excruciating decisions that must be made about the best allocation of scarce resources for the benefit of the greatest number of patients."

Lastly, it should be noted that in New Zealand, in the absence of a national list of guaranteed services, prioritisation decisions are likewise made locally by each DHB according to its own set of principles and guidelines for resource allocation. Additional non-binding national

evidence-based guidelines are also available, which are designed to support professionals in assigning priority levels in the treatment of patients and indicate whether a certain treatment is appropriate or inappropriate.

9.3 Positive list of guaranteed or reimbursed benefits, budget constraints and cost-sharing arrangements

Despite the heterogeneity of the methods used in the organisation and financing of their respective health systems, there is another strategy that is shared by a large group of countries (Italy, Spain, Denmark, France, Germany, Switzerland, Canada). This strategy entrusts the definition of priorities to the decision-making processes aimed at drawing up and updating the positive lists of services guaranteed in the health system or health insurance system in question. In some countries (Switzerland and Germany), a debate on the desirability of more explicit forms of rationing has been initiated at various times and on several occasions, although so far it has not led to significant changes; elsewhere, however, there is still a long way to go.

The closest system to the Italian one is the Spanish system. There, the allocation of resources is based on two decision-making levels – the national and the regional – and the definition of priorities is connected to the definition of the essential levels of guaranteed health services, to which the autonomous communities must adhere without prejudice to the possibility of financing further services with their own resources, through complementary service charters, in organising the regional health systems. Uniformity is pursued through a positive list of guaranteed services (the "Charter of Common Services"), on the content of which the central government and regional governments must reach an agreement at the Inter-territorial Council, and a negative list of non-guaranteed services, which is compiled taking into account the parameters of effectiveness, efficiency, effectiveness, safety and therapeutic utility, as well as existing care alternatives, the protection of the most vulnerable groups, social needs and the economic and organisational impact.

Similar decision-making procedures are found in Canada (at de facto level) and in Denmark (where the definition of the benefit package concerning inpatient and outpatient care takes place at national level). Of particular interest is the Canadian case law mentioned at the beginning of this chapter that has in several cases confirmed the exclusion of some services from the basket of services. This is regarded as a political and economic choice aimed at safeguarding scarce resources and the sustainability of the system in the long term. As far as Denmark is concerned, the implicit nature of the decision-making processes leading to

the identification of the national positive list, which serves as an explicit benefit package, sets the country's allocation strategy apart from the other Scandinavian countries. On the one hand, the ethical principles identified in 1996 by the Danish Ethics Committee (equality, solidarity, safety, autonomy), are not viewed as guiding criteria for allocative decisions, but rather as useful tools for clarifying and achieving the general objective of the national health service. On the other hand, at present there are no national or local level guidelines in Denmark, as there are in Sweden, Norway and Great Britain.

As regards the Bismarck-inspired or mixed health insurance systems, the mechanisms leading to the definition of the lists of benefits reimbursed by the health insurance funds in France, Switzerland and Germany are also mostly implicit and non-transparent.

In France, the allocation of resources involves the central government (Parliament, Government and Ministry of Health and Social Affairs), the insurance sector, the regional level, and, to a lesser extent, local autonomy. The Parliament is responsible for defining the annual budget of health insurance expenditure (*Objectif National des dépenses d'assurance maladie*), within which a distribution of resources is established among the three macro sectors of outpatient, hospital and socio-health care, which are then concretely allocated by the Ministry of Health. Vertical coordination between the central level and the individual health policies carried out by the *Agences régionales de santé* is guaranteed by the ARS National Council, while horizontal coordination is the responsibility of the Regional Conference of Health and Autonomies. The containment of costs has long been a primary objective in the French system and has been pursued partly through mechanisms of user responsibility and cost-sharing (an increased contribution in case of deviation from the treatment pathways coordinated by the *médecin traitant*, a figure similar to the general practitioner; the provision of a *ticket modérateur*, especially for moderately effective treatments; the recording of all services and prescriptions in a register) and partly through supply-side measures (incentives for pharmacists on the basis of less expensive prescriptions; provision of guidelines and good practices for operators). The identification of priorities is addressed in France through recourse to a technical report issued by agencies such as the HAS and its internal committees, since the inclusion or exclusion of medical devices, drugs or services from the positive list of health services guaranteed and reimbursed by the social security system is based on the opinions drawn up by this authority. The authority operates on the basis of a handbook that envisages criteria of a different nature (economic, clinical, epidemiological, social) and, with regard to the economic-health assessment, refers to the criteria of cost-utility and cost-effectiveness of the intervention, thus taking quality and length of residual life as a reference,

but expressly excludes the cost-benefit analysis, which would lead to valuing the patient's future benefits in monetary terms. However, unlike in the UK, where guidance on health technology assessment is binding on the health service, CCGs and local authorities, the French authority's opinions are not; moreover, in the case of NICE, participation in the assessment processes is much wider, which adds to the technical legitimacy of the prioritisation choices including at procedural level.

In the system of shared self-government typical of the German insurance model, health resources are allocated through complex, multilevel processes: the Federal Parliament decides on the total amount of revenue to be collected for the financing of the public insurance system, as well as on the level of user contributions; the Federal Government determines the total health budget and allocates the available resources among the member states of the federation; the GB-A is in charge of setting priorities, allocating the available resources among the different care sectors and monitoring the achievement of the health objectives set by the municipalities; the *Länder* are in charge of financing the construction of new hospitals, while the health insurance funds and the hospitals themselves are responsible for the maintenance of the existing ones through the charges applied to the users; the local government is involved in the activity of identifying priorities, through the setting of specific public health objectives, mostly defined in terms of results; lastly, the health insurance funds are in charge of financing outpatient care (primary and specialist) and hospital care. Health policy is determined through the setting of common objectives at federal level and the identification of specific health objectives or priority areas of intervention at state level.

As for the process of setting priorities, even though a debate on setting priorities in healthcare was called for in the first decade of the new millennium, this led neither to extensive public involvement nor to explicit political choices being made. This is perhaps also due to the high level of involvement of the legal system in the management of healthcare in Germany and to the jurisprudential orientation with which the Federal Constitutional Court has affirmed the obligation of the State to protect life and physical integrity when designing the system of benefits. The specific situation of the patient must be taken into account in the case of life-threatening illnesses for which there are no conventional medical treatments (see St. Nicholas judgment later in this text, which could have opened the door to reimbursement for methods of questionable efficacy). Priority setting is therefore entrusted to the GB-A, which is charged with defining the basket of services covered by public health insurance with regard to outpatient care and hospital service, and assessing the quality and efficiency of services according to the HTA reports issued by a

technical advisory body evaluating the benefits of different existing medical interventions and the additional benefits of innovative ones or newly introduced pharmaceutical products in relation to existing ones. The criteria used to compile the positive list include both diagnostic and therapeutic appropriateness and convenience/efficiency (for inpatient and outpatient services), while the requirement of appropriateness, which applies in the hospital context, is replaced for outpatient care by the requirement of medical necessity. Lastly, while there is no formal document in Germany comparable to NICE's Social Value Principles in the UK, value judgments of a social nature such as the criterion of need are not entirely foreign to the prioritisation choices made by German institutions. This is demonstrated by the fact that the method used to express the cost-benefit ratio of medical interventions and decide which ones ensure the best use of the scarce resources available (the "efficiency frontier") can only be used for treatments relating to the same pathology, and therefore cannot result in a denial of access to treatment for particularly serious illnesses.

In Switzerland, since the end of the 1990s there has been a lively, albeit inconsistent, debate on prioritisation, which has been profoundly influenced by the attitude of the mass media to individual cases of refusal to reimburse overpriced treatments by health insurance funds. With regard to the process of prioritisation in Switzerland, it should be noted first of all that the concept of *rationnement des soins* is similar to the concept of *priority setting* (rather than the concept of rationing outlined in the first chapter) as it is understood in Scandinavian countries and Great Britain. The only case of explicit prioritisation in Switzerland is the federal law on organ transplantation, which combines technical criteria (the urgency of the transplant and its expected effectiveness, thus also taking into account the age and nature of the patient's pathology) with equity concerns (such as the attempt to ensure that patients with a less urgent physiological condition and therefore a longer waiting time have an equal chance of receiving the available organs). Apart from this exception, the Swiss Federal Council has expressly denied both the desirability of any form of explicit rationing (to which it declares to prefer the path of rationalisation, i.e., the improvement of the organisational efficiency of the health system or its level of coverage, as well as the reduction of its costs), and the possibility of deducing any implicit rationing intent based on the existing regional disparities in access to care. On the other hand, the literature emphasises the fact that, while the LAMal neither in any way refer to nor limits access to the healthcare system on the basis of the characteristics of the beneficiary, neither does it prevent an implicit rationing of care. Examples have been reported concerning the selection of beneficiaries on a case-by-case basis and in the absence of clear and predetermined criteria

on the part of healthcare professionals ("bedside rationing"), to the detriment of the elderly, those living on the margins of society and those suffering from a handicap or chronic illness. The potential for discrimination and the shortcomings of the implicit rationing in terms of transparency and accountability have consequently been the subject of criticism and appeals from the scientific community for years, with repeated calls for the establishment of clearly defined and binding health objectives as part of a genuine national health policy. Lastly, decisions on inclusion in or exclusion from baskets of health services are made on the basis of a centralised procedure at federal level, which involves consulting expert committees and paves the way for uniform decision-making criteria applicable throughout the country. The positive lists drawn up by the OFSP indicate which medical services, medicines, therapies, diagnostic services and medical devices can be reimbursed by compulsory health insurance (and at what maximum price), while all those that are excluded can be included in supplementary insurance plans. The law stipulates that only "appropriate, effective and affordable" services can be reimbursed. The three criteria (also known as "*principe EAE*") are cumulative and are substantiated in, respectively:

- the ability to produce the effect sought in the specific case *(adéquation*);
- the ability to produce a general effect *(efficacité*);
- presenting an appropriate cost-benefit ratio *(economicité*).

The imposition of a legal constraint on the cost-effectiveness of the service demonstrates the willingness of the system to take into account the issue of limited resources for medical treatment. The verification of compliance with these criteria, including the possibility of seeking sanctions against providers who breach the obligation to limit benefits to what is required by the interests of the insured person and the purpose of the treatment, is entrusted, in specific cases, to the insurers themselves, who may refuse reimbursement and ultimately, if the applicable refusal measures are challenged, to the courts. In this respect, the case law of the Federal Constitutional Court has established that judges must respect the discretion of the bodies responsible for compiling the lists, not least because of the technical nature of the lists and that the analogical argument cannot be used to fill the alleged gap and extend the objective scope of the list. A case in point is the position taken by the court in the Myozyme case. The court upheld the denial of reimbursement for treatment with an off-label drug on the basis of both its excessive cost and the inadequate clinical benefit expected. This happened after the court projected the outcome of its decision not only on the individual case under examination, but on all insured persons and, therefore, on the general sustainability of the precedent for health insurance companies. The ruling generated much

discussion in that by establishing a precedent for health insurance companies, the court acted more like a legislator than a court of law, clearly distancing itself from the position taken by the English courts in the aforementioned Child B. case.

Chapter Three

Health resource allocation and priority setting in Italy
by Alessandra Cerruti and Caterina Di Costanzo

1. *The constitutional framework and health reforms*

Like most healthcare systems based on a universalistic model, the Italian system is characterised by a tension between opposing forces. These are, in essence, a centripetal pull towards uniformity and a centrifugal one towards differentiation (as is the case with the Spanish system[1]), and the push for efficiency and economic sustainability within a system traditionally defined by the principles of equality, equity and solidarity (similar to the English system[2]).

In this sense, the protection of health in the Italian system can be regarded as a paradigmatic example of an increasingly relevant issue: how to balance the multilevel recognition of the fundamental nature of the constitutional right to health with the need to ensure the financial stability of the system that organises and distributes the services enshrined in that right.

As in many European countries, the Italian health system has been a veritable laboratory of institutional experimentation and has undergone a series of reforms in response to the growing need to contain public expenditures, of which health expenditure accounts for a significant part. Those reforms have concerned the reorganisation of competences between the different levels of government (decentralisation), the revision of the management models of the public structures providing health services (corporatisation and managerialisation), the introduction of instruments

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[1] The Italian and the Spanish systems handle the unit-differentiation dynamic differently. The existing cooperation and negotiation mechanisms in the field of the constitutional protection of health, designed to allow an institutional collaboration between the central level and autonomous region level and to minimise litigation between the State and the autonomous regions have been very effective in the Spanish system, but much less so in the Italian system; see chapter 2 above.

[2] See L. Dimasi, *Il welfare sanitario in Italia e in Europa: quali prospettive?* in Sanità e diritti fondamentali in ambito europeo e italiano, edited by L.S. Rossi and C. Bottari, Santarcangelo di Romagna, Maggioli, 2013, esp. pp. 34-35; M. D'Angelosante, *L'incidenza delle regole di organizzazione e di distribuzione delle competenze sulla conformazione del mercato dei servizi sanitari: sistemi universalistici e occupazionali a confronto nello spazio comunitario*, in I servizi sanitari: organizzazione, riforme e sostenibilità. Una prospettiva comparata, edited by A. Pioggia, S. Civitarese Matteucci, G.M. Racca and M. Dugato, Santarcangelo di Romagna, Maggioli, 2011, pp. 17 ff.

inspired by a market-based approach aimed at introducing regulated competition (e.g., the introduction of institutional accreditation mechanisms for private structures that provide health services) and an effort to increase the efficiency of the system through cost and risk-sharing instruments such as co-participation mechanisms related to moral hazard situations.[3]

1.1. *The path of Italian health reforms*

The analysis of health reforms in Italy, which began with the establishment of the national health service (*Servizio Sanitario Nazionale* - SSN) in 1978 and which was followed by numerous legislative adjustments that have progressively reduced its characteristic features, reveals a number of factors. First, a dual series of invariants, being the attribution of the obligations to provide health care to the public sphere, as provided for by the constitutional principle that entrusts the Republic with the protection of health, alongside the coverage of health expenditure through general taxation[4]. These have consistently reinforced the evidence that seems to place the issue of the implementation and effectiveness of the right to health in close correlation with the issue of the sustainability of the health service[5].

The introduction of the SSN with Law no. 833 of 1978 and the replacement of the social insurance system (that is, health insurance funds)

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[3] On these aspects, see C. Tubertini, *Garanzia della salute e sostenibilità finanziaria,* in I servizi sanitari: organizzazione, riforme e sostenibilità. Una prospettiva comparata, edited by A. Pioggia, S. Civitarese Matteucci, G.M. Racca and M. Dugato, cit., pp. 138 ff. Economists consider co-payments as an instrument not (or at least not only) aimed at earning revenue, but above all at managing demand and controlling excess expenditure due, for example, to third-party payers, from which both insurance systems and univariable systems suffer. It is a cost and risk-sharing measure that, in the presence of corrective measures that prevent it from being applied in violation of the principle of fairness, is particularly suitable for containing cases of moral hazard. Therefore, it is, in this respect, efficient, while the private expenditure that a part of the population incurs out-of-pocket, after having contributed to the Beveridgian health system by paying taxes, and induced by a series of factors such as waiting lists, constitutes a revealing index of inefficiency. On this issue see V. Rebba, *I ticket sanitari: strumenti di controllo della domanda o artefici di inequaglianze nell'accesso alle cure?* in Politiche Sanitarie, 2009, no. 4, pp. 221 ff.

[4] On the guiding principles of the 1978 reform, see F. Roversi Monaco (ed.), *Il servizio sanitario nazionale. Commento alla legge 833/1978*, Milan, Giuffrè; on the adjustment of the SSN, see C. Bottari, *Tutela della salute ed organizzazione sanitaria*, Turin, Giappichelli, 2011.

[5] See R. Nania, *Il diritto alla salute fra attuazione e sostenibilità*, in L'erogazione della prestazione medica fra diritto alla salute, principio di autodeterminazione e gestione ottimale delle risorse sanitarie, edited by M. Sesta, Santarcangelo di Romagna, Maggioli, 2014, pp. 31 ss.

with a publicly financed health system characterised by global services, universal recipients, equity of access to the services, equality of treatment and uniformity of the services, represented a profound innovation with respect to the previous regulatory framework and was hailed by many as a sign of Italian society adopting a civilized approach to the issue[6]. The profound change triggered by Law no. 833 also allowed for the implementation of Article 32 of the Constitution[7], which with this marked shift in perspective found its chief expression and interpretation precisely in Law no. 833 for many years[8].

Art. 32 of the Constitution outlines the contours of the right to health as both a collective interest and a subjective right, in its dual dimension as the right to freedom and the right to services, an approach that has been the subject of a lively and ample debate since the work of the Constituent Assembly[9]. Art. 32 does not prescribe the imposition of a specific

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[6] As Adelfio Elio Cardinale, Undersecretary of State for Health, stated in the Preface to the 2011 Report on the Health Status of the Country, which can be downloaded from the Ministry of Health website www.salute.gov.it: "Our National Health Service, despite its lights and shadows, is a great social achievement."

[7] Article 1 of Law no. 833/1978, adopting the wording of Article 32 of the Constitution and, supplementing it with the organisational component, provides: "The Republic shall safeguard health as a fundamental right of the individual and as a collective interest through the SSN. The protection of physical and mental health may not under any circumstances violate the dignity and freedom of the human person. The SSN consists of all the functions, structures, services and activities intended to promote, maintain and recover the physical and mental health of the entire population without distinction of individual or social conditions and in a manner that ensures the equality of citizens with respect to the service. The implementation of the SSN is the responsibility of the State, the Regions and the local authorities, guaranteeing the participation of citizens."

[8] See M. Luciani, *Salute (Diritto alla salute)*, in Enciclopedia giuridica Treccani, XXVII, Rome, 1991, pp. 8-9; D. Morana, *La salute come diritto costituzionale*, Turin, Giappichelli, 2015, pp. 79 ff.

[9] Consider, in this regard, the critical position expressed by one member of the Constituent Assembly, Francesco Saverio Nitti, on the effects of the wording of Article 32 of the Constitution: in the session of 19 April 1947, Nitti seemed to anticipate a problem that would shake the foundations of the system a few decades later: "You know what the situation is in Italy, you know what hospitals are like, what the situation is like in at least nine-tenths of Italy, where there is a lack of everything and there will be for many years. Are we now suddenly making a commitment to provide all these things, that we will not be able to provide for many years? Now, do you think it is good procedure to make a promise in the name of the Republic that cannot be kept? And why make it a matter for the Constitution? When the people ask us tomorrow: since the Republic guarantees these things, how and in what form can it guarantee them? I don't want to bore you with a lot of figures; I will do that next time when we talk about the financial situation. I will then tell you what the economic and financial situation is. Too many things have been disguised and too many things are still being disguised; I will talk about the things we can do and also about the things we cannot do and which are promised with no earnestness at all. Lastly, we should, God willing, discuss

organisational model[10], but identifies a threshold for free access to health services based on a defined level of indigence, which was subsequently developed by the case law of the Constitutional Court as a relative and not absolute concept[11]. Law no. 833 later favoured an extensive interpretation of Article 32 with respect to free treatment, providing for universal and free access to healthcare services[12].

The reforms of the 1990s

The reforms of the 1990s were necessitated and driven by a number of factors, one of the most important being the need to rationalise healthcare spending, which was beginning to be seen as out of control. The overall reorganisation of the sector began with enabling law no. 421 of 1992, implemented by Legislative Decree no. 502 of 1992 and amended by Legislative Decree no. 517 of 1993 and Legislative Decree no. 229 of 1999. These reforms pertain mainly to a stronger connection between health protection and the rational use of available resources on the one hand, and the introduction of an approach aimed at containing overall expenditure in the reorganisation of health services and the promotion of individual responsibility of demand (including, in part, through the establishment of forms of cost-sharing) on the other.

The two cornerstones of the SSN, namely regionalisation and corporatisation, take on greater relevance in light of the experimental solutions tested in the institutional and administrative reorganisation of

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the economic and financial situation using the language of reality. We have to say which obligations we can take on and which we cannot, and we will have to say how many things we will have to give up. Therefore, let the name of the Republic not be compromised in these misunderstandings, because we would also take away that gravitas that is indispensable to it."

[10] Article 32 of the Constitution provides that: "The Republic shall safeguard health as a fundamental right of the individual and as a collective interest, and shall ensure free medical care to the indigent. No-one may be obliged to undergo any health treatment except under the provisions of the law. The law may not under any circumstances violate the limits imposed by respect for the human person." The fundamentality attributed to the right has been interpreted in a variety of ways by case law, but the Constitutional Court has ruled out that the "pre-eminent character" of the right to health over other rights can be derived from it. See paragraph 9 of the Conclusions on points of law of the Judgment of the Constitutional Court no. 85 of 2013.

[11] See Constitutional Court Judgment no. 309 of 1999, which states that the notion of indigence "does not have a precise and always identical meaning", since the criteria available to the legislator for determining the content of that notion "may vary according to the greater or lesser burden of care".

[12] See M. Luciani, *Salute (Diritto alla salute)*, in Enciclopedia giuridica Treccani, cit., pp. 4 ff; B. Caravita, *La disciplina costituzionale della salute*, in Diritto e Società, 1984, pp. 22 ff.

the complex health system, inspired above all by the need to ensure economic efficiency. Article 1 of enabling law no. 421 of 1992 establishes that "For the purposes of the optimal and rational use of the resources allocated to the SSN, the pursuit of its utmost efficiency in the interest of the citizens, distributive equity and the containment of health expenditure, with reference to article 32 of the Constitution, the Government of the Republic, having consulted the Standing Conference for relations between the State, the Regions and the Autonomous Provinces of Trento and Bolzano, shall be delegated to issue one or more Legislative Decrees within ninety days of the entry into force of this law."

Firstly, the regionalisation of the health sector, implemented by Legislative Decree no. 502 of 1992, anticipated a broader regionalist approach on numerous matters concerning the protection of fundamental rights. The resulting regionalist system, which after its introduction led to a temporary re-centralisation of the regionalised competences by gradually granting significant substitutive powers to the State to be exercised in the event of serious regional failings. One case in point is Deficit Recovery Plans: these were envisaged in 2005 and have been operational since 2007, after an update of their content by the 2007-2009 Health Pact.

The Legislative Decree no. 502 of 1992, in addition to the regionalisation and corporatisation of health care, introduced the principle of equality between public and private providers of health care services and the possibility of providing for co-payment of health care costs in relation to certain services (see art. 4, (7)(c) of Legislative Decree no. 502 of 1992). The same consideration about institutional experimentation also applies to the corporatisation process, which the delegated legislator was charged to review and implement by enabling law no. 419 of 1998. In this context, a series of instruments that had been largely untried by public administration organisations were introduced (indicators, classifications, evaluations, performance analysis, incentives and sanctions, cost centre accounting).

These principles are confirmed and elaborated in Legislative Decree no. 229 of 1999, which enhances the quality of health care and introduces the integration of social and health services. The decree underscores the relevance of the problems of providing effective tools for the governance of a multilevel public system such as the SSN, aimed at ensuring the unitary management of the service and a uniform guarantee of protection in a system subject to the organisational differentiation of regional models. The progressive corporatisation of regionalised health services has highlighted the need to make administrators more responsible and to adopt management models in line with the organisational and managerial

standards of fiscal federalism, based on economic efficiency and effectiveness in the identification of the relations between the definition of essential levels and the availability of financial resources. Pressure from Brussels on setting constraints in the form of objectives to be pursued to contain the annual debt and deficit and to stabilise the budgets of the Member States on the one hand, and internal pressure (sometimes structural (fiscal contraction and increase in health demand) and at others times cyclical (implosion of the party system and the denunciation of corruption linked to the degeneration of the party power system)) on the other have, from time to time, led to the revision of organisational aspects, legislative competences, and political and administrative responsibilities.

The relevance of these factors is also confirmed by subsequent legislation that raised cost-sharing for healthcare spending by mandating a more frequent and more significant reliance, in terms of individual costs, on co-payment. (Co-payment was introduced for the first time with Legislative Decree no. 89 of 1989, converted into law no. 154 of 1989; it stipulated their type and amount, which were subject to continuous adjustments until the approval of the so-called *superticket*, an additional fee that was set differently in the various regions. This additional fee was envisaged in 2011 and, ultimately, eliminated as of 1 January 2020.) In parallel, the overall amount of healthcare spending was further reduced through the "linear cuts". Co-payments and linear cuts in healthcare spending have had a strong impact on the overall supply of health services, limiting access for those individuals in the most vulnerable economic and social groups by virtue of the amount to be paid, the unequal nature of these instruments and the lack of uniformity across regions, regardless of whether deficit recovery plans exist in them.

The beginning of the new millennium was marked by a series of reforms, including the 2001 constitutional reform that redesigned Title V of the Constitution and the division of competences between the State and the Regions[13].

The reforms of the last few years indicate a re-centralisation of competences in the field of health. Examples include the role assigned to Age.Na.S. in assessing performance levels and coordinating the "network" of regional health systems[14], and the limitation of regional autonomy

[13] On the 2001 constitutional reform, see section 3.1 below.

[14] Article 5 of Legislative Decree no. 266 of 1993, which established the Agency, provides that it shall be "endowed with legal personality and subject to the supervision of the Ministry of Health, with the task of supporting regional activities, comparative evaluation of the costs and yields of the services rendered to citizens, and reporting dysfunctions and waste in the management of personal and material resources and supplies, transfer of innovation and experiments in health matters." On the Agency see E. Jorio, *Diritto sanitario*,

determined by an extensive interpretation of the State's functions as public finance coordinator, for example with regard to deficit recovery plans[15]. The reforms have also led to a reorganisation of the ways in which care is provided, based on the principles of efficiency and containment of health expenditure applied towards de-hospitalisation and the consequent shift from secondary care to primary care[16]. This much-awaited shift, however, has still not been implemented in full, although its importance and necessity became once again apparent during the COVID-19 (Coronavirus disease[17]) pandemic that began in late 2019.

The issue of the recognition of greater regional autonomy for non-autonomous Regions, pursuant to article 116, paragraph 3, of the Constitution, has fuelled recent debates[18], but was set aside, at least for the duration of the health emergency, by reflections in the wake of the COVID-19 pandemic, which highlighted the need for uniform management and the importance of coordination between the national and regional levels of government[19].

Milan, Giuffrè, 2006; T. Feola and A. Di Corato, *Servizio sanitario nazionale. Stato e Regioni nel governo della salute*, Turin, Minerva Medica, 2006.

[15] See, for example, Constitutional Court Judgments no. 417 of 2005, no. 237 of 2009, no. 52 of 2010.

[16] Law no. 189 of 2012, converting Legislative Decree no. 158 of 2012, reorganises primary care within the dehospitalisation process that has been underway for a number of years and has been increased by the economic crisis. Article 1 states that "the Regions shall define the organisation of territorial primary care services, promoting integration with social services, also with reference to home care, and hospital services, in order to improve the level of efficiency and the capacity to take care of citizens". To this end, the law provides for general practitioners to set up single-practice organisational entities known as "Aggregazioni funzionali territoriali" (Territorial functional groupings, AFT), which share, in a structured manner, objectives and care pathways, quality assessment tools, guidelines and audits. It also provides for the launch of multi-professional organisational entities, called "unità complesse di cure primarie" (complex primary care units, UCCP), which provide care services through the coordination and integration of physicians, other professionals affiliated with the SSN, nurses, midwives, technical, rehabilitation, preventive and social professionals with health relevance.

[17] On the identification of the name of the new coronavirus, see the Declaration of the Director-General of the WHO of 11 February 2020.

[18] Following the initiatives undertaken in particular by Lombardy, Veneto and Emilia-Romagna, the differentiated autonomy would address the removal of spending constraints on personnel, agreements with universities concerning residents, the system of corporate governance, etc.; see *Dossier del Servizio studi del Senato* no. 16 of 2018 "Il regionalismo differenziato e gli accordi preliminari con le Regioni Emilia-Romagna, Lombardia e Veneto (Differentiated regionalism and preliminary agreements with the Emilia-Romagna, Lombardy and Veneto Regions)."

[19] M. Di Giulio, *L'emergenza Covid-19, i rapporti centro-periferia e le lezioni che dovrebbe apprendere*, in Il Mulino, 23 March 2020; F. Palermo, *Il virus è centralista?*, in Il Mulino, 26

2. *The complex relationship between the effectiveness of the constitutional right to health and the sustainability of the health system*

It is a generally accepted scientific consensus that it is no longer possible to make any structural distinction between rights that do not have a cost and rights that do have a cost[20], and this is all the more true with reference to the constitutional right to health. This is a multidimensional right, composed of a range of diverse subjective situations some of which refer more closely to the rights to freedom and others to the rights to services[21], the guaranteeing of which constitutes the largest disbursement among the social rights with a significant cost for public authorities. While this awareness has never brought the primacy of public duties over private ones in guaranteeing the right into question, it has fuelled a scientific and political reflection on the complex relationship between the effectiveness of the constitutional right to health and the guarantee of the financial sustainability of the health system[22]. In fact, we are potentially witnessing an increasing conflict (and consequent need for mediation and negotiation) between the naturally expansive vocation of the constitutional protection of health, derived from the characteristic multidimensional nature of the right, and the need to safeguard the sustainability of the system through the

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February 2020.

[20] See the foundational work by Holmes and Sunstein, which essentially deconstructs the paradigm that differentiated the implementation of freedom rights, deriving from a liberal cultural matrix, free of cost, from the implementation of social rights (as more fully developed in the post-World War II constitutions) that entailed high costs for the states. See S. Holmes and C.R. Sunstein, *The costs of rights: why liberty depends on taxes*, New York, Norton, 1999.

[21] See A. Simoncini and E. Longo, *Art. 32*, in *Commentario alla Costituzione*, edited by R. Bifulco, A. Celotto and M. Olivetti, Turin, Utet, 2006; B. Pezzini, *Il diritto alla salute: profili costituzionali*, in Diritto e Società, 1983, no. 1; M. Luciani, *Salute (Diritto alla salute)*, in Enciclopedia giuridica Treccani, cit., p. 5.

[22] On this very broad topic, see the contributions contained in M. Sesta (a cura di), *L'erogazione della prestazione medica tra diritto alla salute, principio di autodeterminazione e gestione ottimale delle risorse sanitarie*, Santarcangelo di Romagna, Maggioli, 2014; A. Pioggia, S. Civitarese Matteucci, G.M. Racca and M. Dugato (eds.), *I servizi sanitari: organizzazione, riforme e sostenibilità. Una prospettiva comparata*, Santarcangelo di Romagna, Maggioli, 2011. On the political side, mention should be made of the work of the 12th Senate Committee on Health and Hygiene on the subject of "The sustainability of the SSN with particular reference to the guarantee of the principles of universality, solidarity and equity", also in relation to the debate that has developed in the context of the present survey. The summary of the Senate Committee's fact-finding investigation can be found at http://www.senato.it/leg/17/BGT/ Texts/Appendices/00000189.pdf.

use of tools to define the criteria for making allocation choices and identifying healthcare priorities.

2.1. *The composite configuration of the right to health*

The normative-economic complexity of the right to health, already fully outlined in the constitutional text itself[23] and requiring a balancing of multiple demands, derives from the "composite" nature of health protection, which has an individual dimension and a collective root[24] and is truly unique among the European constitutions of the second post-war period[25].

The Italian Constitution, in both its subjective and objective form[26], states quite clearly that the right to health is multidimensional. This applies both to the negative profile that is closely related to the protection of personal freedom (that is, the protection of the personal sphere from the interference of public or private powers, which refers to the exclusion of health treatments, except those provided by law for the purpose of protecting public health and within the limits of respect for the person according to art. 32, paragraph 2) and to the positive one, that is, the right to receive appropriate assistance to protect the psycho-physical integrity of

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[23] See C. Mortati, *La tutela della salute nella Costituzione italiana*, now in Raccolta di scritti, Milan, Giuffrè, 1972, pp. 433 ff. where we read: "The Italian Constitution is the only contemporary constitution which, in conferring constitutional importance on the interests connected with the health of citizens, has given them a complete discipline."

[24] R. Balduzzi and D. Servetti, *La garanzia costituzionale del diritto alla salute e la sua attuazione nel Servizio sanitario nazionale*, in Manuale di diritto sanitario, edited by R. Balduzzi and G. Carpani, Bologna, Il Mulino, 2013, pp. 20 ff.

[25] Prior to the Republican Constitution, health was a subject of public interest for hygienic-preventive reasons and therefore it was included among public order functions under the Ministry of the Interior and Prefectures. Putting the individual right and the collective interest on the same level is a republican innovation that does not, however, allow the health of the individual to be subordinated to collective needs. See A. Pioggia, *Diritto sanitario e dei servizi sociali*, Turin, Giappichelli, 2014, pp. 22 ff.

[26] Subjective multidimensionality concerns the public and private subjects involved in protection, the individual, the community. Objective multidimensionality concerns the object of protection, i.e., the subjective situation protected from time to time in concrete individual situations (right to psycho-physical integrity, right to a healthy environment, right of access to health services, right to self-determination, etc.). On the issue of multidimensionality see R. Balduzzi and D. Servetti, *La garanzia costituzionale del diritto alla salute e sua attuazione nel Servizio sanitario nazionale*, edited by R. Balduzzi and G. Carpani, cit. Servetti, *La garanzia costituzionale del diritto alla salute e la sua attuazione nel Servizio sanitario nazionale*, in Manuale di diritto sanitario, edited by R. Balduzzi and G. Carpani, cited above, pp. 25 ff.

the person (according to the first paragraph of art. 32), whose interest is also safeguarded[27].

According to some of the main interpretations, from time to time the interest of the community translated, in turn, into an external limitation of individual freedoms (and the case of the SARS-Cov-2 pandemic shows, in this sense, how the collective interest in the protection of health can function as a factor compressing freedoms such as freedom of movement and freedom of assembly), or a specification of possible forms of protection as a raison d'être or precondition of the individual right to health. This applies, first of all, to the expression of the duty of social solidarity set out in Article 2 of the Constitution and, as an institutional projection of the duty of social solidarity, to the duty of public authorities to protect the health of the community. Consider for example the dramatic problem of balancing the medical needs of the individual with the interests of the community on matters involving compulsory health treatments and compulsory vaccinations[28]. Secondly, there is the duty of institutional actors to monitor and to prevent health from being compromised or violated by someone or something. In this sense, it is also in the public interest to ensure that the constitutional right to health is promoted and that the financial viability of the health system, which is still a means to the end of protecting health, is safeguarded.

This complexity is further identified as a specific feature of the right to health first in the jurisprudence of legitimacy and secondarily by the constitutional jurisprudence. The case law of the 1970s defines this right as primary and absolute, i.e., free from conditioning of any kind[29]. The notion of health is also redefined on the basis of the definition contained in the

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[27] See D. Morana, *La salute come diritto costituzionale. Lezioni*, Turin, Giappichelli, 2015, pp. 1 ff.

[28] On this point see the arguments of R. Balduzzi and D. Servetti, *La garanzia costituzionale del diritto alla salute e sua attuazione nel Servizio sanitario nazionale* in Manuale di diritto sanitario, edited by R. Balduzzi and G. Carpani, cited above, pp. 41-43. The second paragraph of Article 32 provides that "No-one may be obliged to undergo any health treatment except under the provisions of the law" and that this law "may not under any circumstances violate the limits imposed by respect for the human person.". Article 33, paragraph 2, of the law establishing the SSN provides that compulsory health treatments and investigations shall be carried out with due respect for "the dignity of the person and his/her civil and political rights, including as far as possible the right to freely choose a doctor and a place of treatment'.

[29] Cf. Joint Session (SS.UU.) of the Court of Cassation no. 796 of 21 March 1973 which establishes the *erga omnes* effectiveness of the right to health, even in relation to private individuals; cf. Constitutional Court Judgement no. 88 of 1979 which recognises the compensability of the damage to the right to health (biological damage); on biological damage, see also Constitutional Court Judgement no. 184 of 1986.

preamble to the WHO Constitution, leading to a shift from a negative definition (as the absence of disease) to a positive one (psycho-physical and social well-being, where the latter plays a very important role)[30]. In fact, jurisprudence recognises that the scope of health is not static but rather dynamic, including not only the biological dimension but, more appropriately, also the ethical-social dimension. The potential of this dynamic-relational interpretation of the concept of health has been revealed in many areas. First, this potential became evident in the need to progressively extend protection to the living and working environment, recognising the need to safeguard "the healthiness and hygiene of the natural living and working environment"[31]. From the sphere of health protection issues this is the right to a healthy environment, which constitutes the projection into the social sphere of the protection requirements concerning the psycho-physical dimension of the individual[32]. The dynamic, socio-relational concept of health has also opened up new perspectives regarding health protection in the workplace[33], measures that are aimed at increasing the space for relations which enable the individual to regain their mental and physical well-being. One example is the socialisation of the physically or mentally handicapped through school attendance and job placement commensurate with the individual's working capacity[34]. In some cases, this also refers to the relevance that can be attributed, in a legal context, to the care of the social determinants of health[35].

2.2. *Constitutional jurisprudence on the protection of rights in a context of scarce resources*

The multi-structural nature of the right to health, which leads to different levels of protection, is important for understanding the

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[30] See the Preamble to the WHO Constitution, signed in New York on 22 July 1946.

[31] See Judgement of the Supreme Court of Cassation no. 5172 of 6 October 1979; Constitutional Court Judgement no. 399 of 1996 on the health risks of passive smoking; Constitutional Court Judgement no. 361 of 2003; Constitutional Court Judgement no. 360 of 2000.

[32] On the relationship between the individual's health and his/her living environment, see M. Luciani, *Salute (Diritto alla salute)*, in Enciclopedia giuridica Treccani, cit., p. 6.

[33] The protection of health in the workplace, in the specific case of eradicating harassing behaviour, also concerns the impact that vexatious acts can have on the work environment, is a matter of civil law and falls within the exclusive competence of the State; cf. Constitutional Court Judgment no. 359 of 2003.

[34] See Constitutional Court Judgements no. 167 of 1999 and no. 215 of 1987.

[35] On the "social determinants" of health, see section 1.2 of Chapter 1 above.

development of case law in matters related to health. As regards the protection of the physical and psychological integrity of the human person in the face of the harmful conduct of third parties, the right to health holds *erga omnes* primacy (it is a right guaranteed by the Constitution and, as such, directly protectable and actionable against the perpetrators of the harmful behaviour). However, with regard to the right to health treatments, the right to health is subject to the "determination of the instruments, times and ways of implementing the relevant protection by the ordinary legislator"[36]. These lines pertain to the right to health viewed primarily as a right to health services, on which the scarcity of resources allocated for the protection of the right weighs heavily[37]. The right to health services, in fact, has been qualified in the Italian legal system as the right to receive medical treatment that is not harmful, that is effective, and that is consistent with a technical standard that is constantly evolving and being updated[38].

Since the 1990s, the court has paid increasing attention to the need to curb public spending by using formulas such as financially conditioned rights, by imposing the principles of reasonableness and gradualness of onerous reforms, and consequently by highlighting the need to take into account the limited resources available. The absolute primacy of the right to health, enunciated by the aforementioned jurisprudence of the Court of Cassation, is declared relative by the Constitutional Court, which takes into account the need to guarantee the sustainability of the system. The Constitutional Court has reiterated, in various rulings, the need for the effective protection of the right to be subject to a reasonable balance with the organisational and financial resources and for healthcare expenditure[39], which has been increasing exponentially since the end of the 1980s, to be commensurate with the effective financial availability that conditions the quantity and level of services[40].

The constitutional jurisprudence has confirmed that the financial conditioning to which the protection of the right to health is subject does

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[36] See Constitutional Court Judgement no 445 of 1990.

[37] On the right to health as a right to health services, see A. Rovagnati, *La pretesa di ricevere prestazioni sanitarie all'interno dell'ordinamento costituzionale repubblicano* and E. Cavasino, *Il diritto alla salute come diritto a prestazioni. Considerazioni sull'effettività della tutela*, both in E. Cavasino, G. Scala and G. Verde, I diritti sociali dal riconoscimento alla garanzia. Il ruolo della giurisprudenza, Naples, Editoriale scientifica, 2013.

[38] In Constitutional Court Judgement no. 282 of 2002, the right to health is defined as the right "to be treated effectively, according to the canons of science and the art of medicine [which] is based on scientific and experimental acquisitions, which are constantly evolving". See also Judgment no. 338 of 2003.

[39] See Judgment no. 267 of 1998.

[40] See Judgment no. 356 of 1992.

not apply when the individual right to health is at stake, but rather when the distribution of financial resources among the various subjects of the SSN[41] is at stake. The Court specified that, in the balancing exercise carried out by the legislator, the needs of public finance cannot take on such a preponderant weight as to reduce the irreducible core of the right to health guaranteed by the Constitution as an inviolable sphere of human dignity[42]. On the other hand, there is no mechanical correspondence between the provision of funding for health care and the guarantee of the right to health through the identification of essential levels of care (LEA), because both depend on a series of distinct choices that are made both at the national and regional levels.

In Judgment no. 36 of 2013, following the decision by the Italian Prime Minister concerning a number of provisions in the draft annual and multiannual budget of the Region of Sardinia (with reference to Article 2(3) of the Regional Finance Act 2012[43]), the Constitutional Court states in paragraph 4.1 of the Considerations on points of law that there is no automatic correspondence between the definition of the amount of national funding and the guarantee of essential levels of care, since "the fulfilment of these levels depends not only on the resources to be earmarked, but also on their allocation and use", i.e., on the socio-political choices underlying the allocation decisions[44].

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[41] See, for example, Constitutional Court Judgment no. 200 of 2005 on the subject of authorisation to enter non-public healthcare facilities.

[42] See Judgments no. 309 of 1999, no. 267 of 1998, no. 416 of 1995, no. 218 and no. 304 of 1994, no. 247 of 1992, no. 455 of 1990.

[43] Article 2, paragraph 3, of Regional Law no. 6 of 2012 provides that the Councillor (*Assessore*) responsible for the budget is authorised "in the year 2012, to integrate, subject to the opinion of the competent Council Committee, by withdrawing from the Regional Health Fund referred to in UPB S05.01.001, up to 10,000,000 euros, the endowment of the Fund for non-self-sufficiency, if, following the examination of the applications received, it turns out to be sufficient. The regional administration is required to directly verify any plans with a score from 0 to 5 on the 'health card'".

[44] The case concerned the shifting of some resources from the health fund to the non-self-sufficiency fund. On the basis of the Court's reasoning, this choice "does not lead to an infringement of the essential levels of services, but, on the contrary, is functional to their implementation" since, on the basis of the regulatory framework, the health and socio-social activity in favour of non-self-sufficient elderly people is listed among the essential levels of health care by Prime Ministerial Decree (d.P.C.M.) of 29 November 2001. Therefore, the regional fund for non-self-sufficiency, like the national one, instituted by art. 1, paragraph 1264 of law no. 296 of 27 December 2006 "Provisions for the formation of the annual and multi-year budget of the State" (2007 Financial Law) contributes to ensuring the implementation of the essential levels of care with regard to non-self-sufficient elderly persons.

Subsequent constitutional case law has subjected to constitutional scrutiny the relevant measures to rationalise healthcare spending, which fall under "coordination of public finance" (Judgment no. 183 of 2016 and Judgment no. 203 of 2016), either as a single competence or in conjunction with "health protection" (e.g., Judgments no. 125 of 2015, no. 91 of 2012, no. 330 of 2011, no. 289 of 2010, no. 240 of 2007, no. 162 of 2007). This reconstruction is confirmed by the consistent case law on deficit recovery plans for regions with a deficit (e.g., Rulings no. 266 of 2016 and no. 278 of 2014). In this context, constitutional jurisprudence justifies the legitimacy of state intervention to coordinate public finance according to two main factors: one is the temporary and transitory nature of state intervention to decrease public funding; the other, pertaining to the legitimacy of the corrective measures, concerns the fact that national intervention is limited to the formulation of principles, so as to leave to the Regions enough room to make effective allocation decisions.

In Judgment no. 65 of 2016, the Court declared that the objections raised by the Veneto Region concerning the constitutionality of the alleged imposition of a "quasi-linear" cut in expenditure for the purchase of goods and services in every sector were unfounded[45]. The court states that Article 8(4) of Legislative Decree no. 66 of 24 April 2014 does not provide for an unreasonable "linear" cut, but is limited to prescribing an overall reduction in expenditure and does not require *equal* reductions in all sectors, but simply reductions in all sectors. Moreover, the provisions are not unconstitutional because the imposition of expenditure reductions is fully in line with the exercise of the functions of coordinating public finance that legitimises the State legislator to impose constraints on budget policies on autonomous entities, for reasons of financial coordination related to national objectives, also in light of EU obligations (which should, however, respect the principle of transitionality imposed by constitutional law).

In ruling no. 141 of 2016, which stemmed from the request of the Veneto and Lombardy Regions to identify a constitutionally explicit limit in the definition of the "essential levels of care" (LEAs) in order to allow the

[45] The questions of constitutionality raised by the Veneto Region in relation to Articles 3, 117(3) and (4), 119(3) and (5) and 120 of the Constitution are declared unfounded. Articles 8(4), (6) and (10), and 46(6) and (7) of Legislative Decree no. 1. 24 April 2014, no. 66 (converted, with amendments, into Law no. 89 of 23 June 2014), which, in regulating the participation of the Regions in the public finance objectives, requires them to reduce expenditure on the purchase of goods and services by a set annual amount, starting from 2015, without prejudice to the possibility of alternative measures to contain current expenditure, defining the related procedural process (an agreement at the State-Regions Conference, implementing the decisions taken by the Regions during self-coordination, which can be replaced, in case of regional inertia, by a unilateral intervention by the State).

legislator to contain spending, and which highlighted how a persistent practice of linear cuts was likely to jeopardise the guarantee of essential levels, the court, while declaring the inadmissibility and groundlessness of the complaints, began to attach greater weight to the claims brought forth by the regions. According to the Court, the absence of criteria such as historical expenditure contributes to not finding the rules unconstitutional. Moreover, the discretion left to regional administrators, resulting from the setting of an overall expenditure ceiling, allows for the adoption of criteria, to be established through regional self-coordination, that take into account differentiation, allowing for cuts in areas where expenditure has proved unproductive compared to areas where expenditure has been efficient. With respect to the alleged violation of the principle of jurisprudence, according to which measures to contain public expenditure the burden of which falls on regions, provinces and municipalities, must include a set duration, the Constitutional Court points out that the constant recourse to extending the temporal scope of previous measures through yearly extensions to the original end date may be contrary to transitionality if repeated indefinitely. The use of this regulatory approach could, in fact, result in merely formal compliance to the principle of transitionality, in the absence of plausible and recognisable reasons that would prevent the legislator from redefining the overall framework of financial relations between the State, the regions and local authorities, according to the foreseeable time scales of budget cycles.

In Judgment no. 169 of 2017, the Constitutional Court highlights the need to preserve expenditure that is "constitutionally necessary" insofar as it is aimed at guaranteeing the right to health, in the context of the discussion between the State and the Regions on the financing of LEAs. Negotiations between the State and the Regions on the financing of the LEAs are "an open discussion on the needs and the costs that affect constitutionally necessary expenditure, taking into account the regulation and dimension of territorial taxation as well as the intertwining of state and regional competences in this delicate field"[46]. The question raised by the applicant regions (Veneto and Liguria) concerned the room to manoeuvre granted to the State legislature in reducing the resources allocated to fulfil a constitutionally guaranteed right (that is, the right to health). From this perspective, the Regions complained that the rules laid down by Decree-Law no. 78 of 2015 (and its implementing act) would introduce a "system of linear cuts" to health expenditure, reducing the scope of the guarantee of the essential levels of care and undermining the constitutional autonomy of the Regions (under articles 117, paragraph 3 and 4, 118 and 119 of the

[46] See paragraph 9.3.2 of the Considerations on points of law of Judgement no. 169 of 2017.

Constitution). In the context of the cuts in state funding of the SSN, the Regions highlighted the failure to apply the standard cost mechanism (provided for in Articles 25 to 32 of Legislative Decree no. 68 of 6 May 2011, "Provisions on the revenue autonomy of ordinary statute Regions and provinces, as well as on the definition of standard costs and requirements in the health sector") and the failure to take into account the differences between Italian Regions in meeting essential levels. The use of the linear cuts appeared, to the applicants, to be unreasonable inasmuch as it lacked any assessment of the adequacy of the resources allocated. A further claim raised by the Regions concerned the duration of the cuts introduced by Legislative Decree no. 78 of 2015 (as a result of the amendments introduced by conversion law no. 125 of 2015). According to the Regions, Legislative Decree no. 78 of 2015 permanently reduced the amount of state funding for the SSN, with a "cut" characterised by "generalised and indiscriminate methods" and without any time limitation. Such a "linear cut" would have jeopardised not only the guarantee (and quality) of health services, but also the autonomy of the Regions, which organise their provision for the benefit of users. The Constitutional Court rejected the complaint that the provisions aimed at regulating the expenditure reductions resulting from the decrease in state funding of the SSN were unconstitutional. However, part of the argumentation was based precisely on the limits that the state legislature encounters in reducing the expenditure intended to ensure the enjoyment of the LEAs and on the methods for regulating the relations between the state and the regions in these areas and with regard to the specific problem of covering costs. In this respect, the Court clearly affirmed that the expenditure cannot be reduced below the "minimum" extent necessary to ensure the effective enjoyment of the right to health. The Court did not address the basic objection raised by the regions concerning the excessive reduction of resources for the health sector, which allegedly undermines regional autonomy with regard to guaranteeing the right to health, but restricted itself to noting that, in any case, there remains manoeuvring room for the regions to choose between different options to "recover" part of the cut in state funding when implementing and detailing the measures. Lastly, the court also found that the additional concern raised by the regions regarding the "finality" of the cut in funding – that is, regarding the possibility that the cut would be repeated in subsequent years - was unfounded. In the Court's reasoning, the absence in the contested provisions of a time limit for the validity of the measures to contain expenditure does not automatically imply that they will be indefinitely in force. The "temporariness" of the measure makes it constitutionally admissible insofar as it ensures the

contribution of the Regions to the resolution of a serious situation of economic emergency for the country while "avoiding that such need becomes 'tyranny' by means of a stable duration of the sacrifices imposed on the territorial body and the administered community"[47].

3. The structure of the Italian national health service (SSN): constitutional and public law aspects

The SSN is structured around multiple levels of government. Despite a long series of incisive reforms, the system currently in force remains an evolution of the one established in 1978, which marked the full assumption of responsibility for health protection as envisaged in the Constitution[48]. In other words, the Italian health system is defined by the State being responsible for those functions that require a unitary exercise, and the local level being responsible for the vast network of services "on the ground" that are meant to guarantee the right to health.

The constitutional framework of competences and its evolution

Firstly, the organisational model depends clearly on the distribution of competences provided for by the Constitution, according to which both central and regional authorities are involved in the constitutional protection of health. This is enshrined both in the original wording of 1948 (giving the regional legislator powers over "public charitable work and hospital and health care") and in the text resulting from the reform of Title V by Constitutional Law no. 3 of 2001.

According to the latter, the competence over the "protection of health" is shared between the State and the Regions (Art. 117, paragraph 3, Const.; on the interpretations of the Constitutional Court that complicate the definition of the boundaries of the matter, see M. Luciani, *I livelli essenziali delle prestazioni in materia tra Stato e Regioni*, in Diritto alla salute tra uniformità e differenziazione. Modelli di organizzazione sanitaria a confronto, edited by E. Catelani, G. Cerina Feroni and M.C. Grisolia, Turin, Giappichelli, 2011, pp. 9-55, esp. pp. 15-16), while it is solely the State legislator that is in charge of "determining the essential levels of the services concerning civil and social rights that must be guaranteed throughout the national territory" (Art. 117, paragraph 2(m)). By doing so, the revision confirmed and elevated to the rank of constitutional prescription the set-up of competences already redesigned by the law on

[47] See paragraph 9.1 of the Considerations on points of law of Judgement no. 169 of 2017.

[48] A. Pioggia, *Diritto sanitario e dei servizi sociali*, cit., p. 83.

the basis of the threefold aim of regionalisation, corporate organisation and distinction between health policy and management in the 1990s, in the context of the rationalisation of the national healthcare system contained in Legislative Decree no. 502 of 1992.

As a result, it is now up to the national level of government to plan and monitor the service as a whole, to provide some of the funding and allocate the resources among the regions, and to determine the list of services by setting essential levels of service. On the other hand, the regional level of government is responsible for regulating and legislating on the supply system (albeit within the framework of the fundamental principles and within the limits set by the national legislator) as well as for a significant part of planning and control, as well as for exercising powers of guidance and appointments in respect of the providers and their executive management. Finally, the local level of government, which is now completely excluded from the management side, retains a role in regional planning and in the evaluation of services, while the provision of services is entrusted to a network of structures scattered throughout the territory that enjoy considerable autonomy.

3.1. *The category of essential levels of services*

Before the constitutional reform of 2001, the aim of guaranteeing uniformity in the protection of rights across the national territory was pursued by reserving to the State, in the exercise of its general legislative competence, the authority to regulate the provision of the services intended to satisfy those rights. After the reform, the pursuit of the same goal was ensured instead by identifying the services deemed necessary to satisfy those rights. Moreover, after 2001 the regions became responsible for determining the way in which structures and services are organised. This opened the way to a potentially significant diversification of regional health services[49], leading to a widening gap between regional contexts due to objectively diverse conditions and according to three basic organisational options[50].

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[49] The option to differentiate is recognised by the Constitutional Court, which quickly clarified that the rules concerning the provision of services and the organisation of structures do not fall within the scope of "essential levels" and therefore cannot be subject to pervasive regulation by the state legislator. See, in the field of health, Constitutional Court, Order no. 99 of 2 April 2009, paragraph 3 of the Considerations on points of law. In relation to other essential levels of care, see also Judgements no. 270 of 2003, no. 237 of 2007 and no. 371 of 2008.

[50] See section 3.3 below.

For the purpose of this analysis, what matters most is the possibility that differentiation may also extend to services that are not included among those deemed essential, provided that they are financed by the Region's own resources[51]. What the reformed Constitution does not tolerate, however, is falling below a certain standard of protection: in this sense, in order to safeguard the essential levels of services, it provides for the State to intervene in place of the regional bodies themselves (new art. 120). This provision demonstrates that, while pursuing the objective of giving responsibility to autonomous authorities, especially from a financial point of view, the State cannot completely renounce intervening in a matter as constitutionally important as health care. The central authority therefore retains pervasive powers, which may even take the form of genuine substitute powers, to ensure compliance with the fundamental principle of equality.

Another element that explains the involvement of all levels of government in the organisation and management of the health system is the link between the fundamental right to health recognised by art. 32 of the Constitution and the principle derived from art. 3. The pull towards equality is not only inevitable in a universalistic system and makes the health system one of the instruments of the overall redistributive design of the Constitution, but it also necessarily entails that the recognition of the autonomy of local communities does not supersede the equality of the conditions of protection of the right to health and access to care across the national territory. This necessity is reflected, on the one hand, in the pre-determination by law of the services intended to implement the right guaranteed by the Constitution (i.e., the "essential levels of services concerning civil and social rights" or LEP) and, on the other, in a limit to regional autonomy. The latter is exercised both through the Government's power of substitution, and by interpreting the setting of essential levels not as a "matter in the strictest sense, but as a competence of the state

[51] These are the "additional" levels of care, provided for by the Agreement on essential levels of health care between the Government, the Regions and the Autonomous Provinces, reached on 22 November 2001 at the State-Regions Conference. According to point 10: "Where the Region defines specific conditions for the provision of services included within the Essential Levels of Healthcare Assistance, with particular reference to the services referred to in annexes 2B and 2C [services excluded from the Essential Levels of Care or LEA – eds.], or identifies additional services in favour of its own residents, the charging of the same in healthcare mobility must take place on the basis of: an inter-regional framework agreement, which regulates these specific mobility compensation issues... [and] any specific bilateral agreements between the Regions concerned..."

legislature that can affect all matters"[52], even if they fall under regional competence – in other words as an intersectoral matter[53].

In particular, for the purpose of this research it seems worthwhile to reflect briefly on the controversial category of essential levels of services[54]. This is not only because, as will be seen, the decisions of the national legislator regarding their determination inevitably translate into fundamental allocative practices, reflecting what a society considers essential (and therefore, conversely, superfluous) for the purpose of health protection, but also because retracing the genesis and evolution of the formula helps to outline the evolution of the relationship between the right in question and the resources aimed at fulfilling it. First of all, it should be recalled that the formula used by the constitutional legislator in 2001 evokes concepts already anticipated by previous legislation, starting with Law no. 833 of 1978. Its Art. 3(2) provided that the State should define, in the framework of a National Health Plan, "the levels of health services that must in any case be guaranteed to all citizens" and that the allocation of resources should "tend to guarantee the levels of health services... in a uniform manner throughout the national territory, progressively eliminating the structural and performance differences between the Regions"[55], in order to implement the principles that inspired the SSN such as universality, equity, equal access to services and completeness of the services. It has been noted that this approach rests on "the idea of the instrumentality of resources to achieve uniformity of services and, therefore, of the subordination of resources to the needs of the latter"[56]. In short, the guarantee of essential levels of services emerged in the legal system as an obligation (albeit of a legislative nature) for public authorities that prevailed over considerations relating to the availability (or unavailability) of resources for financing services, since it was intended to guarantee uniformity in the protection of a constitutional right of primary

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[52] Constitutional Court Judgement no. 282 of 2002, paragraph 3 of the Considerations on points of law.

[53] This does not mean, however, that the state legislature can resort to it "in order to identify the constitutional basis of the regulation, by the State, of entire subject-matter sectors", since art. 117, paragraph 2, letter m), can be invoked only "in relation to specific services of which the state legislation defines the essential level of performance" (Constitutional Court Judgement no. 285 of 2005, paragraph 3 of the Considerations on points of law).

[54] See D. Messineo, *La garanzia del "contenuto essenziale" dei diritti fondamentali. Dalla tutela della dignità umana ai livelli essenziali delle prestazioni*, Turin, Giappichelli, 2012, esp. pp. 73 ff.

[55] Art. 51, par. 2 of Law no. 833 of 1978.

[56] A. Pioggia, *Diritto sanitario e dei servizi sociali,* cit., p. 60.

importance. In spite of the explicit mention of the possibility of this happening gradually ("progressively"), the expansive direction and the primacy of the egalitarian objective over economic and financial considerations was clear (because these services were to be guaranteed "in any case" to all citizens)[57].

A radical reversal of this approach occurred with the second reform (*riforma bis*) in the early 1990s. The principle enunciated by the enabling act, which associated the identification of "uniform and compulsory levels of health care" by the national legislature with the definition of a "minimum reference threshold, to be guaranteed to all citizens" but that threshold set "in accordance with the resources established by the financial law"[58], led to its implementing decree providing that the National Health Plan should indicate the "uniform levels of health care... with the specification of the services to be guaranteed to all citizens, in relation to the volume of available resources"[59]. In the light of the reform, it became possible to regard the levels of services, which until then had been objectives relatively independent from the means necessary to achieve them and intended to increase health protection, rather as a variable influenced by and subject to the conditions of public finance[60]. The aim of containing expenditure that emerges from this kind of relationship between the right to health and available resources was, moreover, not at all foreign to the reform, both because of the fiscal crisis that the country was then going through, and because of the prohibitions and constraints arising from the signing of the

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[57] Worth noting is the absence in the law of any reference to the compatibility of the appropriations aimed at satisfying the levels of services and progressively achieving uniformity in the earmarking with the overall financial situation, a reference that is consistently found, instead, from the 1990s onwards. As recalled by R. Balduzzi, *Livelli essenziali e risorse disponibili: la sanità come paradigma*, in La tutela della salute tra garanzie degli utenti ed esigenze di bilancio, edited by F. Roversi Monaco and C. Bottari, Santarcangelo Romagna, Maggioli, 2012, pp. 79-95, esp. p. 81, there were, however, also those who right from the start indicated these as minimum levels, anticipating the step backwards of the early 1990s.

[58] See Art. 1, paragraph 1(g) of Law no. 421 of 1992.

[59] See Art. 1, paragraph 4(b)of Legislative Decree no. 502 of 1992.

[60] In those years, the Constitutional Court was also moving in this second direction, admitting the possibility of a reasonable balance between the right to obtain health services from the State and the limitation represented by the resources actually available, therefore envisaging only a gradual implementation of the former (regarding the right to health, see Constitutional Court Judgement no. 445 of 1990). On the different evolutionary stages of the constitutional jurisprudence regarding the relationship between finance and rights, see F. Pallante, *Il Consiglio di Stato: dall'inderogabilità dei diritti (sociali) all'inderogabilità dell'equilibrio di bilancio?*, in Democrazia e Diritto, 2014, no. 1, pp. 175-189, as well as M. Fierro et al., *La tutela dei diritti e i vincoli finanziari*, in Quaderni di Giurisprudenza Costituzionale, May 2013, available at www.cortecostituzionale.it.

Maastricht Treaty and the project to establish an economic and monetary union in Europe. During the 1990s, therefore, both the interventions of the legislator and the public and academic debate fluctuated strongly between a reductive interpretation and one that called instead for the enhancement of the "performance levels" formula in a protective sense.

In this context, it would therefore fall upon the Constitutional Court to curtail the most dangerous developments for the protection of health, both by rejecting a purely economic interpretation of the formula[61] and by clarifying that economic and financial needs cannot have the effect of reducing "the irreducible core of the right to health protected by the Constitution as an inviolable sphere of human dignity"[62]. It will again be up to the Court to connect the jurisprudential category of the minimum or essential content of rights[63] with those that, after the transposition of the formula anticipated by the ordinary legislator in 1999 through the reform of Title V of the Constitution, will be designated as "essential levels of the services concerning civil and social rights." In the same judgment qualifying Article 117(2)(m) of the Treaty as an intersectoral matter, the Constitutional Court also states that "the legislator itself must be able to lay down the necessary rules to ensure that everyone, throughout the national territory, can enjoy guaranteed benefits, as the essential content of these rights"[64]. This seems to confirm that the services guaranteed through the determination of the essential levels are none other than the set of interventions aimed at reversing the guarantee of the essential content of these rights[65]. While it is certainly true that the Bindi reform of 1999 was innovative in qualifying the levels of services as "essential", it is more difficult to assess the impact generated by the decision to amend Article 1 of Legislative Decree no. 502 of 1992, in favour of a contextual identification of "essential and uniform levels of care" and the financial resources allocated to the SSN. According to the majority, this development marked a turning point doing away with the approach adopted in the

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[61] Cf. Constitutional Court Judgement no. 355 of 1993, paragraph 26 of the Considerations on points of law, on which see also 4.1 below.

[62] Constitutional Court Judgement no. 309 of 1999, paragraph 3of the Considerations on points of law.

[63] In spite of its function as a limit for the legislator, the jurisprudential category of the minimum essential content of rights has appeared to many to be too vague to truly exclude the irresponsibility of the legislator in its balancing activity between budgetary needs and constitutional rights (L. Principato, *I diritti costituzionali e l'assetto delle fonti dopo la riforma dell'art. 117 della Costituzione*, in Giurisprudenza Costituzionale, 2002, no. 2, esp. p. 1178).

[64] See, again, Constitutional Court Judgement no. 282 of 2002, paragraph 3 of the Considerations on points of law.

[65] C. Bottari, *Tutela della salute ed organizzazione sanitaria*, Turin, Giappichelli, 2011, p. 83.

riforma bis concerning the relationship between uniform levels and resources[66]. However, the break seems to stem above all from the concept of "essentiality", which "is ill-suited to define levels of care in a way that is subsequent and subordinate to the definition of the resources allocated to it"[67], placing the emphasis on the qualitative dimension of the services guaranteed and suggesting the primacy of safeguarding the fulfilment of health protection needs over financial considerations about the availability of means[68]. However, the decree contains equally serious concerns about the economic-financial sustainability of the system, so much so that, following the reform, the identification of services was expressly subordinated to "compliance with the financial compatibility defined for the entire public finance system in the Economic and Financial Planning Document"[69]. Thus, a "procedural link between the essential levels of care and financial resources" is established, which, having set in general and macroeconomic terms what resources are to be allocated to healthcare, removes the essential levels from discretionary rationing by the public authorities and in any case preserves their irreducible core, but allows them to be subject to compliance with the criteria of necessity and appropriateness[70]. Nor would it have been plausible to expect anything different, considering that it was precisely in those years that the single currency project was coming into being and that, with the adoption of the Stability and Growth Pact, national budgetary policies called for greater coordination that would have been thwarted by the impossibility of keeping expenditure (and with it, the deficit) within the set limits[71]. It can be said, then, that by referring to the core meaning of a constitutional

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[66] In this sense, for example, see A. Pioggia, *Diritto sanitario e dei servizi sociali,* cit., p. 60.

[67] C. Bottari, *Tutela della salute ed organizzazione sanitaria*, cit., p. 80.

[68] "In the logic of a phrase such as essential levels, there is an implicit need to not link the services to the availability of means, otherwise there would be no reason to define these levels as essential" (R. Balduzzi, *Livelli essenziali e risorse disponibili: la sanità come paradigma*, in La tutela della salute tra garanzie degli utenti ed esigenze di bilancio, edited by F. Roversi Monaco and C. Bottari, cit. Bottari, cit., pp. 79-95, esp. p. 79).

[69] Article 1, paragraph 3, of Legislative Decree no. 502 of 1992, as amended by Legislative Decree no. 229 of 1999, provides that: "the identification of the essential and uniform levels of assistance ensured by the SSN, for the period of validity of the National Health Plan, is carried out at the same time as the identification of the financial resources allocated to the SSN, in compliance with the financial compatibility defined for the entire public finance system in the Economic and Financial Planning Document."

[70] According to R. Balduzzi, *Livelli essenziali e risorse disponibili: la sanità come paradigma*, in La tutela della salute tra garanzie degli utenti ed esigenze di bilancio, edited by F. Roversi Monaco and C. Bottari, cit. Bottari, cit., pp. 79-95, esp. p. 89.

[71] For a discussion of these aspects, see section 4.

principle-value[72] , the third reform (*riforma ter*) simply aims to set a limit to the downward pressure on the levels of services (as minimum levels to be guaranteed) that the formulation of Legislative Decree no. 502 of 1992 risked producing. The juxtaposition of the term "essential" with the formula of the levels of care also, ideally, places the activity of determining levels of care on the same footing as that of finding and allocating resources.

The Legislative Decree implementing this "fiscal federalism" also moves in the same direction, where it provides that the determination of standard national health requirements must be consistent both "with the requirement deriving from the determination of the essential levels of care" (which would seem to open a window of opportunity to consider the needs of the population as a priority) and "with the overall macroeconomic framework and in compliance with the public finance constraints and the obligations assumed by Italy within the EU"[73] (confirming the link between the fulfilment of these requirements and economic considerations).

Finally, while in the last twenty years the essential levels of services have been made the object of constitutional jurisprudence mainly with a view to clarifying their consequences on the exercise of regional legislative competences or to uphold the procedure for their determination (an informal procedure agreed with the autonomies[74]), they are mentioned by the constitutional legislator in the framework of the revision made by Constitutional Law no. 1 of 2012 – a reference that is, in fact, inappropriate and contributes to the semantic uncertainty already surrounding the levels of services (guaranteed, essential, uniform, LEA, LEP, etc.)[75]. The law

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[72] R. Balduzzi, *I livelli essenziali in sanità*, in Le garanzie di effettività dei diritti nei sistemi policentrici, edited by G. Berti and G.C. De Martin, Milan, Giuffrè, 2003, esp. p. 247.

[73] Cf. art. 26, par. 1, of Legislative Decree no. 68 of 2011, implementing the delegation made by Law no. 42 of 2009.

[74] In fact, as is well known, the procedure for determining the essential levels has moved away from the path outlined by the primary legislation (which assigned it to the National Health Plan and, therefore, to the law), and has moved closer to, on the one hand, the framework of institutional cooperation between the State and the Regions (thus turning the levels into an expression of the agreement reached in this regard at the Permanent Conference, later transposed into a governmental decree) and, on the other, the regulatory level, since it was believed that the very nature of the source would have allowed greater flexibility and conformity of the levels to the evolution of the situation. The legislature (in Law no. 405 of 2001, but also in Article 54 of Law no. 289 of 2002) also confirmed the validity of this procedure. On this subject cf. M. Luciani, *I livelli essenziali delle prestazioni in materia tra Stato e Regioni*, in Diritto alla salute tra uniformità e differenziazione. Modelli di organizzazione sanitaria a confronto, by E. Catelani, G. Cerina Feroni and M.C. Grisolia, Turin, Giappichelli, 2011, p. 24.

[75] The uncertainty arises from the decision of assigning to the LEPs the concept of "fundamental functions", which identifies the core of characterising, essential and unavoidable functions of each autonomous level of local government; after 2001, the

commits the State, during adverse phases of the economic cycle or upon the occurrence of certain exceptional events, to contribute "to ensuring the financing, by the other levels of government, of the essential levels of services and of the fundamental functions inherent to civil and social rights"[76]. To this end, the reinforced law implementing the constitutional reform provides for the establishment of an Extraordinary Fund, financed by borrowing[77].

Although, at first glance, the origin of the Fund's financial provision may suggest a return to the "logic of the protection of the right as it may be", it should be noted that the hypothesis of indebtedness contemplated by the rule is not superimposable on the reduction of debt on the financial markets that typified the 1970s and 1980s for many reasons (including to meet the needs of health protection) and the construction of the national welfare system. In fact, the "recourse to debt" that should enable the State to help lower levels of government cope with extremely serious institutional financial shortages (which prevent them from performing their fundamental functions or guaranteeing inalienable levels of constitutional rights), besides being constrained by stringent procedural limits and recovery constraints, is inevitably limited[78]. Above all, this

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Constitution assigns these to the exclusive legislative competence of the State. On the confusion surrounding "performance levels", see recently R. Balduzzi, *Alcune conclusioni: la difficile equivalenza dei sottosistemi sanitari regionali*, in Diritto alla salute tra uniformità e differenziazione. Modelli di organizzazione sanitaria a confronto, edited by E. Catelani, G. Cerrina Feroni and M.C. Grisolia, Turin, Giappichelli, 2011, pp. 149-165, esp. pp. 153; as well as M. Luciani, *I livelli essenziali delle prestazioni in materia tra Stato e Regioni*, in Diritto alla salute tra uniformità e differenziazione. Health care organisation models compared, cit., pp. 9-33, esp. pp. 26-28.

[76] Cf. art. 6, par. 1(g) of Constitutional Law no. 1 of 2012, which defines the timeframe, subject matter and guiding principles for the enactment of the reinforced law provided for by the new Article 81, paragraph 6 of the Constitution.

[77] This is Article 11 of Law no. 243 of 2012. The Fund's resources must also be distributed taking into account the impact on the individual regions of the unfavourable economic situation or exceptional events beyond the control of the State such as serious financial crises or natural disasters with serious repercussions on the financial situation.

[78] In fact, Article 11 provides that the Extraordinary Fund shall be "fed by a share of the resources deriving from recourse to borrowing permitted by the correction, in light of the effects of the economic cycle, of the balance of the consolidated income statement." The latter is a complex operation, regulated by European legislation, which leads to subtracting certain budget items from the differential result between the revenues and expenditures of the public administration as a whole, depending on the trend of the economic cycle and therefore independently of the discretionary activity of the Government. As a result of the correction, the pro-cyclical components of revenue (such as the increase/decrease in VAT or personal income tax revenue due to the increase/decrease in consumption or income) or expenditure (such as the increase in social security expenditure as the cycle worsens) are not taken into account for the compliance with the budgetary target. This implies, in good

procedure does not follow the logic of the need for health (as it would if, for example, it could be activated in the face of an increase in the demand for services included in the essential levels as a result of new high-cost treatments following scientific discoveries), but rather that of the economic cycle, since it is only legitimate in an unfavourable economic situation[79]. Significantly, some have seen in the rules of the Extraordinary Fund a missed opportunity to deal with the financing of LEPs even under ordinary economic conditions, going so far as to hypothesise that this could lead to a reversal of the relationship between financial balance and social rights and therefore propose that a fixed share of the revenue is earmarked for the fulfilment of social rights[80].

3.2. *The national level of government*

At the national level, the central role is played by the Ministry of Health, an administrative body that has seen its share of reorganisations (being split off several times and merged with the ministries responsible for labour, social security and social policies), but which has maintained the same name since 2009[81]. The Ministry is assigned "the functions pertaining to the State in the field of human health protection, coordination of the national health system, veterinary health, health protection in the

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times, fewer resources to ensure balance and, in bad times, more spending possibilities, which can be financed by borrowing on the financial markets without preventing the achievement of the European budget target.

[79] It is in fact a "cyclical correction", which only operates in downturns (while in the favourable phases of the cycle, the Region and local authorities are called upon, pursuant to Article 12 of Law 243/2012, to contribute to the reduction of the overall national debt), made to the financing framework already outlined by the legislation on fiscal federalism, whose relationship with the Equalisation Fund pursuant to Article 119, paragraph 3, of the Constitution is controversial but complementary (F. Guella, *Il Patto di Stabilità interno, tra funzione di coordinamento finanziario ed equilibrio di bilancio*, in Quaderni Costituzionali, 2013, no. 3, pp. 607-608).

[80] G. Grasso, *Il costituzionalismo della crisi. Uno studio sui limiti del potere e sulla sua legittimazione al tempo della globalizzazione*, Naples, Editoriale scientifica, 2012, pp. 111 and 112.

[81] The Ministry of Health was established as an autonomous ministry under this name in 1958. Since the end of the 1990s a number of legislative initiatives have been undertaken aimed at merging it with similar ministries (cf. articles 45 and 55 of Legislative Decree no. 300 of 1999, repealed prior to entry into force of Legislative Decree no. 217 of June 12, 2001, implemented by Law no. 317 of 2001). Nevertheless, its autonomy has always been preserved, except for the brief interlude brought about by the ministerial reorganisation provided for in the 1999 Bassanini reform by Law no. 244 of 2007, until its repeal by Law no. 172 of 2009, after only one year.

workplace, hygiene and food safety"[82]. In particular, as regards the coordination of the health system, Law no. 172 of 2009 specified that this function must be carried out "in agreement with the Ministry of the Economy and Finance for all matters of a financial nature", thus supporting a general tendency towards attributing a prominent role to the Ministry of Health within the government, including in this area of government activity[83]. From a purely organisational point of view, the Ministry of Health currently consists of twelve directorates-general[84] , coordinated by a secretary-general[85].

Support bodies of the Ministry of Health

As regards the central level of government, and especially in order to fulfil its control functions over the SSN, the Ministry relies on the advice and cooperation of numerous bodies and agencies created over the years, which are subject to its direction and supervision.

These include a number of prominent national public bodies, such as:

- Istituto Superiore di Sanità (ISS): created by the fascist regime in 1934, it is an independent body with mainly advisory, research, training and control functions, under the supervision of the Ministry (see www.iss.it).
- Italian Medicines Agency (AIFA): an autonomous public body, established by Article 48 of Legislative Decree no. 269 of 2003, implemented by law no. 326 of 2003, which operates under the direction of the Ministry of Health and the supervision of both that ministry and the Ministry of Economy and Finance (see www.agenziafarmaco.gov.it). It is responsible for "high-level advisory tasks and functions to the Government and to the Permanent Conference for Relations between the State, Regions

[82] Art. 47-bis, par. 2 of Legislative Decree no. 300 of 1999.

[83] G. Della Cananea, *La finanza e i beni*, in Il sistema amministrativo italiano, edited by L. Torchia, Bologna, Il Mulino, 2009, pp. 329-361, esp. p. 329.

[84] These are the DGs in charge of: prevention; planning; health professions and human resources; medical devices and the pharmaceutical service; research and innovation in health; supervision and safety of care; animal health and veterinary drugs; hygiene and safety of foodstuffs and nutrition; digitalisation, health information system and statistics; collegiate bodies for health protection; communication and European and international relations; personnel, organisation and budget (cf. articles 1 and 3-14 of the organisational regulations issued by Prime Ministerial Decree (D.P.C.M.) 11 February 2014, no. 59, as well as the organisation chart of the Ministry, available at http://www.salute.gov.it/portal/ministro/p4_5_1.jsp?lingua=italiano&label=org&menu=organisation).

[85] See Article 2 of D.P.C.M. (Prime Ministerial Decree) no. 59 of 11 February 2014.

and Autonomous Provinces, in the field of pharmaceutical policies with reference to research, corporate investments in research and development, production, distribution, scientific information, regulation of promotion, prescription, monitoring of consumption, monitoring of adverse effects, reimbursement and prices" (Art. 48 (1)), as well as the exercise of regulatory activities for pharmaceuticals (including the management of registration and marketing procedures for pharmaceuticals for human use), the management of pharmaceutical expenditure, drafting the list of reimbursable pharmaceuticals (Article 48(5)) and clinical trials of medicinal products (Art. 12(9), Law no. 189 of 2012).

Other support bodies include the "republican" administrations, i.e., administrative organisations operating in areas where state and regional competences intersect and which, therefore, are functional and require the cooperation of both levels of government (since the "protection of health" is a matter for which the State and the Regions have concurrent competence, examples of public bodies of this type are particularly frequent in the field of health; cf. A. Pioggia, *Diritto sanitario e dei servizi sociali*, cit., p. 96). These include, for example:

- the National Agency for Regional Health Services (Age.Na.S.): established in 1993 as a body with autonomous legal status but subject to the supervision of the Ministry, its tasks include "supporting regional activities, comparative evaluation of costs and returns of services rendered to citizens and reporting dysfunctions and waste in the management of personal and material resources and supplies, transfer of innovation and experiments in health matters" (art. 5 of Legislative Decree no. 266 of 1993; see also www.agenas.it). Among other responsibilities, the Agency monitors and may propose changes to the organisation and delivery of services, including on the basis of an HTA approach.
- the National Institute for Health Promotion of Migrant Populations and Combating Poverty-related Diseases (INMP), created in 2007 and formalized by Law 189/2012 as an autonomous public body supervised by the Ministry; it is responsible for promoting assistance, research and training activities for the health of migrant populations and combating poverty-related diseases and it is the national centre of reference for transcultural mediation in health (www.inmp.it).
- Experimental Zooprophylactic Institutes (IZS), which, through their 10 headquarters and 90 peripheral diagnostic sections, carry out specialised scientific research in the veterinary field, ascertain

the health status of animals, monitor the wholesomeness and quality of foodstuffs of animal origin and livestock farms and collaborate in the performance of veterinary hygiene and public health functions (www.iizzss.it).

- the Institutes for Hospitalisation and Care of a Scientific Nature (IRCCSs), governed by Legislative Decree no. 288 of 2003 as amended.

Both the Zooprophylactic Institutes and the Scientific Hospitalization and Care Institutes are operational bodies of both the State and the Regions, are part of national networks coordinated by the Ministry and are subject to a comprehensive power of control and appointment by the central administrative leadership. IRCCSs, in particular, also play an important role in the provision of services, as hospitals of excellence with national importance that combine diagnostic and therapeutic hospital care with research activities of the highest level. They can have either a public or private legal status and, in the first case, they can be transformed into national foundations at the proposal of the Region. They are subject to regional control, as well as the supervision and appointment of a scientific director by the Ministry of Health (see E. Griglio, *Gli istituti di ricovero e cura a carattere scientifico*, in Manuale di diritto sanitario, edited by R. Balduzzi and G. Carpani, Bologna, Il Mulino, 2013, pp. 267-282).

Finally, the Ministry relies on a large number of joint bodies and other bodies with functions related to health protection, the number and structure of many of which were subject to the reorganisation ordered by Presidential Decree no. 44 of 2013 for spending review purposes. The main ones include: the Higher Health Council (*Consiglio Superiore di Sanità* - CSS); the Technical Health Committee; the Technical Committee for Animal Nutrition and Health; the National Food Safety Committee (dealing with risk assessment in the food chain); the National Centre for Disease Prevention and Control (coordinating body between the Ministry of Health and the Regions for surveillance, prevention and timely response to emergencies); the National Centre for against Animal Diseases and Emergency; the Medical Commission of Appeal; the Committee for the Evaluation and Verification of Public Investments; and the Single Guarantee Committee for Equal Opportunities, the Enhancement of Workers' Welfare and Against Discrimination.

On the other hand, the following bodies were not affected by the recent reorganisation (for more information on this, the reader can visit the Ministry's website): the Crisis Unit; the National Commission for Continuing Medical Education and the National Observatory on Training in General Medicine; the Advisory Board on the protection and knowledge of

fertility and prevention of infertility; the National Commission for the elimination of measles and rubella: the Hepatitis Prevention Working Group and the Polio Working Group; the Single Commission on Dietetics and Nutrition; the National Multi-sectoral Committee on Breastfeeding; the Interdisciplinary Technical Operating Table for the Promotion of Breastfeeding; the National Diabetes Commission; the Commission for the Prevention of Blindness; the Consultative Commission for Plant Protection Products; the National Observatory for Freelance Professionals working in public healthcare; the LEA Committee; the Technical Group on Dentistry; the Commission for Settlements of Damage from Blood, Blood Products and Infectious Diseases and compulsory vaccinations; the Commission for the Protection of Animals for Breeding and Slaughter and the Advisory Committee on Veterinary Medicinal Products; the Scientific Committee on Experimentation; the Working Table for Assistance to Persons in a Vegetative State and Minimally Conscious State; and the Permanent Technical Advisory Council for Transplants. The list includes, particularly with reference to the purposes of this research, the Higher Council for health (*Consiglio Superiore di Sanità* - CSS), the Technical Health Committee and the Standing Committee for the Verification of the Delivery of Essential Levels of Care.

The CSS (art. 7 of Presidential Decree no. 44 of 2013 and art. 4 of Legislative Decree no. 266 of 1993) is a highly prestigious technical advisory body of the Ministry, established in 1865. Among other tasks, it draws up mandatory opinions on central government regulations and international health agreements, on the refusal and withdrawal of registration of medicinal products, and on changes to be made to the list of narcotics. At the request of the Ministry, it can also examine matters concerning public health and propose, on its own initiative, studies and enquiries into relevant problems and events, as well as draft measures concerning public health and standards for hospital buildings.

The Technical Health Committee (articles 3 and 4 of Presidential Decree no. 44 of 2013) is a collegiate body established in 2013, chaired by the Minister of Health and composed of 171 members (some appointed by the Minister of Health, others by various public and private institutions), structured in 13 sections (including one for the definition and updating of the essential levels of care and one for medical devices) that meet as deemed necessary. It has taken over the tasks previously assigned to several existing commissions and committees.

In particular, the Standing Committee for the verification of the provision of Essential Levels of Care (LEA Committee) is responsible for checking that the services to be provided are consistent with the resources

made available by the SSN and for verifying that the Essential Levels of Care are provided with appropriateness and efficiency in the use of resources. Envisaged by the State-Regions Agreement of 23 March 2005, the LEA Committee was established by decree of the Minister of Health of 21 November 2005 and is composed of four representatives of the Ministry of Health, two representatives of the Ministry of Economy and Finance (MEF), one representative of the Department for Regional Affairs of the Presidency of the Council of Ministers and seven representatives of the Regions appointed by the Conference of Presidents of the Regions and Autonomous Provinces. It avails itself of the technical support of agencies such as Age.Na.S. and AIFA and monitors provision on the basis of information from the New Health Information System (*Nuovo sistema informativo sanitario* - NSIS). As will be seen, pursuant to the State-Regions Agreement for the three-year period 2005-2007, the Regions' access to additional funding from the State budget is made conditional on the positive outcome of the certification carried out by this Committee, with final verification by the Technical Board for the verification of compliance established at the MEF.

Finally, for the sake of completeness, it may be useful to mention other bodies, known as “Cabine di regia” (steering committees), operating within the Ministry of Health; these became more common in the 2000s. This was the case for the committee set up in 2002 as a “permanent body with the function of guiding, governing, monitoring and controlling the development and launch of the new health information system” (cf. art. 4 of the Framework Agreement between the Ministry of Health, the Regions and the Autonomous Provinces of Trento and Bolzano of 22 February 2001 for the development of the NSIS, as well as art. 16 of the 2014-2016 Health Pact, which extended its period of operation), but also, more recently, the Steering Committee on health professions (created in 2014), as well as the HTA Steering Committee (on the functions and functioning of this committee, see section 6.1.3 below) and the Steering Committee for monitoring the Pact, provided for in articles 26 and 28 of the 2014-2016 Health Pact.

All of these are joint coordinating bodies, composed of representatives of the ministries responsible for the matter in question, representatives of the regions or of the Conference of the Regions and possibly representatives of the other entities involved (as in the case of the oldest joint body, the Union of Health Professionals).

3.3. *The regional level of government and the network of health authorities*

As noted earlier, the process that emerged (albeit not without contradictions[86]) from the reforms of the 1990s and the recognition of important legislative powers being assigned to the Regions paved the way for the differentiation of the SSN at local level, especially from an organisational point of view. This process is closely connected to the plan first drawn up by the ordinary legislator and then by the constitutional one to implement "fiscal federalism". In fact, it is impossible to separate the organisation of the Regional Health Service (SSR), which absorbs most of the resources of the Regions, and the question of their financial autonomy in terms of income and expenditure. Leaving aside for the moment the aspect of financing, it should be noted that the gap between the regional models has arisen in practice because of an inescapable factual precondition and three different basic organisational models[87].

The precondition concerns the heterogeneous nature of health needs, which are influenced by variables such as the demographic and socio-economic composition of the population in the different regional territories, specific geographical risk factors, the quality and environment of life.

The remaining factors leading to differentiation are linked to the discretionary choices available to the regional administration: the possibility to opt for an open or programmed accreditation system for private facilities[88]; the involvement of the local health authority (ASL) in the production and delivery of services; and the level of user participation in the financing of services.

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[86] The doctrine is unanimous in identifying 1999 as a momentous time against the much broader openings to regional autonomy brought about by Legislative Decree no. 502 of 1992. The reason for this step backwards was mainly of a financial nature (hence it has been said that "it is evident that the 'sword of Damocles' of the balanced budget hangs over the reforming intention of the new order"; C. Bottari, *Tutela della salute ed organizzazione sanitaria*, cit.)

[87] The identification of which is due to G. Cilione, *Diritto sanitario*, Rimini, Maggioli, 2005, pp. 54-55.

[88] This, for example, influences both access to benefits and the conditions of eligibility: while in the first case waiting times decrease but expenses increase, expenditure control is better in planned systems. See S. Donati, *La scelta del luogo di cura tra autodeterminazione del paziente ed esigenze di equilibrio finanziario nel comparto sanitario regionale*, in L'erogazione della prestazione medica tra diritto alla salute, principio di autodeterminazione e gestione ottimale delle risorse sanitarie, edited by M. Sesta, Santarcangelo di Romagna, Maggioli, 2014, pp. 459-489, esp. p. 464.

Nonetheless, it is generally believed that the regional organisational models are moving in a cohesive and centripetal direction, with the notable exception of the Lombardy Region which, especially at the outset, embraced a path of differentiating for its SSR[89].

At present, the Regions are responsible for regulating and controlling the supply system, for a significant part of planning and monitoring, and for exercising guiding powers and making appointments concerning the supplying entities and their management[90]. These functions are mostly exercised directly by the political and management bodies of the region. Within the framework of the fundamental principles and within the limits set by the national legislator, the Regional Council (*Consiglio Regionale*) exercises the broad legislative powers laid out in the *riforma bis* and *riforma ter* and following the constitutional revision of 2001 (organisation and functioning, institutional structure, principles for the organisation of health authorities and for the provision of services[91]). The Regional Cabinet (*Giunta Regionale*) can be involved in the production of secondary legislation: it exercises the function of policy-making with respect to the authorities, monitors and evaluates the performance of the services and the management of the authorities, and determines the allocation of resources within the SSR. Both bodies then cooperate in regional planning.

However, some regional competences can also be delegated to regional bodies or aggregate structures, subject to the regulatory and steering powers of the region. This is the case, for instance, with the Regional Health Authorities[92], performing technical and regulatory support tasks, and the bodies in charge of the procurement of goods and services and other technical-administrative activities, as is the case with the Regional Technical Administrative Support Authorities in Tuscany (ESTAR)[93] and the Supra-zonal Federations in Piedmont[94].

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[89] According to R. Balduzzi, *Alcune conclusioni: la difficile equivalenza dei sottosistemi sanitari regionali*, in Diritto alla Salute tra uniformità e differenziazione. Modelli di organizzazione sanitaria a confronto, edited by E. Catelani, G. Cerina Feroni and M.C. Grisolia, cit., pp. 149-165, esp. pp. 159-162.

[90] See Art. 2, paragraph 1 and 2, of Legislative Decree no. 502 of 1992, as amended.

[91] See Art. 2, paragraph 2-*sexies*, of Legislative Decree no. 502 of 1992, as amended.

[92] For example: Liguria (www.arsliguria.it), Tuscany (www.arsliguria.it) (www.ars.toscana.it), Emilia-Romagna (assr.regione.emilia-romagna.it), Veneto (www2.arssveneto.it), Abruzzo (www.asrabruzzo.it) and Campania (www.arsan.campania.it); until 2012, Piedmont also had one (ARESS). In most cases, these agencies have organisational and operational autonomy and are subject to the direction and control of the regional government, for which they provide technical and regulatory support to the SSR.

[93] As from 1 January 2015, in Tuscany ESTAR (www.estar.toscana.it) replaced the previous management entities (*enti di gestione di Area Vasta*, ESTAV) in order to carry out technical and administrative activities such as the management of competition and selection

The Regional Council and the Regional Government are also supported, particular in health planning, by consultative bodies such as consulting commissions and committees, in order to guarantee the extensive participation of service users and professionals in the sector[95]. In fact, the law requires that citizens, trade unions, voluntary organisations and organisations for the protection of rights be consulted on the implementation of health plans and the verification of the results achieved[96].

This being said, it is useful to reiterate that the obligation to guarantee the basic levels of services concerning social rights (and in particular health rights) falls both on the State and on autonomous authorities. It derives from the attribution to the Republic (and not only to the State apparatus) of the duty to protect health pursuant to Article 32 of the Constitution and from the inclusion of health protection among the matters of shared competence. As a result, it is the Regions that oversee the actual fulfilment of the essential levels and, more generally, the supply of healthcare services, although under the control of the central authority (through the Standing Committee for the Verification of the Supply of Essential Levels of Care). In practice, this is done through Health Authorities (*Aziende Sanitarie*), regional bodies endowed by law with considerable autonomy, which are responsible for receiving and satisfying users' requests for health care.

Health Authorities are instrumental for the management of SSN health services. They were created to overcome the dysfunctions that emerged during the period in which Law no. 833 of 1978 was in force and to ensure

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procedures for the recruitment of staff and the procurement of goods and services.

[94] According to the establishing regional law (art. 2 Regional Law no. 3 of 2012), these are six private law limited liability consortia to which all regional health authorities of the area belong, in charge of managing assets and purchases, planning investments and evaluating health technologies.

[95] The following are involved in the socio-healthcare planning process: the Permanent Conference for socio-healthcare planning (art. 6 Regional Law no. 18 of 2007, which refers to Art. 2, paragraph 2-bis, of Legislative Decree no. 502 of 1992), a consultative body through which local authorities contribute to the definition and evaluation of regional health and social-health policies; the Confederation of Local Health Authority Mayors (art. 7, R.L. no. 18 of 2007), a steering and control body that ensures a link between the Region and the Local Health Authorities; the Committee of District Mayors (art. 8, R.L. no. 18 of 2007), made up of the mayors of the municipalities comprising the district; the universities located within the Region (art. 9), as well as users, professional unions, voluntary organisations, associations for social protection and promotion, social cooperatives and other third sector subjects, through the opening to the technical contribution made by operators, professional associations and accredited scientific societies (art. 10).

[96] Art. 14, par. 2, of Legislative Decree no. 502 of 1992, as amended.

the rationalisation and control of health expenditure, both goals pursued by the legislator via granting autonomy to the service providers in the management of health services and giving them direct responsibility for the resulting outcomes. Moreover, the establishment of Health Authorities (by Legislative Decree no. 502 of 1992 and Legislative Decree no. 229 of 1999) is connected to the reform undertaken at the time for the entire public administration system with a view to guaranteeing impartiality through a two-level decision-making process. According to this process, the political side sets guidelines and objectives in light of the needs of the community and its orientation with regard to those that must be viewed as a priority, while the management side works within this given framework to achieve those goals in compliance with the principle of legality, employing the resources in the best possible way and guaranteeing their effective and economic use[97].

The configuration of the health authorities through which the SSN operates is therefore the result of a decision made by the State legislator and represents a fundamental principle of "health protection", which is intangible for the regional legislator. However, the regional authority can autonomously determine the organisational principles of its own SSR and regulate the organisation and functioning of the local health authorities and hospitals in its territory (art. 2(2) of Legislative Decree no. 502 of 1992, as amended).

The organisation of health authorities

Health authorities are organised into local health unit authorities (*Azienda Unità Sanitaria Locale*), which were replaced following the 1992 reform by Local Health Units (*Unità Sanitaria Locale* – USL) through which municipalities were directly involved in the provision of health services. Health authorities are organised into Local Health Authorities (*Azienda Sanitaria Locale* – ASL), which are regional bodies; they are public law organisations and are granted autonomy with regard to administrative, organisational, assets, accounting, decision-making and technical management (art. 3, paragraph 1 and 1-bis of Legislative Decree no. 502 of 1992, as amended). They are also endowed with entrepreneurial autonomy, which they exercise by laying down internal organisational rules by means of a private law act, and have the institutional task of ensuring the provision of LEAs on behalf of the Region. The law of the State

[97] F. Merloni, *Amministrazione "neutrale" e amministrazione imparziale (A proposito dei rapporti tra "politica" e "amministrazione")*, in Diritto Pubblico, 1997, no. 2, pp. 319-351, esp. p. 329.

guarantees a basic homogeneous model, requiring each authority to include certain roles and bodies (among which, most notably: the General Manager, the Management Board and the Board of Auditors; cf. art. 3(1-quarter) of Leg. Decree no. 502 of 1992, as amended by Leg. Decree no. 229 of 1999, as well as E. Menichetti, *L'organizzazione aziendale: le aziende unità sanitarie locali, le aziende ospedaliere e le aziende ospedaliero-universitarie*, in Manuale di diritto sanitario, edited by R. Balduzzi e G. Carpani, cit., pp. 231-266). Each authority is organised into districts and departments, and there is a tendency towards the vertical integration of functions, bringing together under its umbrella services aimed at both local health care and hospital care.

From an operational standpoint, ASLs are typically organised into Departments (art. 17-bis, Leg. Decree no. 502 of 1992 as amended). This form of organisation, introduced for public hospitals in 1978 in order to optimise medical specialisation while overcoming organisational fragmentation, can be implemented according to different criteria for the aggregation of operational units, which are chosen by the Regions (E. Menichetti, *L'organizzazione aziendale*, cit., pp. 246-247). However, the law provides that each ASL should set up a Prevention Department, in order to guarantee the protection of collective health through activities of promotion, prevention and improvement of the quality of life (art. 7-bis of Legislative Decree no. 502 of 1992 as amended). As regards the districts, which must instead ensure primary health and social-health assistance, these are local branches of the ASL corresponding to a minimum population of at least 60,000 inhabitants, the health objectives of which determine the amount of funding reserved for each district (art. 3-quater to 3-sexies of Leg. Decree no. 502 of 1992, as amended). In this regard, the Balduzzi decree (art. 1 of Leg. Decree no. 158 of 2012, converted into Law no. 189 of 2012), in the context of the reorganisation of local assistance, provides that the district must ensure the provision of care services throughout the day and on all days of the week (24 hours a day, 7 days a week), through mono-professional ("functional territorial aggregations") or multi-professional ("complex primary care units") organisational forms.

In order to fulfil the obligations arising from hospital care, the regions operate not only through the ASLs, but also through other public health authorities and private entities (art. 3, paragraph 1 of Legislative Decree no. 502 of 1992, as amended). Secondary care can be provided either by the hospital centres of the ASLs, which are part of the overall organisation but have economic and financial autonomy and may be merged for functional purposes (art. 4, par. 9, of Legislative Decree no. 502 of 1992), as well as by Hospital Authorities (*Aziende ospedaliere* - AOs). The latter are health

authorities that differ from the ASLs in that their activity is limited to the provision of health services (whereas the ASLs are also in charge of procuring services from the outside, for instance from general practitioners (*medico di medicina generale* - MMG) who provide primary care); they deal exclusively with the provision of specialist, hospital and rehabilitation services (whereas the ASLs are responsible for all the services charged to the SSN); they are remunerated through the DRG tariff system. The creation of AOs (public law organisations with budgetary, financial, managerial and technical autonomy) followed from the right to separate hospital establishments from the USL, introduced by the *riforma bis* in 1992. The AO "constitutes the exception to the rule that favours the vertical integration of functions (territorial and hospital) within the same ASL" (E. Menichetti, *L'organizzazione aziendale*, cit., p. 253). Their subjective autonomy is justified by the possession of certain structural prerequisites (national or inter-regional importance; precise motivation and specific needs; presence of a plurality of centres within the ASL; integration of the activity in the regional planning and collaboration with the ASLs) and the requirements specified in art. 4, paragraph 1-bis, of Legislative Decree no. 502 of 1992 (as amended).

There is also no shortage of public hospitals engaged in the provision of health services alongside research and/or teaching: these include, first and foremost, the *Istituti di ricovero e cura a carattere scientifico* (scientific research institutes for hospitalisation and care) mentioned above, as well as the Hospital-University Authorities (*Aziende ospedaliero-universitarie* - AOU) governed by Article 2 of Legislative Decree no. 517 of 1999 and by special agreements between region and university.

In addition to these entities, secondary care can be provided by hospitals connected to ecclesiastical institutions/bodies or non-Catholic denominations (which are equivalent to public facilities and provide services charged to the SSN, within the limits established by specific agreements pursuant to the combined provisions of Art. 1(18) and 8-quinquies of Legislative Decree no. 502 of 1992 and Legislative Decree no. 112 of 2008, converted by Law no. 133 of 2008), or by accredited nursing homes and private facilities. The involvement of private entities in the sector is a long-standing feature of the system, since it was essentially religious or private hospitals that, prior to the creation of the SSN, provided most healthcare services, but this trend has waxed and waned over the last forty years (cf. Aicardi, *La sanità*, in Trattato di diritto amministrativo. Diritto amministrativo speciale, edited by S. Cassese, Milan, Giuffrè, 2003, volume I, pp. 625-710, esp. pp. 665 ff). Following the strong restrictions imposed by Law no. 833 of 1978 (providing for an agreement with the SSN

and in light of the discretionary nature of the measure), the *riforma bis* left it up to the user to choose between public and accredited private hospitals, provided that the latter meet certain quality standards. However, the excessive growth of expenditure led the legislator to reintroduce an authorisation system (for the creation of the structure and the provision of healthcare services) based on a discretionary approach that does not automatically oblige the SSN to remunerate those facilities, except within the limits of the agreements entered into with the private structures and the ceilings set by the regional planning. This is known as the "three (or four) A system" (Authorisation, Accreditation, contractual Agreements) and it was first introduced by a series of financial laws (in 1995, 1996 and 1997) and then formalised by the *riforma ter*, with Legislative Decree no. 229 of 1999 (in this regard, see also articles 8-bis to 8-sexies of Legislative Decree no. 502 of 1992, as amended).

3.4. *The local level of government*

Although now completely excluded from management, the local government level retains a significant role in the regional planning and in the evaluation of the delivery of services. Local authorities carry out these tasks mainly through the Standing Conference for Regional Health and Social Planning. The Conference is a consultative body at the regional level, which is provided for in general terms by Article 2(2-bis) of Legislative Decree no. 502 of 1992 and then regulated in detail by each region. Its members include the mayor (or the President of the Council of Mayors, depending on the size of the ASL[98] district) and representatives of regional associations of local authorities (such as ANCI and UPI); the regional law may provide for the involvement of other parties (presidents of provinces and mountain communities, representatives of the region or bodies such as universities, presidents of the regional order of doctors, etc.). The Conference issues opinions within the framework of the procedures for the adoption of the Regional Health Plan and the verification of the work of the DGs of the hospital authority, with respect to the revocation or non-confirmation of which the body also has the power of initiative. In addition, the law assigns to the mayor (or to the Conference of Mayors) the task of defining guidelines for the programmatic implementation of the activities of the ASLs in the territory of the municipality, in order to meet the needs

[98] At the ASL level, local health needs are expressed by the mayor of the municipality in which the district is located or by the Conference of Mayors, with powers similar to those of the Permanent Conference for regional health and social-health planning.

of the population, and the transmission of evaluations and proposals in this area to the DG and the region[99].

The municipalities are also responsible for planning the local pharmaceutical supply according to criteria of equity in the distribution and accessibility of the service and, in some cases, for their direct management[100]. Lastly, in their dual role as the head of the local administration and as government officials, mayors may order compulsory medical examinations and involuntary commitments (Article 1(6), Law no. 180 of 1978), issue extraordinary emergency orders in case of health emergencies (ex art. 50, paragraph 5, Leg. Decree no. 267 of 2000) and exercise the power of authorisation related to health matters (e.g., as regards the serving of food and drink to the public).

In the Tuscany regional context, however, the powers of local authorities are organised differently: public law consortia have been created between municipalities and ASLs (*Società della Salute,* or Health Societies - SDS), in order to achieve the integration of the health system with the social welfare system through the association of integrated territorial health, social and health care activities[101].

4. *Health financing in Italy*

In order to address the issue of health financing, it is first necessary to appreciate the breadth of this task by analysing some data. In Italy, the total expenditure on health is slightly lower than the European average (9.2% of gross domestic product, as compared to an average of 9.6%)[102]. For more than 50 years, an upward trend has been observed in all the developing countries due to economic development and the consequent increase in life expectancy and rise in living standards, scientific progress in the medical field, increases in manufacturing costs due to diminishing replacement of labour, and to the broadening of the notion of health[103]. Of this total expenditure, 78% comes from public resources, while the remaining 22%

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[99] Art. 3, par. 14, Legislative Decree no. 502 of 1992, as amended and supplemented; on this basis, other powers are given to the mayors in addition to planning, namely the power to review budgets and to check and control the general performance of the services provided by the ASLs.

[100] Article 2 of Law no. 467 of 1978.

[101] SDSs are provided for in Tuscany by Regional Law no. 40 of 2005.

[102] P. Armeni and F. Costa, *La spesa sanitaria: composizione e evoluzione*, in L'aziendalizzazione della sanità in Italia: Rapporto OASI 2015, edited by CERGAS-Bocconi, Milan, Egea, pp. 143-183, esp. p. 149.

[103] See the analysis by P. Vineis and N. Dirindin, *In buona salute. Dieci argomenti per difendere la sanità pubblica*, Turin, Einaudi, 2004, esp. pp. 83-125.

is private expenditure paid by the users, mainly in the form of co-payments (17.8%)[104].

Public health expenditure is mainly financed by general taxation through national and regional tax revenues. The data show that the share of public expenditure is also on the rise; however, since the 1980s, its growth has been considerably lower than that of private expenditure, which has increased strongly due both to the greater willingness to pay as a result of increased wealth[105] and to the need to compensate for cuts in public spending[106]. In addition, public health expenditure has grown less than other areas in terms of overall state social expenditure, including social security in particular, which accounts for almost 70% of the total[107]. Particularly since 2009, the public revenue component of total healthcare expenditure has slowed down considerably, due to the economic crisis on the one hand and the need to recover from past deficits on the other[108].

In spite of the unfavourable economic situation prevailing in the period under consideration (2011-2016), the sector has repeatedly produced an overall surplus, although some regions have continued to show a deficit[109].

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[104] The data (referring to 2012) are those collected by the World Health Organisation and reported in *European Observatory on Health and Policies, Italy: Health System Review*, in Health Systems in Transition, vol. 16, 2014, no. 4, p. 41, but were also confirmed by the November 2015 OASI Report (P. Armeni and F. Costa, *La spesa sanitaria: composizione e evoluzione*, in L'aziendalizzazione della sanità in Italia: Rapporto OASI 2015, edited by CERGAS-Bocconi, cit., pp. 143-183, esp. p. 150, tab. 4.3). The remaining 4% or so of private expenditure is expenditure on health insurance.

[105] P. Vineis and N. Dirindin, *In buona salute. Dieci argomenti per difendere la sanità pubblica*, cit., esp. pp. 98-99.

[106] This is reported, on the basis of ISTAT data and with reference above all to the severe cuts of the 1990s, by Senato della Repubblica XII Commissione (Igiene e Sanità), *La sostenibilità del Servizio sanitario nazionale con particolare riferimento alla garanzia dei principi di universalità, solidarietà ed equità*, February 2015, available at http://www.agenas.it/la-relazione-della-12a-commissione-del-senato-sullabililita-del-ssn, p. 14.

[107] P. Armeni and F. Costa, *La spesa sanitaria: composizione e evoluzione*, in L'aziendalizzazione della sanità in Italia: Rapporto OASI 2015, edited by CERGAS-Bocconi, cit., pp. 143-183, esp. p. 154.

[108] The annual increase went from 6% to 0.7%, according to the data from C. Carbone and F. Longo, *Evidenze del Rapporto OASI e prospettive future*, in L'aziendalizzazione della sanità in Italia: Rapporto OASI 2015, edited by CERGAS-Bocconi, Milan, Egea, pp. 1-24, esp. p. 1.

[109] The surplus was achieved in the financial years 2012-2013 and confirmed in 2014. In 2014, the regions with deficits were Sardinia (€227 million) along with Liguria, Molise, the Autonomous Province of Bolzano, Tuscany and Valle d'Aosta (all together accounting for the remaining €123.6 million in deficits). On the other hand, the surplus was particularly significant in some of the regions with a recovery plan, including Lazio (544 million euro) and Campania (293 million euro). The data are taken from: Corte dei Conti sezioni riunite in sede di controllo, *Rapporto 2015 sul coordinamento della finanza pubblica*, May 2015, pp.

This is the result of the expenditure containment policies implemented in the 1990s, and more significantly since the early 2000s, of the introduction of specific recovery plans to eliminate the deficit. Here the reader is referred to the discussion in section 4.1 of this chapter, as well as chapter 4 in relation to the recovery plan in Piedmont from 2010 to 2017.

In Italy, expenditure containment policies[110] have affected the financing of health care mainly through repeated cuts, covering the local deficits through taxation and increasing cost-sharing for medicines, specialist services and non-urgent access to emergency rooms by citizens. On the cost side, cost containment policies have focused on personnel costs, price controls on drugs and medical devices with the introduction of specific expenditure ceilings, the revision of tariffs paid to service providers and budgets of the relevant structures, as well as reducing the number of hospital beds. Finally, it should be noted that, despite the concerns expressed in society and the media that often surround the issue, a comparison of the trend of Italian health expenditure with that of the main European countries would seem to confirm the sustainability of the SSN, while the financial restrictions are having negative repercussions on the ability to meet health needs and on the working conditions of health workers[111].

Sources

As regards the regulation of health financing, it is not possible to provide a full outline of the numerous regulatory interventions that have affected the SSN since its establishment here (although numerous publications have done so, including in particular N. Viceconte, *Il finanziamento del servizio sanitario nazionale* in Manuale di diritto sanitario, edited by R. Balduzzi and G. Carpani, cit., pp. 371-390; R. Balduzzi, *La sanità italiana alla prova del federalismo fiscale*, Bologna, Il Mulino, 2012; E.D. Ruffino, *La sanità al bivio: ragionamenti tra globalizzazione e localismo in uno scenario di crisi finanziaria*, Milano, Gruppo24ore, 2011). However, it is worth mentioning some of the most relevant aspects that have contributed to the definition of the current financing system and the decision-making processes that govern the finding and allocation of resources, ultimately enabling the guarantee of the individual right to health.

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177 and 192.

[110] The measures are also summarised in Senato della Repubblica XII Commissione (Igiene e Sanità), *La sostenibilità del Servizio sanitario nazionale con particolare riferimento alla garanzia dei principi di universalità, solidarietà ed equità*, February 2015, p. 8.

[111] Ibid, passim but especially pp. 9 and 44.

First of all, some broad distinctions should be defined. Some provisions, such as art. 51 of Law no. 833 of 1978, articles 11-13 of Legislative Decree no. 502 of 1992 or Legislative Decree no. 446 of 1997, have been exclusively concerned with the financing of the health system, while the most recent interventions are characterised by a more general approach addressing the overall issue of the troubled financial autonomy of the Regions: for example, Legislative Decree no. 56 of 2000 (so-called federalism without amending the Constitution), Constitutional Law no. 3 of 2001, as well as the enabling act on fiscal federalism (no. 42 of 2009) and its implementing decrees. In the wake of the attempts to rationalise health spending undertaken in the 1990s, the reforms of the early 2000s sought to break this line, transforming the previous financing system into a federal system. However, since 2001, on top of these interventions a complex system of agreements between the State and the Regions and by numerous regulations (mostly contained in law decrees or in the annual financial/stability laws) has been superimposed that has profoundly altered the financing mechanisms identified by the constitutional and ordinary legislator. On the whole, this evolution has led from a system of derivative finance to a rewarding and negotiated derivative finance, which arose from the compensations made necessary by the persistent failure to implement fiscal federalism (N. Viceconte, *Il finanziamento del servizio sanitario nazionale* in Manuale di diritto sanitario, cit., pp. 371-390, esp. p. 378). Lastly, this framework was affected by the constitutional reform that, in April 2012, introduced into the Constitution the principle of balancing the budgets of the State, local and regional authorities and all public administrations, incorporating at the highest level of domestic legislation suggestions that were already fully binding on the basis of European secondary legislation and the national rules that conformed to it (and which, in fact, had already taken on a crucial relevance including, in the health sector specifically, the so-called "Domestic Stability Pact").

4.1. *The evolution of health financing between derivative finance and spending constraints*

In order to fully understand the scope of the most recent measures, it should be remembered that the SSN originally arose in a context of derivative finance and transfer, in which it was the central authority (the State) that provided all the resources necessary for the fulfilment of the tasks entrusted to the Republic by the Constitution, including the guarantee of the right to health. In this context, Law no. 833 of 1978 stipulated that the law approving the State budget would determine, on an annual basis,

the appropriation intended to finance the SSN; this appropriation, the *Fondo Sanitario Nazionale*, or FSN (National Health Fund)[112], was then distributed among the newly established Regions and, from them, among the Local Health Units on the basis of indices and standards that the law prescribed to progressively achieve uniformity in supply throughout the national territory[113], and which were based on historical regional expenditure. The allocation of resources at that stage was based on the level of expenditure in previous years and thus, ultimately, on the budgetary needs of the administrations. This system tied the funds transferred by the State to the specific purpose of guaranteeing the right to health, reserving to the State the coverage of any health deficits, but it ended up charging to general taxation the (not always sound) decisions of the Regions, which were guaranteed reimbursement of the expenses incurred, on the basis of a list and without any incentive to contain spending.

It is therefore evident that the 1992 reform aimed to assign greater responsibility to the local entities, by providing autonomy to the Regions in matters related to their respective SSRs and this including from a financial point of view, by providing for the distribution of the social security contributions paid by the employers on the basis of the criterion of the taxpayer's tax domicile[114] and by reducing the burden of the FSN on the State budget[115]. However, this goal was achieved instead mainly through the introduction of the Regional Tax on Productive Activities (IRAP), which became the main source of financing for regional health expenditure in 1998, and a regional surtax on state personal income (IRPEF) that the Regions were to set within a predetermined range[116]. Moreover, Legislative Decree no. 502 of 1992 introduced, for the first time, a distinction between the resources earmarked for financing the uniform levels of healthcare services (coming from the FSN, from welfare contributions and from the revenues of the Local Health Authorities) and those aimed at financing additional services that the Regions had individually chosen to provide. The latter were to be financed through a regional self-financing system through taxes or co-payments charged to the recipients of diagnostic and specialist services[117].

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[112] Art. 51, par. 1, Law no. 833 of 1978.

[113] See paragraphs 2 and 4 of the same Article.

[114] Art. 11, par. 1 and 9 of Legislative Decree no. 502 of 1992.

[115] Article 12 of Legislative Decree no. 502 of 1992.

[116] See Articles 1 and 36 of Legislative Decree no. 446 of 1997, which simultaneously abolished employers' social security contributions.

[117] Cf. art. 13, paragraphs 1 (need to provide for the financial effects derived from the

With the introduction of IRAP, just a few years after the *riforma bis*, the FSN was left solely with the task of balancing the differences in revenues deriving from the unequal economic development of the Italian Regions, setting aside the much more ambitious task of guaranteeing the financing of uniform levels of services.

Preceded by an ineffective attempt to overcome the criterion of historical expenditure and to link financing to the concrete needs of each regional community[118], the first explicit measure aimed at doing away with the system of state transfers can be traced back to Legislative Decree no. 56 of 2000, which, anticipating the constitutional reform of Title V, aimed at reorganising public health expenditure in a federal sense. The abolition of the FSN as provided for in Article 1 had important consequences in terms of resource allocation[119]: it has been noted that, as a result, "healthcare...

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provision of additional levels of assistance, from the adoption of organisational models that differ from the one used as a reference for the determination of the per capita share of the distribution and from the management deficit of USLs and AOs), 2 and 3 (possibility of raising taxes for this purpose and introducing forms of cost-sharing for users) of Legislative Decree no. 502 of 1992. The reasoning of the Constitutional Court shortly after the regulation came into force is interesting: in fact, in declaring the partial unconstitutionality of the first paragraph (specifically the part in which it introduced an "immediate and total exemption" for the State from the repayment of the deficits produced by the USLs and AOs, which were instead left to regional self-financing), the Court anticipated a balancing act between social rights and budgetary needs that was to become very relevant again today, with the right to health prevailing. Considering that the regional resources would probably have been absorbed, in a first phase of regionalisation, above all by the effort to bridge the gap between the uniform levels and the actual situation of the USLs and therefore would not have been available to make up the deficits of the USLs, the Court declared the absence of a "discipline that aims to make the transition to the new system and the operation of the same regime gradual - and therefore controllable, in terms of regional finances, and adequate, in terms of services... in view of the constitutional requirement to preserve, together with the balance of the state budget (art. 81 of the Constitution), the financial balance of regional budgets (art. 119 of the Constitution) and an acceptable qualitative and quantitative level of services aimed at satisfying the interests of individual citizens and the community that are constitutionally relevant (art. 32 of the Constitution)" (Constitutional Court Judgement no. 355 of 1993, paragraph 26 of the Considerations on points of law).

[118] Article 1, paragraph 34 of Law no. 662 of 1997 had modified the mechanism of the so-called dry quota, used to distribute the funds of the FSN among the Regions, transforming it into a weighted quota, which no longer took into account the state of the regional healthcare structures and inter-regional mobility (article 12 of Legislative Decree no. 502 of 1992), but rather, above all, the resident population, the frequency of healthcare consumption, the regional mortality rates, and indicators relating to particular local situations that could influence healthcare needs.

[119] The abolition of state transfers was, however, compensated by the same provision (cf. 4) through regional co-participation in some state taxes and excise duties, such as VAT, IRPEF and excise duty on petrol. In this regard, it is worth noting the potential regressive effect associated with this share of healthcare funding by some studies (due to the greater

entered the competition against other [regional] functions for the allocation of resources, with the disappearance, albeit with some limitations, of the allocation constraints for the sums allocated to the Regions "[120].

In other words, while previously the Regions were to guarantee the right to health on the basis of a binding allocative (and political) choice at the national level, since 2000 the choice of the levels of financing for health was (at least theoretically) entrusted to the Regions, and became subject to competition against other regional sectors. As a result, the decision on the distribution of available funds remained a political matter (now potentially in conflict with the orientation of the majority supporting the central authority), but consequent to the use of the regional tax lever and the unequal conditions of socio-economic development among the Regions, it opened the way to the differentiation not only of the organisational models but also of the levels of financing of healthcare on the national territory. In order to rebalance these inequalities and allow for the coverage of the needs of communities with an insufficient fiscal capacity, Legislative Decree no. 56 of 2000 envisaged, starting from 2013, the establishment of a national equalisation fund for purposes of interregional solidarity, financed by a share of VAT revenues[121], which, however, like most of the reform's provisions, remained unimplemented for a long time[122].

The history of the complex path towards the implementation of federalism, envisaged in 2000 and then resumed and developed by the

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propensity to consume of the lower income social strata), which emphasise the contrast between this effect and the redistributive and solidaristic purpose that characterises the social inspiration of the Constitutional Charter (see A. Pioggia, *Diritto sanitario e dei servizi sociali*, cit., p. 140).

[120] N. Viceconte, *Il finanziamento del servizio sanitario nazionale*, in Manuale di diritto sanitario, edited by R. Balduzzi and G. Carpani, Bologna, Il Mulino, 2013, pp. 371-390, esp. p. 374.

[121] See Article 7 of Legislative Decree no. 56 of 2000, implementing Enabling law no. 133 of 1999. Until then, however, the criterion for allocating resources would still be based, although gradually decreasingly, on historical expenditure because the State undertook to guarantee to the Regions the difference, if any, between the abolished transfers and any new revenues.

[122] On the Fund, see V. Ceriani, *Federalismo, perequazione e tributi*, in Rassegna Tributaria, 2002, no. 5, pp. 1664 ff; see also, for considerations on the function and the more recent history of the State's equalisation intervention, as outlined by Law no. 42 of 2009, M. Belletti, *I "livelli essenziali delle prestazioni" alla prova del "coordinamento della finanza pubblica". Alla ricerca della perequazione perduta*, in L'erogazione della prestazione medica tra diritto alla salute, principio di autodeterminazione e gestione ottimale delle risorse sanitarie, edited by M. Sesta, Santarcangelo di Romagna, Maggioli, 2014, pp. 101-146; G. Arachi and A. Zanardi, *La perequazione delle Regioni e degli enti locali*, in La finanza pubblica italiana. Rapporto 2009, edited by M.C. Guerra and A. Zanardi, Bologna, Il Mulino, 2009.

reform of Title V of the Constitution, is intertwined with that of the Domestic Stability Pact (the "local" version of the Stability and Growth Pact - SGP), which, since 1997, has bound Italy to comply with European rules on public debt and deficit[123]. The Domestic Stability Pact consists of a series of limits to local and regional finance that, starting from Article 28 of Law no. 448 of 1998, the State financial laws (which later became stability laws) have gradually been integrated, corrected and developed[124].

Since its inception, the Domestic Stability Pact has aimed above all to keep adherence to EU objectives for the overall national public finance balances from being jeopardised by budgetary policies conducted (with increasing autonomy and without any responsibility vis-à-vis European institutions) by Regions, Provinces and local authorities. The incidence of health expenditure on the regional budgets explains quite readily why, at first, it received specific attention within the framework of the Domestic Stability Pact[125] and how this was soon translated into a series of autonomous "Health Stability Pacts" (known, more simply, as "Health Pacts") that characterise the most recent phases in the history of SSN financing.

The Health Pacts consist of three-year financial and planning agreements through which the Government and the Regions, within the framework of a shared governance of the healthcare system, agree on the level of financing of the SSN for the period of the agreement, with the dual purpose of guaranteeing the Regions the financial resources necessary for medium-term planning and ensuring compliance with the overall public finance targets that European regulations place on the State[126]. While the

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[123] See in this regard, with particular reference to the consequences on the financing of the SSN, E. Jorio, *Diritto sanitario*, Milan, Giuffrè, 2006, esp. pp. 217-224.

[124] L. Cassetti, *Patto di stabilità interno e livelli essenziali dei diritti* in Le procedure finanziarie in un sistema multilivello, edited by G. Di Gaspare and N. Lupo, Milan, Giuffrè, 2005, pp. 81-102, esp. p. 81.

[125] In fact, Article 28 of Law 448 of 1998 immediately clarifies that the objectives of reducing the annual deficit and the debt-to-GDP ratio also apply to the revenue and expenditure of the Regions for healthcare (par. 4), and initiates a specific assessment process (paragraph 9) and detection of causes (paragraph 10) of SSN deficits. With the diversification at the beginning of the 2000s of the obligations to balance and contain healthcare expenditure with respect to overall spending, the domestic stability pact now excludes this component from its application, which is absolutely pre-eminent in regional healthcare spending; its regulation is instead referred to the specific agreements reached on healthcare matters (cf. art. 1, par. 1 of Legislative Decree no. 347 of 2001, converted by Law no. 405 of 2001).

[126] The agreements therefore coordinate national and regional health policies, with a view to achieving greater efficiency in the use of resources and respecting the deficit and debt constraints of all public administrations. The first of these agreements expressly states, in this regard, that the agreement is motivated by the "need to define a stable framework for

influence of European constraints on healthcare had already been acknowledged by the 1999 *riforma ter*[127], from 2001 to the present it has been, above all, these agreements defined by the State-Regions Conference that have guaranteed the financing of healthcare "in compliance with the financial compatibility defined for the entire public finance system"[128].

The agreements immediately disregarded the provisions of Legislative Decree no. 56 of 2000, reintroducing the state transfers and the National Healthcare Fund that had been abolished by the reform; however, they also confirmed the willingness of the Regions to assume responsibility for covering subsequent healthcare deficits, thus continuing in the direction already indicated by art. 4, paragraph 3 of Law no. 405 of 2001.

The system of derivative finance that emerged (yet again) was to a large extent a system of rewarding and sanctioning by subsequent agreements. On the one hand, the Agreements and Pacts for Health reserved access to additional state funding[129] or 30-year loans for the extinction of the

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the evolution of the public resources allocated to the financing of the SSN, which, taking into account the commitments undertaken with the Stability and Growth Pact, allows for an improvement in efficiency by rationalising costs" (State-Regions Agreement of 8 August 2001 on health matters). Moreover, the Agreements - which have been explicitly called Health Pacts only since 2006 - have always been implemented by means of a specific regulatory provision: for example, the State-Regions Agreement of 8 August 2001 was implemented by Legislative Decree no. 347 of 2001 and by the financial law for 2002 (Law no. 448 of 2001); the Agreement of 23 March 2005 by Law no. 311 of 2004 (financial law 2005); the 2007-2009 Health Pact by Law no. 296 of 2006 (financial law 2007) and the 2010-2012 Health Pact by Law no. 191 of 2009 (2010 Stability Law). For the three-year period 2013-2015, given the urgency of public finance measures, the Government anticipated the new Pact, which was ultimately never approved, with Article 17 of Legislative Decree no. 98 of 2011. Lastly, on 10 July 2014, the 2014-2016 Health Pact was signed and transposed into the Stability Law for 2015 (Law no. 190 of 2014). For this reconstruction, see Ministero dell'economia e delle finanze Ragioneria Generale dello Stato, *Il monitoraggio della spesa sanitaria*, Rome, 2015, esp. pp. 3-4, available at http://www.rgs.mef.gov.it/_Documenti/VERSIONE-I/Attivit--i/Spesa-soci/Attivit-monitoraggio-RGS/2015/IMDSS-RS02_15_09_2015.pdf.

[127] This took place through the introduction of art. 19-ter in Legislative Decree no. 502 of 1992 which, with the same purpose as that already pursued by art. 28(10) of Law no. 448 of 1998 (to verify the levels of assistance, assess the economic-management results and identify the causes of any deficits), assigned to the Ministry of Health the task of identifying reference values regarding the use, cost and quality of services on the basis of which to assess the work of the Regions (paragraph 1); as well as for the Regions and Age.Na.S. to investigate the causes of regional deviations from these values and to reorganise, requalify or strengthen the SSRs accordingly (par. 2), on the basis of operational programmes negotiated between the parties (co. 3).

[128] Art. 1, par. 3, of Legislative Decree no. 502 of 1992, as amended.

[129] In this sense, see, for example, among all the provisions adopted in the 2000s, points 1 and 2 of the Agreement of 8 August 2001 cited above.

consolidated healthcare debt[130] for those Regions that comply with the Domestic Stability Pact and are willing to comply with the various reporting and monitoring obligations provided for therein; on the other hand, they have linked failure to achieve a financial balance to measures such as the automatic removal from office of the general managers of public health bodies[131], the removal and disqualification from office of the presidents of regions in serious financial distress[132], the limitation of regional autonomy in setting IRAP (regional tax on productive activities) and IRPEF (personal income tax) surcharge rates[133] and above all, after Law 311 of 2004, the drafting of specific Health Deficit Recovery Plans (*Piani di rientro dal disavanzo sanitario*, or "PDR"), which are ultimately guaranteed by the commissioning of the regional bodies in default under Article 120 of the Constitution.

It should be noted that the gradual deficit reduction and the achievement, starting in 2012, of operating surpluses is largely due to the warning procedure and the signing of Deficit Recovery Plans (compulsory by law in case of economic imbalances of 7% or higher since 2005, and 5% since 2010), as well as to their largely compulsory and coercive implementation[134]. However, there is no shortage of criticism against the effects of the far-reaching curtailment of regional financial autonomy, which have been substantially justified by constitutional jurisprudence in the name of the need to rebalance the public accounts[135], and in favour of a revision of the PDR system in order to improve the centrality of health policies and, therefore, the quality objectives of health services that have

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[130] Art. 2, par. 46-49, of Law no. 244 of 2007 (2008 Budget Act).

[131] Cf. art. 3, par. 2(c) of Legislative Decree no. 347 of 2001, converted into Law no. 405 of 2001.

[132] See in this regard Legislative Decree no. 149 of 2011 and, on this, A. Cerruti, *Incandidabilità alle cariche pubbliche*, in Aggiornamento enciclopedico 2015, Torino, Utet Grandi Opere, 2015.

[133] The limits in this regard have varied over time and range from the temporary freezing of the right to increase them by art. 3, paragraph 1 (a) of Law no. 289 of 2002 (2003 Budget Act), pending the implementation of fiscal federalism, to the possibility of their automatic increase up to the maximum (Law no. 311 of 2004, 2005 Budget Act) and beyond the maximum (Law no. 296 of 2006, 2007 Budget Act), and the obligation for Regions that fail to comply with the recovery plan to apply fixed increases to IRAP and the IRPEF surcharge beyond the maximum limits set by law (Law no. 191 of 2009).

[134] See, for example, M. Bellentani and L. Bugliari Armenio, *La logica dei piani di rientro e il difficile equilibrio tra autonomia e responsabilità*, in Manuale di diritto sanitario, edited by R. Balduzzi and G. Carpani, Bologna, Il Mulino, 2013, pp. 391 ff; E. Jorio, *I piani di rientro dal debito sanitario e i rischi della legislazione dell'emergenza*, in Sanità Pubblica e Privata, 2009, no. 5, pp. 10 ff.

[135] See T. Cerruti, *I piani di rientro dai disavanzi sanitari come limite alla competenza legislativa regionale*, in Rivista AIC, 2013, no. 4, available at www.rivistaic.it.

always characterised the sector, albeit to a lesser extent than purely financial considerations[136]. In fact, the discipline relating to the PDR is permeated by and finds constitutional justification "only in the close connection between economic-financial verification and the verification of the provision of essential levels of care", which must be ensured (also for the citizens of a Region with a deficit) through a complex system of obligations concerning actions to be undertaken, information to be provided, measures to be communicated and authorisations or approvals from the government[137]. The parallel consideration of both financial imbalances and any shortcomings in the provision of services is now explicitly provided for by Law no. 191 of 2009. This law calls for inclusion in the Deficit Recovery Plan of both: measures to rebalance the provision of essential levels of care, in order to bring it in line with the National Health Plan and with the decree of the President of the Council of Ministers concerning the setting of essential levels of care, and measures to ensure a balanced health budget in each of the years covered by the plan[138].

This, together with the introduction, as of February 2011, of the Technical Monitoring Structure (STEM) which operates within the State-Regions Conference[139], seemed to indicate the prevalence of verification of compliance with the levels of services (i.e., the LEA Committee under Article 9 of the same agreement)[140] over concerns relating to the "technical-financial table" (permanent group for the verification of regional compliance as per article 12 of the agreement of 23 March 2005 on

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136 In this sense Senato della Repubblica XII Commissione (Igiene e Sanità), *La sostenibilità del Servizio sanitario nazionale con particolare riferimento alla garanzia dei principi di universalità, solidarietà ed equità*, February 2015, available at http://www.agenas.it/

137 R. Balduzzi, *Livelli essenziali e risorse disponibili: la sanità come paradigma*, in La tutela della salute tra garanzie degli utenti ed esigenze di bilancio, edited by F. Roversi Monaco and C. Bottari, cit., pp. 79-95, especially pp. 91-92.

138 Art. 2, par. 77, of Law no. 191 of 2009.

139 For an overview of the functions and tasks of the Structure, see the hearing of the President at the State-Regions Conference: *Presidenza del Consiglio dei Ministri Conferenza permanente per i rapporti tra lo Stato, le Regioni e le Province autonome di Trento e Bolzano, Indagine conoscitiva "La sfida della salute tra nuove esigenze del sistema sanitario e obiettivi di finanza pubblica", Audizione della dott.ssa Laura Pellegrini Presidente STEM*, Rome, 16 September 2013.

140 See R. Balduzzi, *Livelli essenziali e risorse disponibili: la sanità come paradigma*, in La tutela della salute tra garanzie degli utenti ed esigenze di bilancio, edited by F. Roversi Monaco, C. Bottari, cited above, pp. 79-95, esp. p. 92, pp. 79-95, specifically p. 92, identifying the reasons for this prevalence both in a cultural factor (the lack of assimilation of the profound meaning of the contextual determination of the levels of services and the available resources), and in the practical circumstance of the easier nature of economic-accounting control with respect to that of the provision of thousands of services pertaining to differentiated and specific organisational contexts.

healthcare matters). In addition to the measures already mentioned, subsequent financial laws and decrees from recent decades, particularly in the years of economic crisis, have finally introduced numerous and varied provisions aimed at rationalising and containing healthcare spending. They have had a particularly strong impact on staff expenditure (leading to significant reductions, especially in the Regions subject to a recovery plan, by freezing salaries and staff turnover[141]) but they have also translated into the setting of ceilings on local pharmaceutical expenditure[142], on expenditure for health care services, hospital pharmaceutical expenditure[143] and expenditure for the purchase of medical devices[144], as well as the reduction ex lege of hospital beds[145] and, in terms of costs, reductions in the financial amounts and services envisaged in existing contracts for the procurement of services and the supply of goods and services[146] and in the maximum rates for specialist outpatient and inpatient services provided by facilities accredited by the SSN[147]. The slowdown of

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[141] This is, according to the Senate, one of the main critical factors for the SSN. While the constraints imposed by the legislator on the expenditure for the person have allowed considerable savings, they "have also produced a reduction in the ability to respond to the needs of the population (increase in waiting lists and limitations of supply, especially in the socio-health component), an increase in the average age of employees (36% of doctors are over 55 years old and 30% of nurses are over 50 years old), an increase in workloads and overtime shifts of staff, as well as a series of problems including widespread ill-health among operators and an increasingly widespread habit of resorting to various forms of outsourcing circumventing the regulations on the freeze" (Senato della Repubblica – XII Commissione (Igiene e Sanità), *La sostenibilità del Servizio sanitario nazionale con particolare riferimento alla garanzia dei principi di universalità, solidarietà ed equità*, February 2015, available at http://www.agenas.it/la-relazione-della-12a-commissione-del-senato-sulla-sostenibilitadel-ssn, p. 41).

[142] For the first time, the ceiling was set at 13% of total healthcare expenditure (Article 5 of Legislative Decree no. 347 of 2001, converted by Law no. 405 of 2001), but subsequent revisions have brought it to the current 11.35% (Article 15, paragraph 3, of Legislative Decree no. 95 of 2012, converted by Law no. 135 of 2012). The Stability Law for 2016 (Article 1, paragraph 569, of Law no. 208 of 2015) specified that purchases of high-cost innovative drugs are to be excluded from this ceiling, except to the extent that they exceed the State appropriations allocated to the specific fund for reimbursement to the Regions for the purchase of innovative drugs.

[143] On the basis of Article 15 of Legislative Decree no. 95 of 2012, this is instead equal to 3.5 per cent of total health expenditure (paragraph 4).

[144] Article 17 of Legislative Decree no. 98 of 2010 sets it, as of 2014, at no more than 4.4 per cent of total health expenditure.

[145] Article 15, paragraph 13(c) of Legislative Decree no. 95 of 2012 sets this at 3.7 beds per 1,000 inhabitants, of which 0.7 for post-acute rehabilitation and long-term care (as compared to 4 beds per 1,000 inhabitants previously).

[146] Art. 15, par. 21 of Legislative Decree no. 95 of 2012.

[147] Art. 15, par. 15-17, of Legislative Decree no. 95 of 2012 and Decree of 18 October 2012 of

expenditure was possible mainly as a result of analysis and monitoring activities, which identified the causes, and the consequent containment measures implemented by the national legislator, especially since 2007[148]. This containment is due to the Health Pacts 2007-2009 (State-Regions Agreement of 5 October 2006) and 2010-2012 (State-Regions Agreement of 3 December 2009), which marked a fundamental paradigm shift from a system based on "regional expectations of the repayment of deficits" by the State to a system based on the "principle of strong accountability" for both financially virtuous Regions and those Regions with high deficits[149].

Constitutional case law on the constraints of state legislation on regional budgetary policies

The trend towards entrusting greater responsibility to autonomous local authorities for the management of their finances runs through the whole of the 2000s and, as noted, involves both legislation (ordinary and constitutional) and the Constitutional Court's jurisprudence (on this, see: *Il federalismo fiscale alla prova dei decreti delegati*, Proceedings of the 57th Administration Science Conference, Varenna, 22-24 September 2011, Milan, Giuffrè, 2012; *Il federalismo alla prova: regole, politiche, diritti nelle Regioni*, edited by L. Vandelli and F. Bassanini, Bologna, Il Mulino, 2012).

The Court, in particular, has often supported this tendency in order to make up for the inertia of the legislator in the implementation of the federalist system envisaged by the reform of Title V of the Constitution, which profoundly innovated the rules on the financial autonomy of the Regions in terms of revenue and expenditure. This has led to a significant jurisprudential "rewriting" of the reform (the main elements of which are clearly illustrated in T. Cerruti, *La Corte costituzionale, arbitro del contenzioso tra Stato e Regioni, fra esigenze di contenimento della spesa pubblica e tutela dell'autonomia regionale*, in Federalismi, 2013, no. 20, available at www.federalismi.it, pp. 6-10).

The failure to adopt the legislation for the coordination of public finance provided for by the new Article 119 of the Constitution, has allowed legislation arising from, on the one hand, from the Agreements between the

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the Minister of Health.

148 A complete review can be found in Ministero dell'economia e delle finanze Ragioneria Generale dello Stato, *Il monitoraggio della spesa sanitaria*, Rome, 2015, esp. pp. 26-27.

149 Ibid, p. 5. On this subject, see also F. Guella, *La sussidiarietà nelle tendenze alla regionalizzazione del patto di stabilità e al rafforzamento del sistema di controllo e incentivazione*, in Istituzioni del Federalismo, 2013, nos. 3-4, pp. 823-855.

State and the Regions of the 2000s and, on the other, from the provisions to decrease public expenditure contained in the financial laws of those years, to pass the scrutiny of constitutional jurisprudence (A. Brancasi, *La finanza regionale e locale nella giurisprudenza costituzionale sul nuovo Titolo V della Costituzione*, in Diritto Pubblico, 2007, no. 3, pp. 857-902). According to the Court, this inertia has prevented the full exercise of regional tax autonomy (Constitutional Court judgment no. 376 of 2003), which was already limited by the constraints on budgetary policies introduced by the State to counteract expenditure trends and to achieve the budgetary objectives set by European rules due to the general slowdown in economic growth. These constraints were considered legitimate because "the need to ensure the universality and comprehensiveness of the healthcare system in our country has clashed, and still clashes, with the limited financial resources that can be allocated annually to the healthcare sector, within the framework of a general planning of interventions in welfare and of a social nature" (Constitutional Court judgment no. 267 of 2007, paragraph 16 of the Considerations on points of law).

The constraints in question require the legislator to balance the need for an equal guarantee of the right to health and the need to make health expenditure compatible with the limited availability of resources (Constitutional Court judgment no. 149 of 2010). The Court also considers it legitimate that this is to be carried out, de facto, on the basis of a set of agreements between the State and the regions, since their transposition into State legislation gave them a binding character. In fact, these State regulations are "the expression of a fundamental principle aimed at containing public health expenditure and, therefore, the expression of a related principle of coordination of public finance" (Constitutional Court judgment no. 100 of 2010, paragraph 3.2.1Considerations on points of law).

What is most relevant for the purpose of this research, however, is another principle, one that affects the freedom of regional authorities to determine the financing of their own SSRs. According to the case-law handed down by the Court in 2004, and subsequently reaffirmed several times, the State legislator can legitimately impose constraints on the budgetary policies of the autonomous authorities, even if these inevitably translate into indirect limitations on their spending autonomy. However, it may only do so "for reasons of financial coordination linked to national objectives, also conditioned by EU obligations", and with measures concerning the size of the current account deficit or the growth of current expenditure, the latter only "on a transitional basis and in view of the specific objectives of public finance rebalancing pursued by the State legislature". In other words, "the State law may only establish an overall

limit, which leaves the authorities themselves wide latitude to allocate resources among the various spending areas and objectives"[150]. In short, the Constitutional Court, while allowing the possibility for the State legislator to interfere in the allocative decisions at the regional level, points out that such interference can never concern the details of the allocative choices of the Region, or rather that, even when focusing on the details (for example, when setting constraints on the growth of total expenditure or its individual components), it cannot do so permanently but only in a temporary way.

4.2. *Fiscal federalism in health and the introduction of the principle of balanced budgets in the Italian Constitution*

Finally, brief mention should be made of the measures that implemented the introductory reform of fiscal federalism, as well as the constitutional reform that included the principle of budget balancing in the Constitution. The current decision-making process of resource allocation and distribution in health care will be examined according to this regulatory framework.

Following Constitutional Law no. 3 of 2001, the new Article 119, paragraphs 2-3, of the Constitution identifies regional and local taxes and revenues as the sources of financing of the functions assigned to the Autonomies, as well as co-participation in State taxes and in the Equalisation Fund with no destination constraints established by State law for territories with a lower fiscal capacity per inhabitant. Paragraph 4 of the constitutional provision further specifies that "the resources derived from the sources referred to in the preceding paragraphs shall enable [the Autonomies] to finance in full the public functions assigned to them". Instead, transfers of resources from the centre to the periphery are reserved for special interventions with specific solidarity objectives or to address situations of poverty situations (according to the new paragraph 5). However, it was only with the entry into force of Law no. 42 of 2009, several years later, that the legislator began to implement the reformed constitutional provision[151] and, as regards health financing, that the

[150] See Constitutional Court Judgement no. 417 of 2005, paragraph 6.3 of the Considerations on points of law, which contains extensive references to Constitutional Court Judgement no. 36 of 2004.

[151] Despite the unquestionable centrality of Law 42 of 2009, the doctrine underlines how the fundamentals of the 2001 constitutional reform of public finance were already present in the reform carried out by Legislative Decree no. 56 of 2000, which, as we have seen, had attempted unsuccessfully to abolish state transfers. See E. Jorio, *Verso il sistema sanitario*

mechanisms introduced by the enabling act, but specified only by Legislative Decree no. 68 of 2011, become fully operational: these are the standard costs and standard requirements for healthcare financing, which we will discuss in more detail below.

In addition to regulating the general revenue and expenditure autonomy of the Regions with ordinary statutes and of the provinces, and providing for the abolition of State transfers to the Regions as of 2013, Legislative Decree no. 68 of 2011 lays down specific rules for the financing of healthcare (Chapter IV), which are formally aimed at innovating the process of creating and distributing State funding (Article 25, paragraph 1 of Legislative Decree no. 68 of 2011). First of all, Legislative Decree no. 68 of 2011 reiterates the need for a simultaneous consideration of the needs of public finance (in particular, the objective constraints and the obligations assumed by Italy at the EU level) and the objective of guaranteeing the LEAs under conditions of efficiency and appropriateness. The amount of resources needed to ensure the latter and determined compatibly with the former is defined by Art. 25(2), as the standard health care requirement and, from 2013, has been determined on the basis of the procedures set out in the subsequent article of that law.

From the point of view of resource allocation, the reform provided for a 5-year transitional regime to gradually allow the Regions to converge towards the new financing system, which sets aside the criterion of historical expenditure in favour of the identification of standard cost and requirement values[152]. At the time of the first application, the need arose to determine these values on the basis of the cost and requirement parameters of certain Regions (benchmark), which would be taken as a reference for all the Autonomies to ensure the guarantee of the LEAs in a context of economic-financial equilibrium[153]. Once fully in place, regional standard costs and requirements (and thus the amount of resources available for health funding in each territorial context) are determined

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federale, in La tutela della salute tra garanzie degli utenti ed esigenze di bilancio, edited by F. Roversi Monaco and C. Bottari, Santarcangelo Romagna, Maggioli, 2012, pp. 23-39, esp. p. 26.

[152] Art. 27, par. 11 of Legislative Decree no. 68 of 2011.

[153] Pursuant to Art. 27, par. 5, of Legislative Decree no. 68 of 2011 and the annex to the resolution of the Council of Ministers of 11 December 2012, in December 2015 the five best Regions were again identified based on criteria of quality of the services provided, appropriateness and efficiency, which, having guaranteed the provision of essential levels of care in a condition of economic equilibrium, not being subject to a recovery plan and being in compliance, as verified by the regional compliance verification board, were ex lege eligible for the role of Benchmark Region. On the basis of the shortlist proposed by the Ministry (Emilia-Romagna, Lombardy, Marche, Umbria and Veneto) and necessarily including the first of these in terms of results, the State-Regions Conference ultimately chose Marche, Umbria and Veneto as the benchmark regions for 2016.

annually by the Minister of Health, in consultation with the Minister of Economy and Finance, following an agreement with the State-Regions Conference and the opinion of the Technical Support Structure set up therein[154]. This is done on the basis of a complex calculation mechanism that provides for the application of the standard costs to the national standard requirements, which in turn are based on the requirements of public finance and the guarantee of the essential levels of care[155]. Standard costs are identified by Art. 27, par. 6, of Law no. 42 of 2009 as the average per capita expenditure incurred in the reference regions, in relation to their population, weighted by age.

As regards the distribution of the available resources, however, before the reform the State assigned to the Regions a global and indistinct share of the financing, on the basis of the macro-levels determined by the Decree of the President of the Council of Ministers on the essential levels of care of 2001 (specifically, allocating 5% of the resources to collective and preventive care, 51% to district/local care and 44% to hospital care). Therefore, the regional authorities enjoyed discretionary powers in allocating the available resources among the Local Health Authorities in their territory, with the sole exception of the restriction on the allocation of local and hospital pharmaceutical assistance, which is subject, pursuant to Article 15 of Legislative Decree no. 95 of 2012, to a predetermined expenditure ceiling[156]. Article 27, paragraph 3 of Legislative Decree no. 68 of 2011 established instead that, as of 2013, the Regions also had to converge on the cost and requirement percentages indicated by the national planning (the 5%-51%-44% distribution referred to above), since these constitute national planning indicators for the implementation of health federalism and compliance with them is complementary to the assessments carried out by the Committee for the Review of Regional Compliance. The aim is to encourage a return to effectiveness and efficiency, especially in those Regions that have been historically characterised by considerable expenditure on hospital healthcare.

Given the breadth of the debate on fiscal federalism and the limited perspective of its analysis in this research, this overview can be concluded by observing that, according to many, despite a clear reforming intent, the provisions of Legislative Decree no. 68 of 2011 substantially replicate previous mechanisms. In particular, according to some, the Decree actually confirms the "economic definition system typical of the FSN" (despite the

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[154] Art. 27, par. 1 of Legislative Decree no. 68 of 2011.

[155] Art. 26 of Legislative Decree no. 68 of 2011.

[156] See footnote 260.

renaming in terms of health needs[157]), as well as the distribution criteria (standard costs being, after all, a revised and corrected version of the age-weighted per-capita quota on the basis of which the allocation was made under Art. 1, paragraph 34 and 34-bis of Law no. 662 of 1996, as supplemented by the agreements between the State and the Regions on health matters)[158]. Others, however, have pointed out that the mechanism of allocating resources through the calculation of regional healthcare requirements does not provide any guarantee of uniformity between the figure thus obtained and the national allocation determined on the basis of the macroeconomic framework, so that the percentage incidence of each Region on the overall healthcare allocation is independent on the setting of a high or low cost[159] and "the choice of the amount of resources to be allocated remains a political choice, an exogenous factor"[160]. This choice is subject to the assessment of the national legislator on the basis of the overall economic and financial conditions and is nowadays pervasively conditioned by the balancing obligations derived from European legislation on the coordination of public finance.

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[157]For example, E. Jorio, *Verso il sistema sanitario federale*, in La tutela della salute tra garanzie degli utenti ed esigenze di bilancio, edited by F. Roversi Monaco and C. Bottari, cit., pp. 23-39, esp. p. 29.

[158] In addition to the author mentioned in the previous footnote, see N. Viceconte, *Il finanziamento del servizio sanitario nazionale*, in Manuale di diritto sanitario, edited by R. Balduzzi and G. Carpani, cited above, pp. 371-390, esp. p. 386. The weighted capitation quota system envisaged by the aforementioned regulations consisted, until 2012, by the following phases: first of all, the identification of the individual LEAs and the relative shares of the FSN assigned (prevention 5%; territorial assistance 51%, of which 17% outpatient, 7% basic, 13.6% pharmaceutical and 13.3% specialist; and thirdly, hospital assistance 44%); secondly, by the definition of the criteria (weights) to be assigned to the regional population for each LEA (e.g., the criterion of the unweighted population for prevention, pharmaceutical assistance and territorial assistance; the share of 13.6% of the regional total for pharmaceutical assistance; the criterion of the unweighted population for half the share and that of the age-weighted population for the remainder, in the case of specialist assistance). Some authors point out that, on the basis of this distribution mechanism, if the resources assigned are divided by the resident population, the capitated quota changes from region to region (just as it changes if other LEAs or percentage quotas of the fund/weighting criteria are chosen), but that, in reality, all the Regions received the same capitated quota for each LEA, even though the different age structure of the population gave rise to an apparent difference in the capitated quotas. Therefore, this value should not be used to evaluate the assignment of FSN resources from a comparative standpoint. C. Cislaghi and C. Zocchetti, *Il finanziamento pro capite regionale: attenti a interpretarlo!*, in Epidemiologia e Prevenzione, 2012, nos. 3-4, pp. 221-223).

[159] N. Dirindin, *Fabbisogni e costi standard in sanità: limiti e meriti di una proposta conservativa*, in Politiche Sanitarie, vol. 11, 2010, no. 4, pp. 147-160.

[160] N. Viceconte, *Il finanziamento del servizio sanitario nazionale*, in Manuale di diritto sanitario, edited by R. Balduzzi and G. Carpani, cited above, pp. 371-390, especially p. 386.

Moreover, after the reform enacted by Constitutional Law no. 1 of 2012 and its implementation by the reinforced Law no. 243 of 2012, such balancing obligations have been directly incorporated into the Italian Constitution: specifically, in Article 81 for the State budget[161], in Article 97 for each public administration[162], and in Article 119(1) for the Autonomies[163]. In the aftermath of the entry into force of the reform, part of the doctrine expressed concern about the possible negative effects of the

[161] Article 81(1) of the Constitution provides that "The State shall balance revenue and expenditure in its budget, taking account of any adverse and favourable phases of economic cycles.". In addition to reaffirming the legitimacy, under ordinary conditions, of negative nominal balances "taking account... of economic cycles", the second paragraph of Article 81 of the Constitution also provides for the possibility that Parliament may authorise the Government to run further deficits "in exceptional circumstances". The combination of the first two paragraphs of Article 81 of the Constitution makes it possible to argue that the difference between the budget balance prescribed for all public administrations and for the State budget lies in the fact that only the former can suffer from "imbalances" due not only to the trend of the economic cycle, but also to exceptional circumstances, while the latter can "fluctuate" below or above the break-even line only as a result of the economic cycle.

[162] Article 97(1) of the Constitution states: "In accordance with European Union law, Government agencies shall ensure that their budgets are balanced and that public debt be sustainable.". The balance to be taken into consideration is the consolidated profit and loss account of the government agencies, which, according to the rules of the European System of Accounts, adds to the results of the management of the central and local administrations (which are already subject to autonomous balance constraints) the data emerging from the budgets of the social security institutions and other institutional units that cannot be counted among the market operators, which certainly include service providers like local health authorities and hospitals. The result of the consolidated profit and loss account, to which SSN bodies also contribute, is very important, because it contributes to defining the deficit value relevant to assessing compliance with the ban on excessive public deficits laid down in the European Treaties.

[163] The principle of balance enshrined in the new Article 119, paragraph 1, of the Italian Constitution is not in line with the European constraints on the State and on all public authorities. In fact, for regional and local finance, there is no provision for calculating the budget balance in structural terms (i.e., the economic cycle trend is not taken into account), nor are explicit exceptions to its implementation allowed. Instead, as of 2016, the balance is translated into a dual obligation of balancing the accounts, which are imposed at the same time on the current items of the budgets of local and regional authorities - as already prescribed by the reform of Title V - and on their net balance to be financed (as already prescribed, in terms of primary sources, by the Consolidated Law on Finance (see Article 9 of Law no. 243 of 2012)). Moreover, as a result of the reform, local entities are subject to the principle of balance twice over: not only at the individual level, but also as parts of the broader regional subset. This is due to the new Article 119(6) of the Constitution, which stipulates that they may only approve investment expenditure "subject to the condition that the comprehensive budget of all local authorities in the region be balanced". This has potentially negative effects on investments, which could be precluded to the virtuous entity due to the presence in the Region of autonomous entities that are much less efficient in the management of their finances.

reform on the guarantee of social rights. First of all, the accounting rigidity that is peculiar to the budgets of local authorities has been criticised, which, also in view of the progressive transfer of powers from the centre to the periphery, suggests the existence of concrete risks for the protection of essential levels of services[164] (risks that the first case law applying the reformed constitutional text seems to confirm, as noted in the first section). In addition, some have pointed out that the negative impact on social policies is not excluded even by the European structural debt constraints (that is, net of measures that are not discretionary but dependent on economic trends) because they do not take into account the "social shock absorbers" (i.e., social expenditures such as unemployment benefits, which by their very nature increase in the presence of negative economic conditions), but these obviously do not represent the full range of social benefits[165]. What is more, the largest expenditure that could be financed through borrowing would be that related to the level of the welfare in place, and would not include the extension of social protection or its increased cost due to factors other than economic ones. Since the very beginning, it would have been reasonable to assume that those factors would include, firstly, investments and, secondly, exogenous factors outside the control of the state, such as the need to deal with epidemics or the arrival on the market of medical devices, diagnostic equipment or medicines at particularly high prices.

5. *Decision-making processes*

Lastly, within the legislative framework outlined above, it is necessary to consider in more detail the mechanisms that are most interesting for the purposes of research into resource allocation. In particular, special attention will be placed on the actors and criteria involved in health planning, on the one hand, and in the identification of resources and the distribution of SSN funding on the other.

In general terms, since the 2000s, both processes have been part of the "shared governance" (*governo condiviso*) of health, according to a sort of regional self-coordination externally directed by the State[166], and the most

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[164] I. Ciolli, *I diritti sociali*, in Il diritto costituzionale alla prova della crisi economica, ed. F. Angelini and M. Benvenuti, Naples, Jovene, 2012, pp. 83-114.

[165] A. Brancasi, *La nuova regola costituzionale del pareggio di bilancio. Effetti su rapporti Parlamento-Governo e sugli indirizzi delle politiche sociali: il caso italiano*, in Rivista Telematica dell'Associazione "Gruppo di Pisa", 2012, p. 8.

[166] G. Carpani, *La Conferenza Stato-Regioni. Competenze e modalità di funzionamento*

recent developments in the functioning of the SSN can be seen in this light. A great deal has been said and written about this issue[167], which has its roots in the partial disalignment between the level of government responsible for determining the essential levels of services (the State) and those responsible for their concrete management (the Regions and health authorities). In spite of the efforts made by the central government to attribute responsibility to the other decision-making levels, the structure described above inevitably generates a certain gap between the decisions taken with regard to expenditure and those taken with regard to services, considering that the Constitution not only justifies but encourages fundamental uniformity. In addition to increasing the recourse to the Constitutional Court for the resolution of disputes arising from the distribution of competences and mutual encroachments, this setup requires a coordination and concerted effort between the different levels of government involved. This is why, since the first ordinary legislative measures were adopted in view of the federalist constitutional reform, the State-Regions Conference and the Joint Conference (*Conferenza Unificata*) as well as the so-called "Health Pacts" have taken on a progressively greater role.

Lastly, it should be noted that the aim pursued through the financial and programmatic agreements concluded between the State and the Regions (and the guarantee of some involvement of local authorities, which are now excluded from the provision of services) is both to improve the quality, appropriateness, and uniformity of the services and the system, which are jeopardized by the differentiation inherent in the devolution of the powers, and to ensure the compatibility of their funding with the overall objectives of public finance, which are the exclusive responsibility of the State but are necessarily influenced by the spending decisions of the lower levels. This illustrates the tension between the planning of health interventions and the allocation of the resources necessary for this purpose, which has always characterized the SSN and is particularly evident with reference to the essential levels of services, which are intended to guarantee the irreducible core of the individual right to health. This dual purpose also explains the decision to focus on decision-making processes in the health sector from the point of view of service planning and the procurement and distribution of financial resources.

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dall'istituzione ad oggi, Bologna, Il Mulino, 2006, p. 69.

[167] For bibliographical references, see G. Carpani, *Cogestire la sanità. Accordi e intese tra Governo e Regioni nell'ultimo decennio*, in La tutela della salute tra garanzie degli utenti ed esigenze di bilancio, edited by F. Roversi Monaco and C. Bottari, Santarcangelo Romagna, Maggioli, 2012 pp. 97-135.

5.1. *Service programming*

First of all, the organisational complexity of the SSN necessarily requires intensive planning to ensure the pursuit of health protection[168]. While this objective can be found in the law establishing the SSN, it was the *riforma bis* that made it the basis of all health care activities.

Formally, to this day the main planning instrument of the central power is the National Health Plan (NHP), already provided for by Law no. 833 of 1978 as a summary of "all the main health policy decisions of the country, from the identification of the levels of care, to the financing of services at the local level"[169], further confirmed by Legislative Decree no. 502 of 1992. The NHP is a three-year planning document, drawn up by the Government in collaboration with the Parliament, the Regions (which submit proposals) and the most representative trade union confederations. The adoption of the NHP assumes that a "weak" agreement with the Autonomies has been reached[170]. While the provisions for the establishment of the SSN required the Plan to be approved by law, since 1985 this requirement has no longer been in place; it was first replaced by a non-legislative resolution of the two Chambers of Parliament[171], and then by a Presidential Decree to be adopted following the mandatory but non-binding opinion of the competent parliamentary commissions and the most representative trade union federations representing the needs of the service's users[172]. In the event that no agreement is reached in the Joint Conference, under certain defined situations and for specific reasons the Government is allowed to proceed unilaterally[173]. The NHP sets out the fundamental principles and values of the SSN, as well as the objectives and strategic directions for quality improvement, scientific research and evaluation of the efficiency and effectiveness of the service[174]. According to the law, the NHP was meant to

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[168] A. Pioggia, *Diritto sanitario e dei servizi sociali*, cit., p. 131.

[169] Ibid, p. 132.

[170] In particular, while the proposal phase is dominated by the Regions (which, individually or in coordination, draw up draft plans that the Government will have to take into account), it is up to the Ministry of Health Department for Planning to investigate and examine the proposals. The draft plan thus prepared must then be submitted to the competent parliamentary committees and to the most representative trade union confederations, whose opinion, although not binding, must be taken into account if the Government wishes to depart from it, giving reasons.

[171] See Article 1 of Law no. 595 of 1985.

[172] Art. 1, par. 5 and 9 of Legislative Decree no. 502 of 1992, as amended.

[173] Art. 3, par. 3, Legislative Decree no. 281 of 1997.

[174] Pursuant to Art. 1, paragraph 10, of Legislative Decree no. 502 of 1992, as amended, "the

represent a "synthesis of political decisions" and allowed for "the strategic choices (health objectives to be pursued, organisational, educational and operational decisions, e.g., reducing waiting lists)", taking into account national, international and European scenarios, the needs of the population, the institutional context and expected scientific and technological development, as well as "the values (dictated by the Constitution and the law) relating to the effectiveness of the right to health and the resources available"[175]. As such, it would undoubtedly have been the most interesting document to examine for an investigation into the setting of health priorities given the limited resources available.

However, following the constitutional reform of 2001, the NHP was first deprived of the function of defining the essential levels (to which it now merely refers[176]) and economic-financial details, and was ultimately replaced: at the lower level by the Regional Health Plans (RHPs), and at the national level by documents resulting from consultation with the Autonomies. In fact, especially with regard to the higher phases of the planning process, the entry into force of the new Title V of the Constitution indicates a substantial suspension of the planning model outlined by the law, in favour of a negotiated management that has deprived the NHP of its coordinating role and delegated the identification of the system's development lines to pacts, agreements and understandings. Therefore, rather than being the place where the direction and coordination of the regional health services are defined, it has now become "a general

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National Health Plan indicates: a) the priority areas of intervention, also for the purposes of a progressive reduction of social and territorial inequalities in health; b) the essential levels of health care to be ensured for the three-year period of validity of the Plan; c) the per capita share of funding for each year of validity of the Plan and its breakdown by levels of care; d) the guidelines aimed at guiding the SSN towards the continuous improvement of the quality of care, including through the implementation of projects of supra-regional interest; e) the target projects, to also be achieved through the functional and operational integration of health services and social-welfare services of local authorities; f) the general aims and the main sectors of biomedical and health research, also envisaging the relevant research programme; g) the requirements relating to basic training and the guidelines relating to the continuous training of staff, as well as the needs and the development of human resources; h) the guidelines and the relevant diagnostic and therapeutic pathways, with a view to fostering, within each healthcare facility, the development of systematic methods of reviewing and evaluating clinical and care practice and to ensure the application of the essential levels of care; i) the criteria and indicators for verifying the levels of care provided in relation to those envisaged."

[175] G. Carpani, *La programmazione*, in Manuale di diritto sanitario, edited by R. Balduzzi and G. Carpani, Bologna, Il Mulino, 2013, pp. 325-339, esp. pp. 327 and 325.

[176] Cf. the Agreement between the Government, the Regions and the Autonomous Provinces of Trento and Bolzano of 8 August 2001, containing additions and amendments to the agreements sanctioned on 3 August 2000 and 22 March 2001 in the field of health, point 15.

framework, made up of the macro-lines of action resulting from the process of consultation with the Regions, which the various agreements, plans and programmes that give consistency to the overall functioning of the entire system are to be reconciled with and coordinated within"[177].

Most notably, these include, from a financial standpoint, Health Pacts (which are general in scope) and Deficit Recovery Plans (PDR) which are individual in scope). As regards coordinating health activities, these are acts that are not expressly provided for by the law, but which bear the wording "National Plan" and are adopted by the Ministry with prior agreement or in the form of State-Region agreements pursuant to Article 4 of Legislative Decree no. 281 of 1997 or Article 8 of Law no. 131 of 2003[178]. Examples in this sense are the Rehabilitation Master Plan, the National Plan for Limiting Waiting Time or the National Vaccine Plan, as well as the National Health Research Programme. The NHP in particular has been progressively replaced in practice by the Health Pacts. In fact, the last formally approved Health Plan dates back to the three-year period 2006-2008[179], since the contentious approval process of the subsequent plan was never concluded, ultimately failing at the point of preliminary approval by the Council of Ministers in January 2011.

However, as already noted health programming does not stop at the national level. In fact, within 150 days from the entry into force of the NHP (but in more recent practice, also regardless of it) the Regions each adopt their own RHP, which represents the specific strategic plan of interventions of each Region[180]. Although not all the Regions systematically resort to formal planning and, in any case, they do so in significantly different ways, it can be said that, in general, the RHPs contain the specific objectives for health services based on the specific needs of the regional population, as well as some important detailed rules, such as those concerning the distribution of hospital beds or the number and location of hospitals[181].

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[177] A. Pioggia, *Diritto sanitario e dei servizi sociali*, cit., p. 133.

[178] G. Carpani, *La programmazione*, in Manuale di diritto sanitario, edited by R. Balduzzi and G. Carpani, cit., pp. 325-339, esp. p. 331.

[179] The Plan was approved, following agreement at the Joint Conference, by Presidential Decree of 7 April 2006.

[180] See Art. 1, paragraph 13 and 14 of Legislative Decree no. 502 of 1992, as amended. The Regional Health Plan, in fact, "represents the strategic plan of interventions for health objectives and the functioning of services to meet the specific needs of the regional population, including with reference to the objectives of the National Health Plan".

[181] The current Health Plans are grouped together and can be consulted on the Age.Na.S. website, at: http://www.agenas.it/aree-tematiche/organizzazione-dei-servizi sanitari/programmazionesanitaria-e-psr/psr-vigenti-2013.

The RHPs have a "double nature"[182], as they represent: on the one hand, the declination at regional level of the macro-objectives identified initially by the State only, but now agreed with the Regions when drawing up the Health Pacts; on the other hand, an essential tool for the planning of regional strategies and policies in the health field and for the integration of health interventions with socio-welfare ones. Theoretically, they should be sent to the Ministry of Health for an assessment of their consistency with the national guidelines expressed in the NHP; however, this is an undertaking that is left to the Regions, except in the case of Regions that are subject to a PDR and therefore that are required to pursue conformity of the Operational Recovery Programme, not only with respect to the LEA, but also to the NHP[183]. In this case, opinions from the Ministry of Health and the Ministry of Economy and Finance are required to certify that the regional objectives are in line with the objectives set out in the NHP and are taken into account when verifying the provision of the LEAs and adherence to economic-financial requirements[184].

Lastly, numerous public and private actors in the field of health care are involved in drawing up the RHPs. These include, first of all, local autonomies, which act through the Permanent Conference for regional health and social-health planning, charged with giving opinions on the RHP adoption procedure, as well as private non-profit social entities engaged in social and health assistance, as well as trade unions representing public and private health operators and private structures accredited by the SSN. If the Region fails to adopt the RHP, the law allows the Government to exercise substitutive powers to ensure the applicability of the provisions of the NHP[185] (though these have never been invoked). Moreover, in view of the persistently strong dependence of the amount of funding allocated by the central power, it has been noted that RHPs hardly address the issue of investments and economic-financial policies for the SSR[186] in any explicit form.

In addition, annual legislative interventions at the national level, mostly aimed at containing health expenditure, complicate the medium-long term planning activity entrusted to the Regions, which end up undergoing

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[182] G. Carpani, *La programmazione*, in Manuale di diritto sanitario, edited by R. Balduzzi and G. Carpani, cit., pp. 325-339, esp. p. 332.

[183] Art. 2, par. 77, of Law no. 191 of 2009.

[184] G. Carpani, *La programmazione*, in Manuale di diritto sanitario, edited by R. Balduzzi and G. Carpani, cit., pp. 325-339, esp. p. 336.

[185] Art. 2, par. 2-*octies*, Legislative Decree no. 502 of 1992, as amended.

[186] G. Carpani, *La programmazione*, in Manuale di diritto sanitario, edited by R. Balduzzi and G. Carpani, cit., pp. 325-339, esp. p. 332.

numerous and continuous updates following each financial law (as will be seen more specifically with reference to the 2011-2016 period in Piedmont in chapter 4)[187]. This confirms that devoting particular attention to the effects of the lack of resources on the individual right to health requires a consideration of regional health policies in close correlation with the national impetus for achieving public finance objectives and with the Health Pacts adopted during the consultation process.

Lastly, to a certain extent, planning is also the responsibility of the health service's bodies "on the ground": local health authorities. Although the regulation of the instruments for this purpose is the responsibility of the Regions, leading to a lack of homogeneity in the relation between the programming of local authorities and its implementation, it can be said that within the ASLs and AOs the programming function is generally divided among various bodies[188].

The Director-General and the Management Board are in charge of long-term strategic planning and monitoring of results (in the case of Local Health Authorities, this also includes on the basis of evaluations and proposals submitted by the mayor or the Conference of Mayors of the municipalities that belong to the said authority). It is also up to regional legislation to regulate the forms of participation of citizens' organisations and the voluntary sector in the local planning process[189]. The resulting Local Implementation Plans (*Piani attuativi locali* - PAL) are fundamental to coordinating the Health Authority's activities with the social and health needs of the local community, in line with regional objectives.

At the district level, the main planning document is the PAT (*Programma delle attività territoriali*, or Programme of Territorial Activities). The PAT is drawn up by the District Director, after consulting the relevant Committee of District Mayors and with the involvement of citizens' organisations and volunteers. It is then formally adopted by the ASL DG after consultation with the Committee of Mayors. This document, which takes into account regional priorities, identifies the needs and the necessary health and socio-sanitary interventions, which services to entrust to the district and the local authorities, and the resources for socio-sanitary integration between the Municipality and the ASL[190].

Lastly, all Directors of the Department under which the Local Health Authorities and Hospitals are organised, who draft an annual Plan of activities and plan the use available resources in a medium-term

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[187] Ibid, p. 337.

[188] A. Pioggia, *Diritto sanitario e dei servizi sociali*, cit., p. 138.

[189] Art. 14, par. 2, of Legislative Decree no. 502 of 1992, as amended.

[190] Art. 3-quater, par. 3, of Legislative Decree no. 502 of 1992, as amended.

perspective, and the individual medical officials in charge of the various services in the short term are called upon to put the planned activities in place[191].

5.2. *The identification and allocation of resources for health financing*

In the current system of governance of the health system, the issues of planning and financing intersect in the programmatic and financial agreements between the State and the Regions, which make up the three-year Health Pact. However, it is not solely this act that identifies and sets the amount of resources available to ensure the constitutional guarantee of the right to health.

In this regard, a distinction must first be made between the share of resources earmarked for financing additional services (besides the LEA) which may be determined by the Regions, and that which aims instead to guarantee compliance with the LEA, providing the relevant parties with the necessary financial provision. As noted, under the Constitution, it is the Regions' responsibility to procure and guarantee the part of the budget earmarked for financing any additional levels of services; the considerations below are therefore not applicable to this budget component, as the relevant decision-making processes take place exclusively at the regional level.

On the other hand, the identification of the overall financial resources available for the financing of the SSN, to which the State contributes, involves several levels of government (mainly the national and regional levels) engaging in the consultation process. Its amount depends, of course, on the tax revenues actually collected during the financial year (which, of course, can only be determined at the final balance stage), but also on the Government's economic policy forecasts and decisions and, to an increasingly penetrating extent, on those of the European institutions with powers of political guidance and control over the budget policies of the Member States, such as the European Council and the Commission. It would appear, therefore, that it is precisely with regard to financing that the system of health governance is taking on the broadest scope, envisaging the consistent involvement of supranational regulations and actors. Let us consider these processes in greater detail.

First of all, based on the existing nature of the relationship between the right to health and resources as illustrated above, the identification of the share of funding earmarked to guarantee the essential core of the right to health can disregard neither the set essential levels of services nor the

[191] A. Pioggia, *Diritto sanitario e dei servizi sociali*, cit., p. 138.

overall macroeconomic scenario. The former are determined in the Prime Ministerial Decree (d.P.C.M) of 12 January 2017, while the latter are defined in the annual Economic and Financial Document (DEF). As is well known, the latter is the main economic-financial planning instrument at the national level, and for our purposes it is characterised by the fact that it also contains the evaluation of the country's economic situation and public accounts which, on the basis of European regulations on the coordination of economic and budgetary policies, must be sent each year to the European institutions and is generally known as the Stability Programme. Among other things, the DEF also includes a performance assessment for the previous year and a set of forecasts for the following financial year for the main expenditure areas, including health care[192].

As mentioned above, however, the final identification of the overall resources available for financing the SSN, to which the State contributes, can only take place on the basis of the final figures. What is more, once tax revenues are collected, they need to be distributed among the territorial authorities, since taxation income often disregards the constitutional nature of the revenues and provides for an allocation, at a later moment, to the regions on the basis of criteria such as the taxpayer's fiscal domicile. To this end, the Interministerial Committee for Economic Planning (CIPE[193]) issues an annual document that explains the breakdown of the overall resources both in terms of their origin and their destination[194].

As shown by the annual document from CIPE[195], the national health requirement consists of an undifferentiated share (i.e., resources that are

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[192] Art. 10, par. 3(f)of Law no. 196 of 2009, as amended by Law no. 39 of 2011.

[193] Established in 1967, CIPE is a political decision-making body in the economic and financial sphere that performs coordination functions in the field of economic policy planning to be pursued at the national, European and international levels; it examines the general socio-economic situation with a view to adopting short-term measures; it identifies the guidelines and actions necessary for the achievement of economic policy objectives; it allocates financial resources to development programmes and projects as well as those intended for the National Health Fund.

[194] To take the example of 2014, the relevant CIPE resolution was adopted on 29 April 2015 and provided for a total of €109 billion in funding, of which: 105 billion was to the "indistinct funding" (i.e. without destination constraints) of the Essential Levels of Care (LEAs), adjusted for healthcare mobility; 2 billion to tied and programmed destinations, based on the National Healthcare Plan; 1.4 billion (or other legal provisions) for purposes such as the regularisation of foreigners, the overcoming of judicial psychiatric hospitals and the financing of medical scholarships; 632 million for restricted activities of other entities such as ISZ, CRI, or the contracting of loans with the Cassa Depositi e Prestiti in order to refinance past health debts; and finally, almost 2 billion for provisions reserved for a subsequent ex post distribution among the Regions, on the basis of the sanction and bonus systems established by Art. 9, paragraph 2, of Legislative Decree no. 149 of 2011.

[195] For a practical example, see Tables 11 and 12 in Chapter 4, which use the data extracted

not tied to specific spending purposes) and a share tied to specific health objectives. The former is financed through the SSN entities' own revenues, IRAP and the regional IRPEF surcharge, the co-participation of the Autonomous Regions and Provinces (which, with the exception of Sicily, essentially cover the costs of their own SSR) or, for non-autonomous Regions, through the State budget via the Regions' co-participation in VAT revenues and, for Sicily, through the FSN. The tied portion of the resources, on the other hand, draws its funds exclusively from the FSN and, therefore, from the State budget.

The resources coming from the state budget (VAT-sharing and FSN) are therefore determined, for each financial year, on the balance sheet date. Before the ex-post determination of the quota that is actually available, the Regions (and, consequently, all the lower bodies that provide healthcare services) will make allocation decisions on the basis of revenue and expenditure forecasts contained in their respective budgets, which may well correspond with the final figures. This process may therefore lead to budget deficits at Regional or lower levels. However, State funding is paid to the Regions during the course of the year, even, when necessary (i.e., in the absence of other liquidity), by resorting to cash advances, in order to avoid conditioning based on tax revenues and thus, ultimately, on the economic cycle. Above all, this ensures that the financing does not lapse even in the event of unfavourable economic conditions. To this end, in the State budget the estimates by the Ministry of the Economy and Finance include a special guarantee fund to compensate for any shortfall in IRAP and IRPEF revenues for the previous year following their final determination.

Lastly, for the Regions that have adopted measures suitable for the proper management of healthcare budgets Article 15(23) of Legislative Decree no. 95 of 2012 envisions the allocation of an additional bonus share of funding from the State budget, which was originally equal to 0.25 per cent of the ordinary resources guaranteed through the FSN as of 2013, but was increased in 2014 to 1.75 per cent[196].

Once the total resources have been determined in this way, they must be reallocated among the Regions by the end of March, again through a resolution from CIPE at the proposal of the Ministry of Health and subject to agreement at the State-Regions Council[197]. For each of the

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from the CIPE resolutions to analyse the process of financing regional healthcare in the 2011-2016 period.

[196] Art. 42, par. 14-ter of Legislative Decree no. 133 of 2014.

[197] On the basis of this distribution, for example, in 2014 8 billion euros was allocated to Piedmont and almost 7 billion euros to Tuscany. See Table D of the Agreement on the

aforementioned macro-levels of assistance the current distribution criterion provides for the application of a standard cost derived from the average per capita expenditure in relation to the population weighted by age group, recorded in three benchmark Regions identified annually. Once the values for the regional funding shares for each level and sub-level of care have been obtained, their sum is used to identify the total funding needs for each region. This figure can then be adjusted according to the intra-regional health mobility recorded on the basis of the final data in order to know the exact amount of resources allocated to each regional territorial entity[198].

The Health Pact of July 2014, for example, results from this overall framework. While bearing witness to a fiscal federalism that is still incomplete, it reaffirms the commitments linked to the periodic verification of the implementation of the convergence process with the standard healthcare costs and requirements[199]. With regard to the distribution of funding between the regions of the non-tied quota (that is, the funding required for the LEA), the 2014-2016 Health Pact established that, by 31 July 2014, the criteria, and therefore the weights, for determining the standard regional costs and requirements would have to be re-examined and re-determined[200]. To this end, the 2015 Stability Law also established that, starting from 2015, the weights for determining the average per capita expenditure (capitated quota) would be defined by decree by the Minister of Health, in agreement with the MEF, subject to the agreement with the State-Regions Conference, and would be determined on the basis of the criteria indicated in art. 1, par. 34, of Law no. 662 of 1996: resident population, frequency of health consumption by age and sex, population mortality rates and indicators related to specific local situations considered useful in order to define the health needs of the Regions and territorial epidemiological indicators[201]. The assessment of the doctrine that pointed out the substantial correspondence between the allocation criteria

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Verification and Revision of the 2014-2016 Health Pact of 2 July 2015 (on the basis of Art. 30, par. 2, of the Pact itself adopted with the Agreement of 10 July 2014 which provided for it to be revisable depending on the needs of the overall macroeconomic framework, as well as the amendments consequently approved by the Stability Law for 2015 (Law 190/2014)).

198 The distribution procedure is explained (in Italian) at http://www.camera.it/leg17/465?tema= fiscal_federalism.

199 See in this regard Camera dei deputati – XVII legislatura, *Il federalismo fiscale. Lo stato di attuazione della legge n. 42 del 2009 al 1° aprile 2015*, in Schede di lettura, 2015, n. 134/1, pp. 52-53.

200 See Art. 1, par. 2, of the Pact.

201 See Art. 1, par. 681, of Law no. 190 of 2014.

provided for by the legislation on fiscal federalism and the previous system of the weighted per capita quota seems therefore confirmed[202].

6. *The allocation strategy in Italy amidst problems of sustainability of the health service and reduction of resources*

As we have seen, the financial sustainability of the health service has been a central issue in the reforms pursued since the 1990s.

In the absence of a real debate on the criteria and methods of allocation, the issues involved have justified the ongoing reorganisation of the health service and, subsequently, the reduction of public funding.

Numerous health reports produced by institutional[203] and non-institutional[204] actors highlight the latest trends in the SSN. The SSN is relatively inexpensive compared to other European health care systems[205] and the health outcomes seem to indicate[206] it is one of the most effective[207]. Nevertheless, in recent decades, there has been a progressive disinvestment in public health, especially in the hospital setting, staffing and health facilities[208].

In the context of public defunding, just over 37 billion euros have been "deallocated" from the health service over the period 2010-2019, of which

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[202] See footnote 158.

[203] See the data contained in the 2020 Report on Public Finance Coordination issued by the Joint Session (SS.UU.) of the Court of Auditors and the report of the Parliamentary Budget Office on *The State of Health Care in Italy*, 2 December 2019.

[204] The reference is to the data contained in the Report on the Sustainability of the National Health Service of June 2019 prepared by the GIMBE Foundation.

[205] Italy is in a fairly central position, with a share of 6.5% of GDP in 2018 (against 6.6 of the unweighted OECD average), lower than that of the most northern and central European countries. Private expenditure (voluntary insurance schemes and direct household expenditure) is not much higher than the average (2.3% vs. 2.2%).

[206] Life expectancy at birth, according to OECD, Health Status, 2019, for 2017, is 83 years on average.

[207] See 2020 Report on Public Finance Coordination prepared by the Joint Session (SS.UU.) of the Court of Auditors, p. 287.

[208] Another sector that should be highlighted, due to its strategic importance, is that of prevention, where a significant push for a decrease in expenditure occurred in the decade 2005-2015. See M. Gmeinder, D. Morgan and M. Mueller, *How much do OECD countries spend on prevention?*, OECD Health Working Papers, 2017, no. 101, Paris, OECD Publishing, p. 32. The National Bioethics Committee, in its 2017 opinion "In defence of the National Health Service" (*In difesa del Servizio sanitario nazionale*), highlights on page 5 the importance of certain factors such as low investment in prevention, which sees Italy in last place among OECD countries for health spending, while the share of general expenditure allocated is equal to that of countries such as Spain, Portugal and Greece.

25 billion over the period 2010-2015. The financing of the SSN in the period 2010-2019 grew by 0.9% per year on average, which is less than the average annual inflation of 1.07%[209]. Health expenditure forecasts, in the current legislative framework, contained in the 2019 DEF Update Communication, indicate a constant decrease with respect to GDP, from 6.6 per cent in 2019 to 6.5 in 2022[210].

Measures for the reorganisation of the health service

The reduction in public funding was accompanied by the introduction of a series of measures to reorganise the health service. On the one hand, there have been a series of reforms concerning instruments to contain and rationalise expenditure, such as the setting of expenditure ceilings, the centralisation of purchases (including, in part, through CONSIP regional purchasing centres) and the renegotiation of supply prices for medicines and medical devices. CONSIP, set up in 1997 to manage the IT services of the Ministry of the Treasury, is the purchasing centre of the Italian public administration system; it is a joint stock company the sole shareholder of which is the Ministry of Economy and Finance of the Italian government.

The reorganisation measures were introduced by a series of rationalisation measures such as Law Decree no. 98 of 6 July 2011, which was converted into Law no. 111 of 15 July 2011 (Urgent provisions for financial stabilisation); the Legislative Decree no. 52 of 7 May 2012, implemented in Law no. 94 of 6 July 2012 (Urgent provisions for the rationalisation of public spending); Legislative Decree no. 95 of 6 July 2012, converted into Law no. 135 of 7 August 2012 (Urgent provisions for the revision of public spending with no change in services to citizens, as well as measures to strengthen the capital of authorities in the banking sector); Legislative Decree no. 158 of 13 September 2012, converted into Law no. 189 of 8 November 2012 (Urgent provisions to promote the development of the country through a higher level of health protection).

Two major spending rationalisation efforts were launched with regard to hospital care and outpatient services. These consisted, respectively, in the decree of the Minister of Health no. 70 of 2 April 2015, on the definition of qualitative, structural, technological and quantitative standards relating to health care (the "hospital standards decree" adopted on the basis of Article 15 of Legislative Decree no. 95 of 2012), and the decree of the Minister of Health of 9 December 2015 on the "Conditions of deliverability

[209] See GIMBE, *Rapporto sulla sostenibilità del servizio sanitario nazionale*, June 2019, pp. 21 ff.

[210] See Ufficio parlamentare bilancio, *Lo stato della sanità in Italia*, 2 December 2019, p. 2.

and indications of prescriptive appropriateness of outpatient care services deliverable within the SSN" (the "appropriateness decree"), which tightened up the definition of appropriateness for the prescription of many services. The provision of financial penalties on doctors who did not comply with the prescriptive instructions contained in the decree was perceived by doctors as a violation of their professional autonomy. In Judgment no. 169 of 2017, concerning the constitutionality of certain provisions, including Article 9-quater of Legislative Decree no. 78 of 19 June 2015 ("Urgent provisions on territorial entities. Provisions to ensure the continuity of security and territorial control arrangements. Rationalisation of the expenses of the SSN as well as rules on waste and industrial emissions"), converted, with amendments, by Law no. 125 of 2015, on the basis of which the "Appropriateness Decree" was adopted, the Constitutional Court stated that the doctor assesses the individual case under his/her care on the basis of the most up-to-date and accredited technical-scientific knowledge, reviewing the treatment deemed most suitable to ensure the protection of the patient's health from time to time. In light of this principle, the "prescriptive appropriateness" provided for in Article 9-quarter, par. 1 of Legislative Decree no. 78 of 2015, the parameters contained in the ministerial decree must therefore be understood as an invitation to the prescribing doctor to make transparent, reasonable and informed decisions when deviating from the instructions of the ministerial decree (on this, see paragraph 8 of Judgment no. 169). Finally, the Appropriateness Decree was repealed by Article 64, paragraph 2, of the Prime Ministerial Decree of 12 January 2017 (Definition and updating of the essential levels of care, referred to in Article 1, co. 7 of Legislative Decree no. 502 of 30 December 1992).

With regard to the rationalisation of expenditure, the provision of Article 15 of Legislative Decree no. 95 of 2012, converted with amendments by Law no. 135 of 2012 ("spending review"), on the basis of which the hospital standards decree was adopted, places an obligation on the Autonomous Regions and Provinces to adopt measures to reduce the standard number of accredited hospital beds, as well as those actually charged to the Regional Health Service, to a level not exceeding 3.7 beds per 1,000 inhabitants, including 0.7 beds per 1,000 inhabitants for post-acute rehabilitation and long-term care.

The effects of disinvestment in healthcare are also analysed in depth in the Report of the Court of Auditors on the coordination of public finance, approved at the meeting of the Sections responsible for control purposes on 15 May 2020, which highlights the critical issues that have affected the SSN. These include: the unacceptable differences in the quality of the

services offered in the various areas of the country; staff shortages due to the constraints imposed during the reorganisation phase, the limits on the planning of the necessary professional resources, but also a gradual shift away from the public system; the inadequacies of territorial assistance in the face of growing non-self-sufficiency and chronic illnesses; the slow progress of investments that have been sacrificed in favour of other current needs[211].

The reduction in funding that has occurred over the years has led to a contraction of the resources allocated to the hospital sector in the absence of adequate planning for territorial services. The need to enhance the scope of local care has been on the health agenda for many years and was re-proposed in the Health Pact approved by the State-Regions Conference in December 2019 in relation to enhancing the ability to plan spending at community level. The COVID-19 pandemic has further highlighted the strategic importance of local services in the management of health emergencies[212].

Some key points in the analysis of the system have been appropriately detailed by the Court of Auditors in the aforementioned report: the gradual reduction of public expenditure on healthcare and the growing role of expenditure borne by citizens, the reduction of permanent staff and the growing use of fixed-term contracts or consultancies; the reduction of hospitalisation facilities and local assistance; the slowdown in investments.

Looking at the international scenario, Italy's performance between 2009 and 2018 shows a particularly large reduction in the resources allocated to healthcare in real terms[213].

The prolonged diversion of resources from health care, the failure to expand health care facilities on the ground, and the difficulties in adapting the supply of health care services to the needs of a population with evolving demographic and epidemiological characteristics has translated in an increase in household expenditure, which has continued to grow between 2012 and 2018[214].

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[211] See 2020 Report on Public Finance Coordination prepared by the Court of Auditors, p. 285.

[212] It has been observed that in regions where there is an efficient tertiary care service, the system has reacted more efficiently (e.g., Veneto) than in regions where the care model is predominantly hospital-centric (e.g., Lombardy), cf. G.P. Pisano, R. Sadun and M. Zanini, *Lessons from Italy's response to coronavirus*, in Harvard Business Review, March 2020.

[213] See 2020 Report on Public Finance Coordination prepared by the Joint Session (SS.UU.) of the Court of Auditors, p. 289.

[214] Ibid, p. 290. Direct household health expenditure grew between 2012 and 2018 by 14.1% compared to 4.5% for general government. Expenditure covered by voluntary funding schemes also increased (+31.5%).

On staff reduction, the Court of Auditors distinguishes between regions with and without a recovery plan.

In the Regions under the Deficit Recovery Plan, permanent staff was reduced by more than 16,000, almost all of them full-time, while part-time staff remained unchanged. The reduction was particularly significant in Molise, Lazio and Campania, where reductions ranged from 9% to 15%. These figures were only slightly less sweeping in Calabria and Sicily, while Abruzzo and Apulia have kept the reductions to a minimum, especially in consideration of the increases in temporary staff. In the regions not subject to the plan, the decrease was much smaller (-2.4%). The 1.7% reduction in full-time contracts (-6,700) was accompanied by a 7% cut in part-time employment (-3,700). The largest decrease was recorded in Liguria with a 5.4% drop, followed by Piedmont, Emilia and Lombardy (between 3.7 and 3.3%)[215].

Another important factor, also highlighted by the COVID-19 pandemic, is the reduction in the number of hospital beds in the SSN. Though it may seem a contradictory trend, it is in fact a Europe-wide development, but the drop towards 3.2 beds per 1,000 inhabitants has placed our country below the standards of France and Germany, which have 6 and 8 beds, respectively, putting Italy closer to countries like Spain and the United Kingdom, with 3 and 2.5 beds per 1,000 inhabitants respectively[216]. The consideration that emerges from these data is that there has been too much dehospitalisation too quickly, in the absence of a corresponding commitment to strengthen local structures.

Lastly, the reduction in resources has also affected the modernisation and upgrading of health infrastructure. Between 2008 and 2017, investment fell from 7.8 billion euros to less than 6 billion. After a fluctuating trend between 2008 and 2011, the decline was continuous until 2016 (-35%), before a slight recovery began in 2017[217].

The contraction of resources in terms of personnel and the reduction of hospital beds is also emphasised in the "Concluding document of the cognitive survey on the sustainability of the SSN with particular reference to the guarantee of the principles of universality, solidarity and equity" approved by the commission and published by the 12th Senate Health and Hygiene Committee in January 2018[218]. With regard to the availability of

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[215] Ibid, pp. 300-301.

[216] Ibid, p. 310.

[217] Ibid, p. 321.

[218] On this aspect, see also Ufficio parlamentare bilancio, *Lo stato della sanità in Italia*, 2 December 2019, p. 2. The turnover freeze in place since 2005 has resulted in a failure to replace retiring staff and therefore a loss of more than 40,000 FTEs nationwide in the years

beds and the related trends, paragraph 14 of this document reads: "Italy has a total number of beds (3.4 per 1,000 inhabitants) that is systematically lower than the average for the OECD countries and the major European countries (8.3 in Germany, 6.4 in France, 3.0 in the United Kingdom)".

The trend from 2005 to 2012, as reported in the same paragraph of that document, shows a continuous and progressive reduction in the number of beds. On the reduction of the health workforce, paragraphs 33 and 34 contain some important data. Paragraph 33 states:

> Compared to 2009, the year with the highest number of employees in public health, there are 40,364 fewer employees. The figures clearly show the effect of the numerous regulations on staff reduction, which have been applied differently in the SSN for the Regions with a recovery plan. Over the period 2001-2015, the average age of all SSN staff increased by 6 years and 7 months. At the end of 2015, the average age reached 50.1 years, higher than the average for the rest of the civil service.

The Senate Committee on Hygiene and Health highlighted the potential criticalities that could arise in the near future due to the emergence of a number of factors, such as the systemic lack of security in healthcare work, the increase in the average age of healthcare professionals, and the retirement of many professionals:

> With regard to human capital, the Senate Committee on Hygiene and Health has repeatedly stressed the seriousness of the situation. In a labour-intensive sector, understaffing is becoming a real risk for the provision of care. The unblocking of turnover and the stabilisation of all temporary staff are two inescapable necessities in order to guarantee the characteristics of equity and universality on which our SSN is based, as well as the quality of services. With regard to doctors, ANAAO estimates that over the next 10 years, public health will lose an average of two doctors per day, that is, 730 doctors per year, without their experience being passed on to the next generation of professionals. The average age of the doctors in service is around 54 years, which is higher than the average age of the rest of the employees.

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from 2008 to 2017. See also IRES Piemonte report, *Verso un Piemonte più sostenibile*, 2019, p. 28.

In the regions of Tuscany and Piedmont, for which a specific study and analysis was carried out (the results of which are set out in Chapter 4 of the report), some interesting variations were also recorded, both in terms of hospital services, the trend in the number of beds in certain specialist areas particularly affected by the COVID-19 emergency (infectious diseases, intensive care, pneumology) and the trend in the number of medical and nursing staff over the years.

As regards hospital care services, in the years 2011-2016 there was a decrease in both regions; the number of beds in the specialised areas decreased in the years 2010-2018, except for the number of beds in intensive care in Tuscany, which increased, as an average annual variation, by 1.8%. As for the trend in staffing, in the years 2010-2017 (which is the last year for which data are available) the nursing staff decreased in both regions, while the medical staff decreased in Piedmont but increased in Tuscany, although only by 0.2%[219].

The emergency situation resulting from the spread of the SARS-COV-2 virus in the last months of 2019 in Italy and in other countries such as France and Spain has highlighted the need to implement a significant turnaround in this area[220]. The specific contingency can be interpreted as a dramatic reagent that clearly brought to light the areas of greatest allocative distress[221].

If we look at the legislative measures issued by the State and the reorganisation measures adopted by the individual Regions and Local Health Authorities in the emergency sector, we see how their respective actions have been aimed on the one hand at increasing the number of healthcare personnel in service and on the other at enhancing the hospital setting, in particular the number of beds and mechanical ventilation devices available for intensive care and local assistance.

It can be argued that the emergency situation has highlighted a lack of planning of sufficient resources to respond in an appropriate manner to a

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[219] For these data, see Chapter 4, paragraphs 4.1, 4.2 and 7 below.

[220] It should be noted that the 2019 DEF had already provided for a reversal of the trend in SSN funding. The 2019-2021 Health Pact redefined the new level of national health needs by setting the National Health Fund at 116.5 billion euros for 2020 and 118 billion euros for 2021.

[221] On the measures set out in Legislative Decree no. 18 of 17 March 2020, so-called "Cura Italia", converted with amendments by Law no. 27 of 2020, and by Legislative Decree no. 34 of 19 May 2020, so called "Decreto Rilancio", converted with amendments by Law no. 77 of 2020, containing a plan to strengthen the SSN in order to address the impact on the health system caused by the spread of the virus, see the document of the Study Service of the Chamber of Deputies *Misure sanitarie per fronteggiare l'emergenza coronavirus* of 10 June 2020.

situation that is certainly of major proportions and in some respects not entirely predictable, but that in the future could become less and less exceptional. This requires a broad reflection on the general conditions in which the SSN finds itself.

From a broader perspective, the need has emerged to rethink planning from a number of angles, including with a view to dealing with possible unforeseen events since the occurrence of health emergencies may shift from being merely a matter of exceptional situations to being a critical one that could become cyclical, at least to a certain degree[222].

In this sense, the aspect of preparedness, i.e., the preparation of public health action strategies in the context of an emergency with the provision of a transparent chain of decision-making responsibilities, will have to be increasingly integrated into national public health strategies, as highlighted in numerous WHO documents[223] and, more recently, at the national level, in the opinions that the CNB recently published on the COVID-19[224] emergency as well.

6.1. *Tools for guiding allocation choices and setting priorities*

In the Italian system, among the instruments to regulate the allocation of resources and to make the right of access to services knowable, transparent and concretely exigible are the concrete definition of the levels of assistance ("clause on levels of care"), which, as noted, can be classified as minimum, uniform or essential, and the normative definition of the services

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[222] In the first two decades of this millennium, we have seen a cyclical occurrence of health emergencies, including global ones. These include SARS, which in 2002 spread from southern China to 37 other countries in a matter of weeks; bird flu, caused by the H5N1 virus, which started in southeast Asia at the end of 2003 and spread to many countries around the globe; swine flu, caused by the H1N1 virus, which spread from a few farms in Mexico to over 80 countries in 2009; MERS, Middle East respiratory syndrome, also caused by a coronavirus, which affected thousands of people between 2013 and 2019.

[223] Preparedness means a long-term strategy for dealing with emergencies. The definition proposed by the WHO at https://www.who.int/activities/preparedness-environmental-health-emergencies is as follows: "Emergency preparedness is a programme of long-term development activities whose goals are to strengthen the overall capacity and capability of a country to manage efficiently all types of emergency and to bring about an orderly transition from relief through recovery and back to sustainable development". See WHO, *A strategic framework for emergency preparedness*, Geneva, 2017; WHO, *Health emergency and disaster risk management framework*, Geneva, 2019; WHO, *Critical preparedness, readiness and response actions for COVID-19*, 19 March 2020.

[224] On this aspect, see CNB, *Covid 19: la decisione clinica in condizioni di carenza di risorse e il criterio del "triage in emergenza pandemica"*, 15 April 2020, pp. 6 ff. (on which see also infra, paragraph 8); CNB, *Covid-19: salute pubblica, libertà individuale, solidarietà sociale*, 28 May 2020, pp. 8 ff.

to be provided by the health system to be set out in a defined "basket" or list.

The guarantee of the essential levels of care also appears in the 2019-2021 Health Pact as the fundamental instrument for guiding allocation choices and improving the efficiency and sustainability in the system.

Another instrument for guiding allocation choices is the evaluation of activities carried out within the framework of HTA by agencies such as Age.Na.S., AIFA and bodies such as the Steering Committee (*Cabina di regia*), which was established by decree of the Minister of Health of 12 March 2015, in implementation of Article 26 of the 2014-2016 Health Pact[225].

In this regard, the 2015 Stability Law has implemented the provisions of Article 26 of the Health Pact[226] regarding the promotion of the rational use of medical devices on the basis of cost-effectiveness assessments. The priorities for the purposes of care are identified by the Ministry of Health, not only in light of the National Health Plan, but also on the basis of the indications provided by the Steering Committee, with the involvement of the Regions, Age.Na.S. and the Italian Drug Agency (AIFA), after hearing the representatives of patients, citizens and industry[227]. The activity of identifying priorities is also carried out by the Ministry by forecasting essential requirements to be included in tender specifications for the acquisition of medical devices at a national, regional, intra-regional or corporate level, and the elements for classifying medical devices in

[225] Articles 26 and 27 of the Health Pact include an explicit intention to promote HTA as a tool for guiding decision-making processes in health care. Paragraph 552 of Law no. 208 of 28 December 2015 "Provisions for the formation of the annual and multi-year budget of the State" (2016 Stability Law) provides for the functions of the Steering Committee established at the Ministry.

[226] Also in implementation of Directive 2011/24 of the European Parliament and the Council.

[227] See Art. 1, paragraph 587(a), 2015 Stability Act. The 2014-2016 Health Pact and the Stability Laws for 2015 and 2016 have outlined a new institutional model of cooperation between the central and regional levels for the pursuit of behaviours aimed at achieving the objectives of clinical effectiveness, management efficiency and sustainability of innovation. In the context of priority setting, the Ministry of Health plays a "strategic" and guiding role in the governance of health technologies: it defines priorities, evaluates the evidence collected and presented to formulate policies, guidelines, recommendations; it monitors over time the effects of the implementation of the recommendations issued, this also in part through the use of tools developed in recent years such as health technology flows at the ASLs. In all these activities, the Ministry of Health relies on the advice and support of bodies, including Age.Na.S., AIFA (for technologies in which there is a combination of drug and medical device), and the Regions, in the form of the Steering Committee, as named in the Health Pact.

homogeneous categories are based on reference prices, with specific reference to home treatment of chronic pathologies[228].

Additionally, in the field of health technology assessment, the National HTA Programme for medical devices was set up as a collaborative network between the Regions coordinated by Age.Na.S.[229].

6.1.1. *The clause on levels of care between identification of available resources and guarantee of services*

The identification of levels of care fulfils a number of functions concerning the guarantee of uniformity of services throughout the national territory and the protection of equality of access to services[230] and also performs a regulatory function in the allocation of health care resources.[231]

This clause therefore closely concerns not only the issue of rationalising health expenditure, as can be deduced from the agreement of 8 August 2001 (which establishes the instrument for identifying the essential levels and at the same time places a series of constraints on the management of health expenditure[232]), but also makes it possible to modulate the provision of services in accordance with differentiated methods and criteria that

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[228] See Art. 1, par. 587(b) of the 2015 Stability Law.

[229] See Art. 1, par. 587(c) of the 2015 Stability Law.

[230] The same need to guarantee inter-territorial cohesion/equality was derived from the clause on essential levels, which established the uniformity of services throughout the territory and the threshold above which regional health systems can provide additional services with additional resources from regional finances. The Constitutional Court, expressing its opinion on the content of the Essential Levels of Care, in Judgement no. 282 of 2002, clarified that this is "a competence of the state legislature that can cover all matters, with respect to which the legislature itself must be able to set the necessary rules to ensure that everyone, throughout the national territory, can enjoy guaranteed services, as the essential content of these rights, without regional legislation being able to limit or condition them". This view of the Constitutional Court leads us to consider as essential everything that, in its absence, would undermine human dignity, i.e., the irreducible core of law. See Constitutional Court Judgements no. 309 of 1999 and no. 509 of 2000.

[231] It should be noted that while in Legislative Decree no. 552 the levels of care are qualified as unique, in Legislative Decree no. 229 they take on the quality of "essential". In Legislative Decree no. 229, in particular, the essential levels of care must be identified at the same time as the financial resources allocated to the SSN. Article 26 of Legislative Decree no. 68 of 2011 seems to go beyond the aforementioned contextuality where it provides that, starting in 2013, the identification of financial resources and the determination of the national healthcare requirements, on the basis of the fundamental principles of Enabling law no. 42 of 2009 (which the Legislative Decree helps to implement) must be carried out not at the same time, but "consistently with the requirements resulting from the determination of the Essential Levels of Care".

[232] See State-Regions Conference, meeting of 8 August 2001.

represent a tool for managing available resources.

The clause on the levels of care is contained, with different formulations, in various legislative acts, starting from the law establishing the SSN, through Article 117, paragraph 2, letter m, of the Constitution after reform in 2001, to the legislation on fiscal federalism. Its interpretation rests on a number of bases, that variously identify it as "the new frontier of theoretical reflection on rights and freedoms"[233], "the connecting bridge between the protection of values linked to the pursuit of the substantial equality of citizens, which constitutes the essential aspect of the 1948 Constitution, and the limitation of the drive for differentiation of sub-state territorial communities which is instead the basis of the new Title V"[234], or "the keystone of the relationship between welfare and federalism" as well as "a great opportunity to redefine welfare as a whole", representing "a protection and guarantee for needs and risks that today are not covered and rebalancing inequalities and injustices between categories, sectors and territories"[235].

The clause on essential or uniform levels of services could therefore, potentially, contribute to the concrete expression of the principle of comprehensive services, thanks to the reference to appropriateness, balancing it with the financial needs of the system. The obligation of financial coverage of the LEAs, the first qualifying element for guaranteeing effective access to services, was derived from it.

The compilation of the list of services guaranteed by the health system was affected by the complex and multidimensional nature of the right to health, and therefore followed the expansive logic of its protection. The definition of guaranteed services could potentially limit the discretion of the organisation responsible for providing the service and places the constraints deriving from the scarcity of economic and financial resources in the context of planning and predetermining the conditions and methods of access to care aimed at strengthening the effectiveness of the right to health[236]. The provision of a basket has made it possible to justify the right of access to benefits whenever a refusal on the basis of financial

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[233] Thus S. Gambino, *I diritti sociali e la "riforma federale"*, in Quaderni Costituzionali, 2001, no. 2, p. 353.

[234] Thus F. Pizzetti, *La ricerca del giusto equilibrio tra uniformità e differenza: il problematico rapporto tra il progetto originario della Costituzione del 1948 e il progetto ispiratore della riforma costituzionale del 2001*, in Le Regioni, 2003, no. 4, 600.

[235] L. Torchia, in the foreword to *Welfare e federalismo*, edited by L. Torchia, Bologna, Il Mulino, 2005, pp. 10, 14 and 15.

[236] See C. Tubertini, *Le garanzie di effettività dei LEA al tempo della crisi*, in Welfare e servizio sanitario: quali strategie per superare la crisi, edited by C. Bottari, F. Foglietta and L. Vandelli, Santarcangelo di Romagna, Maggioli, 2013, pp. 121 ff.

considerations created an unreasonable obstacle to accessing those benefits[237].

This is the context in which the guaranteed services were defined in the 2001 decree implementing the rules contained in Art. 1 of Legislative Decree no. 502 of 1992 as amended in 1999. As regards the definition of guaranteed services, it is now clear that a series of reflections have shaped the basket of services on the basis of the need to contain public spending and to strengthen the protection of the fundamental right while ensuring the universality and comprehensiveness of services[238].

Article 1 of Legislative Decree no. 502 of 1992, as amended in 1999, defines the LEAs as the set of services that are guaranteed by the SSN, either free of charge or through cost-sharing, because they provide, in specific clinical conditions and according to scientific evidence, a significant benefit in terms of individual or collective health, in relation to the resources employed. The provision clarifies, in paragraph 7, that the following types of assistance, services and health care procedures cannot be included in the essential levels, and therefore cannot be charged to public finance:

> *a) [those that] do not meet care needs protected under the principles governing the SSN;*
>
> *b) [those that] do not meet the principle of efficacy and appropriateness, i.e., whose efficacy is not demonstrable on the basis of the available scientific evidence or those that are used for individuals whose clinical condition does not correspond to the recommended indications;*
>
> *c) [those that,] in the presence of other forms of assistance aimed at satisfying the same needs, do not satisfy the principle of cost-effectiveness in the use of resources, or do not guarantee an efficient use of resources in terms of the way in which assistance is organised and provided".*
>
> *Paragraph 8 provides for the services defined as innovative services "for which there is insufficient and definitive scientific evidence of effectiveness" and "which may be provided in healthcare facilities accredited by the SSN exclusively within the*

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[237] See Consiglio di Stato, section V, Judgement no. 744 of 2009; Consiglio di Stato, section V, Judgement no. 4084 of 2011.

[238] C. Tubertini, *Pubblica amministrazione e garanzia dei livelli essenziali delle prestazioni: il caso della tutela della salute*, Bologna, Bonomia Università Press, 2008; Id., *Diritto alla salute, organizzazione e risorse finanziarie. lo stato attuale della questione*, in Diritto amministrativo e società civile. Volume I – studi introduttivi, Bologna, Bononia University Press, 2018, pp. 545562.

framework of experimentation programmes authorised by the Ministry of Health.

Legislative Decree no. 502 of 1992, as amended by Legislative Decree no. 229 of 1999, provided that essential and uniform levels throughout the national territory were to be determined by the national health plan. In practice, however, the procedure adopted for the implementation of the decree establishing the essential levels led to the adoption of a decree by the President of the Council of Ministers, on the proposal of the Minister of Health, in agreement with the Minister of the Economy and Finance, in agreement with the Permanent Conference for relations between the State, the Regions and the Autonomous Provinces of Trento and Bolzano[239].

6.1.2. *Updating the essential levels of care*

From a formal point of view, the Prime Ministerial Decree of 2001, containing the definition of the Essential Levels of Care, was replaced by the Prime Ministerial Decree of 12 January 2017 "Definition and updating of the Essential Levels of Care, referred to in Article 1, paragraph 7, of Legislative Decree no. 502 of 30 December 1992".

The scientific debate that followed the revision of the Essential Levels of Care has shown that the identification of the essential levels corresponds to, on the one hand, the need for equity and uniformity of the services throughout the national territory and, on the other, the need for an effective planning that pursues the long-term sustainability of the system[240].

The 2016 Stability Law envisaged updating the LEAs by means of the procedure identified in 2001[241], in addition to the opinion of the competent

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[239] See Art. 6, par. 1, Legislative Decree no. 347 of 18 September 2001, implemented in Law no. 405 of 2001. The procedure in question has also been ratified through the intervention of the Constitutional Court in several stages (in addition to Judgement no. 88 of 2003, Judgement no. 134 of 2006 and Judgement no. 8 of 2011), although one weakness has been pointed out: it consists of the risk of shifting the balance to the advantage of government action and to the detriment of other actors, such as parliament and the social partners (the most representative trade union confederations); the underlying logic reflects considerations dictated by the need to provide financial coverage for the services and is therefore not related to balancing the guarantee of constitutional values and the availability of economic resources.

[240] V. Molaschi, *Programmazione e organizzazione dell'equità in sanità. L'organizzazione come "veicolo" di eguaglianza*, in Rivista di Biodiritto, 2019, n. 2; G. Guerra, *I nuovi livelli essenziali di assistenza sanitaria*, in Politiche Sanitarie, 2017, n. 18.

[241] Provided for in Art. 6, par. 1, Legislative Decree no. 347 of 18 September 2001, converted into Law no. 405 of 2001.

parliamentary committees[242] included in an amendment approved by the Senate.

The Parliamentary debate on the draft decree

The parliamentary debate on the draft decree submitted for opinion was rich in contributions and reflections on expected updates of the LEAs.

The opinion approved by the Senate Committee on Hygiene and Health (Commission on Hygiene and Health in consultative session on government acts - draft decree of the President of the Council of Ministers defining and updating the essential levels of care - favourable opinion with conditions and observations - Wednesday 14 December 2016), provides a number of observations on the draft decree. First of all, there is a need to approve the decree in order to improve and rationalise the quality of care. In addition, on a methodological level, the question is raised of the need to make explicit the ethical, economic, organisational and scientific criteria to be used in decisions on the inclusion or exclusion of services.

The process of implementing and updating the new LEAs is, in fact, defined as an ongoing process that must take into account technological, organisational and managerial innovations, accompanied by the training of personnel and the qualitative and quantitative adaptation of professional resources with respect to the supply of services.

Among the conditions attached to the approval of the positive opinion it is the extension of participation in the National Commission for the updating of the essential levels of care to representatives of citizens' and patients' associations, the increase in SSN funding so as to adequately cover the implementation of the essential levels of care and avoid an increase in co-payments and the provision of an exemption to the turnover freeze in those Regions (subject to a recovery plan) that are particularly deficient in terms of the provision of health services.

In the opinion submitted by the Social Affairs Committee of the Chamber of Deputies (Social Affairs Committee - draft decree of the President of the Council of Ministers on the definition and updating of the essential levels of

[242] Paragraphs 312 to 323 of the 2016 Stability Law concern the revision of the essential levels of health care. In this regard, an increase in expenditure of no more than 800 million euros per year is envisaged for the first revision, new procedural rules are defined, including when fully operational, and a National Commission is established for the updating of the essential levels of care and the promotion of appropriateness in the SSN, which is also responsible for assessing whether the application of the essential levels of care takes place in all Regions with the same quality standards and includes all the services envisaged by the specific essential levels of care.

care - favourable opinion with conditions and observations - 14 December 2016), among the most interesting observations for our purposes are the request that the economic and financial sustainability of the essential levels of care be guaranteed and the introduction in the essential levels of care of activities and services through the use of remote monitoring technologies.

In the alternative draft proposal that was presented, the favourable opinion is subject to conditions, such as the need to guarantee adequate economic resources to support coverage of the Essential Levels of Care and the Government's explicit indication of the services that have been newly included and those that are otherwise guaranteed or no longer guaranteed, stating the scientific reasons for these changes. The contextual proposal for a negative opinion highlights the fact that the draft decree focuses more on issues of financial sustainability and compliance with budgetary constraints than on the need to provide universal guarantees for the essential levels of care, with, consequently, the use of appropriateness in an economic rather than clinical sense. The draft negative opinion states that while there has been an increasing transfer of services from the hospital to the outpatient setting, with the risk of an increase in the costs borne by citizens in terms of co-payments, there has not been a corresponding transfer of resources from the hospital to the local area, and the appropriations provided are insufficient to ensure the enforceability and uniformity of the right to social and health care.

The revision procedure consisted of an initial phase for the drafting of the proposal and a final phase for the evaluation of the implementation by the regions. The management of these phases was entrusted to the Commission chaired by the Minister of Health, who is called upon to present an annual report on the state of implementation of the regulations providing for the revision of the LEAs.

The National Commission for the updating of the Essential Levels of Care and the promotion of appropriateness in the SSN was established to guarantee the efficacy and clinical and organisational appropriateness of the services provided by the SSN within the scope of the essential levels of care, and also in order to ensure that the services are appropriate and effective, including with respect to scientific and technological advancements[243]. It should be pointed out that in the health sector, the

[243] The Commission, appointed and chaired by the Minister of Health, is composed of the Director of the Directorate General for Health Planning of the Ministry of Health and fifteen qualified experts and the same number of alternates, four of whom are appointed by the Minister of Health, one by the ISS, one by Age.Na.S., one by AIFA, one by the Ministry of Economy and Finance, and seven by the Conference of Regions and Autonomous Provinces. This Commission carries out the following activities in particular: a) a systematic evaluation of the health and social-healthcare activities, services and performances relevant to health

inclusion of services in the essential levels is not an absolute fact, but an indication that must be periodically updated to reflect evolving technological advances and the social demand for health services[244]. The revision of the current provision on LEAs was initiated to implement the provisions of the State-Regions Agreement of 10 July 2014 on the 2014-2016 Health Pact.

The process of revising the essential levels of care was concretely implemented through the work carried out by four working groups, composed of representatives of the Ministry, the Regions and Age.Na.S., which between April and December 2014 drew up the draft decree presented by the Minister of Health to the Senate Health Commission in February 2015.

The proposal to update the LEAs incorporates most of the provisions of the draft revision set out in Prime Minister Prodi's Decree of 2008 that had not been endorsed by the State Accounting Office. A number of innovations, the need for which became increasingly apparent, for various reasons, in subsequent years, have been introduced on the basis of that draft: these include treatments against compulsive gambling, the introduction of heterologous fertilisation in the LEAs[245], detailed forecasts on social and

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included in the LEAs, in order to assess their continuation or to define conditions of deliverability or indications of appropriateness; b) collecting and evaluating proposals for the inclusion in the LEAs of new services, activities and performances; c) applying HTA assessments on health and biomedical technologies and organisational models and procedures for the updating of LEAs and the identification of conditions for supply or indications of appropriateness; d) assessment of the economic impact of changes to LEAs; e) assessment of requests from SSN facilities for authorisation to provide innovative services as part of experimentation programmes, pursuant to Article 1(8) of Legislative Decree no. 502 of 30 December 1992, as subsequently amended; f) verification that the LEAs are being applied in all Regions with the same quality standard and include all the services envisaged by the specific LEAs. See paragraph 557 of the 2016 Stability Law. From an organisational point of view, it should be noted that the Commission's term of office is three years. At the request of the chairman, representatives of the CSS, scientific societies, medical federations and external experts with expertise in the specific subjects under discussion may attend the Commission's meetings to provide their own technical and scientific contribution. See M. Conticelli, *La legge di stabilità per il 2016 – la salute: misure per l'efficienza e la produttività*, in Giornale di Diritto Amministrativo, 2016, no. 2, p. 178.

[244] Article 5 of Law no. 189 of 2012 converting Legislative Decree no. 158 of 2012 required an update of the essential levels by 31 December 2012 with particular reference to chronic and rare pathologies and the inclusion in the essential levels of the diagnosis and treatment of gambling addiction. This article was repealed by paragraph 554 of the 2016 Stability Law, which provides for different deadlines and specific instruments to monitor the revision.

[245] Following Constitutional Court Judgement no. 162 of 2014 declaring the unconstitutionality of the prohibition on heterologous fertilisation contained in Law no. 40 of 2004 in cases of absolute and irreversible infertility and/or sterility, a number of regions proceeded to adopt rules relating to heterologous fertilisation techniques. In particular, by

health care, the inclusion of services with features reflecting the latest technological advances and the consequent exclusion of technologically obsolete services, and the priority need to revise the list of rare diseases and chronic diseases[246].

There were, ultimately, many reasons to revise the LEA decree: the transfer of several services from the hospital setting to the outpatient setting identified as a key element for the rationalisation of expenditure in the 2014-2016 Health Pact required a new regulatory context; the process of obsolescence of the LEA decree's defining framework gave rise to clinical variability, leading to regional differences in clinical practices that in some cases constituted a threat to the unity of the system and to the guarantee of the appropriateness and efficiency of local choices, to name a few. Ultimately, measures to increase economic and social sustainability (on this issue, patients with amyotrophic lateral sclerosis (ALS) undertook a hunger strike in the autumn of 2012) could only be implemented through a revision of the regulatory framework on the essential levels of care[247]. The updating of the LEAs has given rise to a number of critical issues that need to be addressed before the new services could be included. For example, the effective provision of the new specialist and prosthetic services, included in the new LEAs calls for a decree, still to be defined, on the tariffs to be paid to both public (ASL, AO, AOU, public IRCCS) and equivalent or accredited private providers (private IRCCS, religious hospitals, outpatient clinics and laboratories, orthopaedic companies, etc.). In the absence of the decree on these tariffs, only the services and facilities listed in the 2001 decree (previous LEAs) are provided for, regardless of whether exempt

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virtue of DGR no. X-2344 of 12 September 2014, Lombardy provided that the use of medically assisted procreation techniques would be paid for in full by the patient, pending the adoption of national legislation. In Tuscany, with DGR no. 650 of 2014, it was established that the services connected to medically assisted procreation of the heterologous type had to be subject to cost-sharing, as was also the case for the services of medically assisted procreation of the homologous type. After heterologous fertilisation services were included in the essential levels of care, the forms of cost-sharing were standardised at the national level by requiring users to pay a co-payment fee. It is clear that in the phase preceding the revision of the essential levels of care, the provision of services at full cost to the patient or with cost-sharing depended above all on political criteria of greater or lesser openness to heterologous assisted fertilisation techniques.

246 With regard to rare diseases, 110 new types of rare diseases compared to the list annexed to Ministerial Decree no. 279 of 2001; as regards chronic diseases, 6 new pathologies have been included compared to the one envisaged by Ministerial Decree no. 329 of 1999, but the service packages concerning pathologies already envisaged have been reduced or revised.

247 See Ministry of Health, Health Planning Directorate, Technical Report on the Draft Decree of the President of the Council of Ministers concerning: "New definition of the essential levels of health care" (*Nuova definizione dei livelli essenziali di assistenza sanitaria*), pp. 1 ff.

patients are old or new, and regardless of whether due to pathology or pregnancy.

The decree for the revision of the LEAs

The revision decree, which defines the LEAs in 63 articles and 18 annexes (whereas the 2001 decree consisted of only one article and four annexes), is of a different structure than the LEA decree it is called upon to repeal.

The text of the measure is divided in four parts: the first article identifies the three macro-areas covered by the essential levels ("Collective prevention and public health", "District care" and "Hospital care"); the second article is devoted to identifying the areas of "Collective prevention and public health"; the third article is devoted to identifying the areas of "District care"; art. 36 identifies the areas of "Hospital care"; the last part (articles 50-63) is dedicated to the identification of the areas of "Healthcare". This final section (articles 50-63) is devoted to care for specific categories of patients (including invalids, people affected by rare diseases, people affected by chronic diseases, people affected by cystic fibrosis, chronic nephropathic patients under dialysis treatment, people affected by Hansen's disease, people with HIV/AIDS infection, people in prison and in custody, pregnant women and maternity care, people with autistic spectrum disorders, citizens of non-EU countries who are registered with the SSN, citizens of non-EU countries who do not have a valid residence permit).

For the specific areas in which the services to be provided are illustrated in "lists" or "nomenclatures" (outpatient specialist care, prosthetic care), the new nomenclatures are included in the measure (in specific annexes) and contain all the relevant regulations.

The annexes are as follows: Annex 1 Collective prevention and public health; Annex 2 Disposable aids; Annex 3 Devices for persons suffering from diabetes and rare diseases; Annex 4 Nomenclature of outpatient special care services; Annex 4A Risk factors for the provision of bone densitometry services; Annex 4B Conditions for the provision of refractive surgery; Annex 4C Criteria for defining the conditions for the provision of dental services; Annex 4D List of notes and corresponding conditions for the provision of services - indications of appropriate prescription; Annex 5 Custom-made aids and serial aids (Lists 1, 2A and 2B); Annex 6A DRGs at high risk of non-appropriateness in ordinary inpatient care; Annex 6B Services at high risk of non-appropriateness in day surgery - transferable to outpatient care; Annex 7 List of rare diseases exempt from cost-sharing;

Annex 8 List of chronic and invalidating diseases and conditions; Annex 8-bis List of chronic and invalidating diseases and conditions (old list); Annex 9 Hydrothermal care; Annex 10 Specialised services for the protection of responsible motherhood, excluded from the cost-sharing scheme before conception (10A), special services for the monitoring of physiological pregnancy, excluded from cost-sharing (10B) and conditions of access to invasive prenatal diagnosis, excluded from cost-sharing (10C); Annex 11 Disposable medical devices; Annex 12 Provision of prosthetic care services.

These new nomenclatures are highly innovative, as they include technologically advanced services and exclude obsolete services dating back to the 1990s version of the national nomenclature.

Specialist outpatient services paid for by the SSN are listed in the Ministerial Decree of 22 July 1996 (1,702 types of services), and the relative maximum tariffs were updated by Ministerial Decree of 18 October 2012. It should be pointed out that, considering the delay in updating the nomenclature at the national level and the autonomy granted to the Regions in providing for the introduction of new codes and services, a certain heterogeneity and variability emerges in the different lists of the regional nomenclatures, for example ranging from 2,558 categories of services that are found in the nomenclature of the Emilia-Romagna Region (where 34% are additional services compared to those of the 1996 nomenclature), to 1,720 for the Sardinia Region (with 1% additional services).

In the definition of the nomenclature for outpatient specialist care, particular attention was paid to clinical appropriateness: for a large number of services (69), in particular in the sector of diagnostic imaging and laboratory work, "indications of prescriptive appropriateness" have been identified, which are useful for the prescriptive activity of doctors. For a smaller number of services (33), "conditions for provision" have been identified, which are binding for the purposes of guaranteeing the essential levels of care (see attachment 4D to the decree on essential levels of care). The obligation for the prescribing doctor to include in the prescription an indication of the diagnostic purpose or suspected condition has also been introduced (see art. 15 of the Prime Ministerial Decree, under the heading "Specialist outpatient care"; see also Ministry of Health - Health Planning Directorate, Technical Report on the Draft Decree of the President of the Council of Ministers containing "New definition of essential levels of health care", pp. 20 ff).

In areas where no closed service lists are available, for example in the area of "Collective prevention in living and working environments" or district care, specific services were identified, with no attempt to producing

exhaustive lists and avoiding reference to the regulations in force, by filtering the normative provisions concerning specific activities and services falling within the competence of the respective services (Prevention Departments, Family Advice Centres, SERTs (pathological addiction treatment services), Mental Health Departments, Rehabilitation Services, etc.). The measure therefore reorganises services in these areas, which were previously provided for across many legislative acts, without extending or widening the scope of each area.

For the socio-health area, in particular, the different types of care characterised by different levels of complexity and services have been identified and described in order to guarantee homogeneous management across the national territory. This means that integrated home care for chronically ill and non-self-sufficient patients has been divided into four levels of progressive intensity (from basic to high intensity home care, replacing the "home hospitalization" option; see Article 22 of the decree on the new LEAs) and, similarly, residential care for the same patients has been organized into 3 types according to the characteristics of the facilities and the availability of the necessary staff, for the purpose of providing "extensive care and functional recovery treatments" and "long-term care, recovery and functional maintenance treatments". In the field of semi-residential care, the SSN guarantees long-term care, recovery, functional maintenance and reorientation in a prosthetic environment (see art. 30 of the decree on the new LEAs).

Specific attention has also been paid to the issue of organisational appropriateness by updating the list of DRGs "at high risk of non-appropriateness in ordinary inpatient care" (see attachment 6A of the decree on the new LEAs), with the inclusion of 66 additional DRGs that had been already identified in attachment B) to the 2010-2012 Health Pact. For these, the Regions are called upon to establish the percentages of hospital admissions that can be carried out appropriately and the measures aimed at discouraging inappropriate admissions, in part through the provision of a list of procedures that can be transferred from the day-surgery regime to the outpatient regime. The latter had been included in annex A) to the 2010-2012 Health Pact which, similarly to what is provided for the DRGs, determines that the Regions are competent to identify percentages of appropriate admissions and disincentivising measures as well as to clarify the appropriateness criteria for all admission regimes.

6.1.3. *Health Technology Assessment*

Technology assessment in health care takes place primarily through the work of a variety of bodies and agencies that perform their functions at various levels: national, regional and local.

The object of the assessment is clearly vast, ranging from drugs and medical devices to any type of health technology, and includes organisational innovations and medical and surgical procedures subject to evaluation on the basis of the analysis of clinical, economic and organisational evidence to support allocation choices.

In Italy, health technology assessment is carried out by agencies such as Age.Na.S., AIFA, the Regions, Universities and Research Centres. More specifically, these include several regional agencies (Liguria, Emilia-Romagna, Abruzzo, Puglia) and regional offices (Veneto, Lombardy, Sicily, Lazio, Tuscany, etc.), in addition to hospital and university hospital authorities (operating through offices/working groups/commissions for HTA at the local level).[248]

As noted, on the basis of the 2014-2016 Health Pact, the Steering Committee (*Cabina di regia*) for the definition of priorities in healthcare was established at the Ministry of Health to guarantee the assessment of health technologies in a way that allows for coordination between the national, regional and local levels in order to ensure uniformity across the system[249]. The creation of the Steering Committee is intended to overcome the fragmentation of evaluation activities and restore the centrality of the programming and monitoring role of the Ministry of Health, supported by the technical reference bodies (Age.Na.S. and AIFA). The Steering

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[248] See Centro studi Assobiomedica, *Mappatura dei meccanismi di HTA regionali in Italia*, November 2012, no. 13. On the fragmentary and decentralized nature of HTA activities and the variability of the methodologies used, see P.R. Boscolo, O. Ciani, R. Tarricone and A. Torbica, *La funzione di HTA nelle aziende sanitarie italiane: un potenziale ancora inutilizzato?*, in L'aziendalizzazione della sanità in Italia: Rapporto OASI 2015, edited by CERGASBocconi, cit., pp. 585 ss. It should be pointed out that, at the local level, with respect to clinical and financial criteria the application of HTA consists primarily of evaluations of congruity of the requests from clinicians regarding the purchase of medical devices, rather than the performance of complex multidimensional HTA procedures. See P.R. Boscolo, O. Ciani, R. Tarricone and A. Torbica, *La funzione di HTA nelle aziende sanitarie italiane: un potenziale ancora inutilizzato?*, cit., p. 599.

[249] The *Cabina di Regia* (Steering Committee) is composed, according to the provisions for its establishment in the decree of the Ministry of Health of March 12, 2015, of the director of the General Directorate of Medical Devices and Pharmaceutical Service of the Ministry of Health acting as President; two representatives of the Ministry of Health; four representatives designated by the State-Region and Autonomous Province Conference; one representative designated by Age.Na.S.; and one representative designated by AIFA.

Committee was established by decree of the Minister of Health of 12 March 2015, implementing Article 26 of the 2014-2016 Health Pact. It performs a number of functions, namely: a) defining the priorities for the multidimensional technical assessment of medical devices on the basis of the criteria of the relevance of the health condition as well as the relevance, safety, efficacy, economic impact and organisational impact of medical devices, in accordance with the relevant European guidelines (EUnetHTA); b) promoting and coordinating the multidimensional assessment activities carried out by the National Agency for Regional Health Services (Age.Na.S.), by the regional authorities and by public and private entities with proven experience in HTA operating within the National Programme for medical devices; c) validating the methodological guidelines that are applied for the production of multidimensional technical evaluation reports in the National HTA Programme; d) overseeing the publication, dissemination and verification of the impact reports at the national level of the outcomes of the evaluations referred to in point b) according to the validated methods referred to in point c) to promote their use by the Regions and the healthcare authorities to inform decisions on the adoption and introduction of medical devices and on divestment[250].

The national direction thus established is aimed at guaranteeing the effectiveness and timeliness of the assessments, the elimination of duplications, the definition and coordinated use of tools for the governance of medical devices, this including in consideration of the assessments produced in the context of the European HTA network envisaged by Article 15 of Directive no. 24 of 2011 on cross-border care. The evaluation activities carried out by the Steering Committee impact a variety of health scenarios: political, managerial and clinical alike. The evaluations concern the political scenario where their object is the inclusion of services and performances in the LEA, the reimbursement prices of drugs and the allocation of technologies on the territory; they have a managerial impact when they affect the activation or deactivation of hospital services, the adoption of biomedical technologies and the introduction of new diagnostic tests; and lastly, they affect the clinical level when they condition the content of diagnostic and therapeutic protocols.

A second body, the functions of which include health technology assessment, is Age.Na.S.

Age.Na.S. is an autonomous body endowed with specific expertise in the health sector, by virtue of which it carries out technical support activities for the Government and the Regions. It performs important functions in areas in which there is a strong need for cooperation between different

[250] See Law no. 208 of 28 December 2015 (2016 Stability Law), par. 552.

levels of government, such as the development of assessment and monitoring tools (like standards and indicators) and the activities carried out in the context of recovery plans[251].

The Unified Conference of 20 September 2007 also established, as a strategic sector of Age.Na.S.'s operations, the evaluation and management of technological innovations (HTA) and dissemination at the regional level of the results of the studies and evaluations carried out.

In the field of health technology assessment[252], Age.Na.S. performs two substantially contiguous tasks, one coordinating the network of assessment activities carried out at the regional and supranational levels, the other supporting the activities of the Ministry of Health by drawing up HTA reports and horizon scanning documents[253].

In the framework of ordinating network activities, Age.Na.S. promotes and manages two significant networks for the evaluation of health technologies: firstly, the RIHTA (Italian Network for HTA – established in 2009), an interregional collaborative network that promotes the sharing of experiences gained by bodies that, in Italy and at various levels, carry out HTA assessments or similar activities[254]; secondly, the Agency also participates in the networks of international agencies and the European

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[251] In parallel with the process of regionalisation of the health sector, the Agency's scope and breadth were expanded. Concerning this Agency, see F. Moirano, A. Angelastro and G. Caraccia, *Il ruolo di Agenas nella riflessione sui processi di trasformazione dei sistemi socio-sanitari nelle Regioni italiane,* in Verso differenti sistemi sanitari regionali, edited by G. Bertin and C. Cipolla, Venice, Edizioni Ca' Foscolo Digital Publishing, 2013, pp. 11 ff.; T. Feola and A. Di Corato, *Servizio sanitario nazionale*. *Stato e Regioni nel governo della salute*, Turin, Minerva Medica, 2006.

[252] See http://www.agenas.itlhealth_TA.ht1nl. The Trento Charter on Health Technology Assessment (Carta di Trento sulla valutazione delle tecnologie sanitarie) adopted by the Italian Health Technology Assessment Society states that "health technology assessment is the comprehensive and systematic multidisciplinary assessment (description, examination and judgement) of the health care, economic, social and ethical consequences of existing and new health technologies, both directly and indirectly, in the short and long term. It is the bridge between the technical-scientific world and the decision-makers". The approach is therefore characterised by the adoption of a broad concept of technology, by orientating the evaluation to support a decision (political, managerial or clinical), by the multidimensionality and multi-professionalism of the evaluation, and by the centrality given to scientific evidence and the scientific method in the evaluation.

[253] From 2009 to March 2019, Age.Na.S. produced 22 HTA documents and 24 Horizon Scanning (HS) reports on behalf of the Ministry of Health. The HTA documents have various denominations including full reports, summary reports and methodological documents. The horizon scanning documents are intended to identify technologies with potential impact on the health system before their deployment in clinical practice. See Age.Na.S., *Manuale delle procedure HTA*, December 2014, pp. 14 ff.

[254] The Italian network for HTA was set up by a collaboration agreement, pursuant to art. 15 of Law no. 241 of 1990, signed at the State-Regions Conference on 11 February 2010.

Union that conduct HTA in order to share information and strategies aimed at strengthening the capacity for innovation and governance of the technologies of our health service[255].

In the framework of the evaluation activity supporting the Ministry of Health, the collaboration with the General Directorate of Medical Devices and Pharmaceutical Service of the Ministry (DGFDM) started with the financial law for 2007 (law no. 296/2006) on the basis of annual agreements for the production of HTA and horizon scanning reports concerning medical devices.

The HTA reports drawn up by Age.Na.S. are the result of a complex process in which a plurality of factors are taken into consideration[256].

The reports provide a multidimensional assessment that focuses on key aspects of the technology such as clinical framing, identification of the technology and alternatives (comparators), current use of the technology in SSN facilities, clinical effectiveness analysis, safety analysis, patient perspective analysis, organisational analysis, and analysis of the economics of using the technology.

The identification of new or developing devices, technologies or practices in need of evaluation is done through different channels. It can be done through the processing and analysis of the data contained in the Ministry's New Health Information System (NSIS)[257] (in particular the Information Flow on the consumption of medical devices, which identifies devices that absorb the highest expenditure and the variability of use of the different types); or through the reporting of technologies for which the various stakeholders (Ministry, Region, operators, industry parties, health companies, scientific societies, private individuals) express the need for evaluation. Reports are filtered on the basis of general criteria, such as completeness of information received, verification of any recent evaluations already published or in the process of being published. The criteria taken into consideration by AGNAS may concern clinical and epidemiological aspects (burden of disease), therapeutic benefits, benefits for the patient, the presence of alternatives, the cost-effectiveness profile, the impact on public health, innovativeness and equity.

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[255] The Agency has joined several networks: EUROSCAN, INAHTA, HTAI (International Scientific Association of HTA). In addition, the Agency has participated in the EUNETHTA network since 2005. On these, please refer to the individual websites: https://www.euroscan.org/; http://www. inahta.org/; www.htai.org www.eunethta.eu.

[256] See National Agency for Regional Health Services, *Manuale delle procedure HTA*, Rome, December 2014, available on Age.Na.S. website at http://www.agenas.it/images/agenas/hta/Manuale_procedure_HTA.pdf.

[257] On the NSIS see www.nsis.salute.gov.it.

In some contexts, these criteria are associated with a weighting system in relation to the needs expressed by the decision-makers.

The list of technologies resulting from the identification/designation system, as far as medical devices are concerned, is subject to evaluation according to priority criteria (epidemiological criterion, demand criterion, availability or cost-effectiveness criterion, economic-organisational criterion) submitted to and approved by the Single Commission for Medical Devices (CUD)[258].

The methodology leading to the evaluation report is set out in a protocol which defines the policy question and the research question for each of the domains considered and on the basis of which the analysis is carried out[259]. Specifically, the protocol specifies the methods used to search for evidence (identification of sources, databases, studies, consultation of stakeholders) and the comparator against which the technology will be assessed, the types of primary and secondary outcomes, the research strategy, the criteria for inclusion/exclusion of studies, and the tools for assessing the quality of studies and for the possible collection of context data. In order to make the evaluation as suitable as possible for answering the question of the assessment, the protocol is drawn up in collaboration with clinical experts in that technology and with the reporting entity and/or the initiators of the request.

AIFA carries out activities for the evaluation of pharmaceutical health technologies. It should be noted that marketing authorisation and drug technology assessment are two fundamentally different activities from a structural and functional perspective. The marketing authorisation is issued by AIFA, as part of a multilevel system in which the European

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[258] The Single Commission on Medical Devices (CUD), established by Law no. 289 of 27 December 2002, art. 57, identified as a technical advisory body of the Ministry of Health, has the task of defining and updating the directory of medical devices, classifying all products in specific categories and subcategories. These criteria fulfil a number of measurement and evaluation functions. The epidemiological criterion is intended to measure the ability of the technology in question to contribute to the appropriate clinical and organisational management of a health problem or health situation measured by the incidence of the problem or its complications (morbidity and mortality), through the availability of effective interventions and, lastly, the uncertainty documented by wide clinical variability. The demand criterion is used to assess the immediate interest in the technology on the part of users, the health administration, the public, patient associations and individual patients, as it is likely to be of relevance in the medium term for the appropriate clinical and organisational management of an important health problem. The economic-organisational criterion is understood as the ability of the technology in question to produce more health, with the same resources employed, or to contribute to a more adequate clinical and organisational management of a major health problem than current (and in some cases future) alternatives.

[259] See Age.Na.S., *Manuale delle procedure HTA*, December 2014, pp. 23 ff.

Medicines Agency (EMA) also plays an important role. Through its committees, the EMA carries out all the necessary assessments (chemical-pharmaceutical, biological, pharmaco-toxicological and clinical) to ensure the safety and efficacy requirements of the drugs.

Health technology assessment represents a subsequent level in which certain aspects of the effectiveness and cost of medicines are highlighted in the context of promoting good practice (use of equivalent medicines, price negotiations with pharmaceutical companies), performing international comparisons of the price system, and developing the innovative medicines sector.

In the area of innovative medicines and the evaluation of healthcare technologies by AIFA, the stability laws for 2015 and 2016 set out a number of important rules[260].

In the field of health technology assessment, in order to guarantee homogeneous access of patients to all medicines and to provide information on the comparative effectiveness of medicines, especially innovative medicines or those of exceptional therapeutic importance, AIFA is called upon to prepare HTA assessments, in support of the Ministry of Health and the Regions[261].

6.2. *The specification of criteria for identifying the benefits that can be provided. Appropriateness and guidelines*

For the purposes of the concrete identification of the services that can be provided, two fundamental factors can be identified, and these are

[260] Paragraphs 569 and 570 of the 2016 Stability Law set out new provisions on the administration of and access to innovative drugs with a view to system sustainability and treatment planning. Paragraph 569 clarifies that the expenditure for the purchase of innovative pharmaceuticals does not contribute towards the expenditure ceiling for local pharmaceutical care, except for the amount that exceeds, annually for each of the years 2015 and 2016, the amount of resources constituting the endowment of the Fund for the reimbursement to the Regions for the purchase of innovative pharmaceuticals, being 500 million euros for each of the years 2015 and 2016 (90% of these resources are to be found in the resources of the National Health Fund). The expenditure ceiling for local pharmaceuticals is established by Art. 15, par. 3, of Legislative Decree no. 95 of 6 July 2012, converted, with amendments, into Law no. 135 of 7 August 2012. Particular attention is paid to pharmacological appropriateness, both in terms of patient protection and cost savings, as well as to the funding of various trials. Lastly, paragraph 570 states that the Ministry of Health, having consulted AIFA and in consultation with the State-Regions Conference, must adopt a strategic programme on innovative treatments every year, which shall define, in part, the priorities for intervention, the conditions for access to treatments, the parameters for reimbursement, expenditure forecasts, pricing schemes, guarantee and transparency instruments, and the methods for monitoring and evaluating the interventions themselves.

[261] See Art. 1, par. 588, 2015 Stability Law.

closely interconnected: the first is appropriateness and the second refers to the indications contained in the guidelines.

A first relevant factor in identifying the services that can actually be provided is the assessment of the circumstances in light of the criterion of appropriateness.

It should be considered that the regulatory identification of the services included in the essential levels seems to be closely connected, by their nature, to the concept of appropriateness, representing a tool for the reconciliation and coordination of the principles of universality of access, globality of coverage, and containment of public spending[262].

Above all, it should be emphasised that this notion, which is peculiar to the healthcare sector[263] and is articulated in the figures of clinical, organisational[264] and temporal[265] appropriateness, has always represented an assessment index that is potentially capable of constituting a synthesis of the criteria of clinical effectiveness and organisational efficiency[266], aimed at establishing which services, among those envisaged in the essential levels, can be provided in practice.

The identification of the services that can be provided on the basis of the rules of appropriateness is based on two sets of criteria defined by the legislator on the basis of scientific evidence and applied by the doctor according to his/her professional autonomy and responsibility.

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[262] See F. Taroni, *I LEA quindici anni dopo: ancora un miraggio, ancora utili*, in Politiche Sociali, 2014, no. 3, pp. 431 ff.

[263] The concept was introduced by Law no. 449 of 1997 on the basis of Recommendation no. 17 of 1997 of the Committee of Ministers of the Council of Europe.

[264] On the aspects of clinical and organisational appropriateness, see R. Grilli and F. Taroni, *Governo clinico. Governo delle organizzazioni sanitarie e qualità dell'assistenza*, Rome, Il Pensiero Scientifico, 2004.

[265] The Decree of the Prime Minister (d.P.C.M.) of 16 April 2002 supplemented the decree of November 2001 with a further series of indications (annex 5) in which the guidelines on priority criteria for access to diagnostic and therapeutic services on maximum waiting times are set out. The d.P.C.M. of 12 January 2017 updating the essential levels of care incorporates the guidelines developed on the subject of the timeliness of services. For the purposes of defining the conceptual contours of appropriateness, refer to Constitutional Court Judgements no. 282 of 2002 for clinical appropriateness, no. 338 of 2003, no. 134 of 2006 for organisational appropriateness and no. 80 of 2007 for timeliness.

[266] In order to understand the role of appropriateness in synthesising the criteria of clinical effectiveness and organisational efficiency, reference should be made to the definition given in the National Health Plan 1998-2000. Here, a distinction is made between clinical appropriateness and organisational appropriateness: clinical appropriateness refers to the provision of proven medical care and interventions in settings with a favourable benefit-risk profile for the patient, while organisational appropriateness refers to the choice of the most appropriate delivery methods in order to maximise patient safety and well-being while maximising effectiveness and reasonable consumption of resources.

In its well-known Judgment no. 282 of 2002, the Constitutional Court pointed out that the identification and application of criteria to determine the appropriateness of therapeutic practices is conditioned on two rights: "the right to be treated effectively, according to the canons of science and medical art; and the right to be respected as a person, in particular regarding one's own physical and mental integrity". Respecting these is charged not only "to the ordinary remedies provided by the legal system", but also to the instruments rooted in the "supervisory powers concerning the observance of the rules of professional ethics, attributed to the bodies of the profession". With regard to the identification of which effective services to provide, the decision states that "it is not, as a rule, the legislator who can directly and specifically establish which therapeutic practices are allowed, with what limits and under what conditions". Their delineation is the task of the doctor who, in his/her professional capacity, "always with the patient's consent, makes professional choices based on the state of knowledge available" and "on scientific and experimental learning, which is constantly evolving"[267].

A second factor, as mentioned above, is the indications contained in the guidelines.

In other words, the guidelines are an aid to healthcare professionals in choosing diagnostic and therapeutic strategies by providing those considered most appropriate by the scientific community for a given pathology in the light of scientific evidence[268].

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[267] The basic rule concerns the doctor's autonomy in his/her professional choices, exercised in compliance with the patient's wishes and instructions, on the basis of the state of scientific and experimental knowledge. On this subject, see Constitutional Court Judgments no. 282 of 2002, no. 338 of 2003 and no. 151 of 2009. The technical rules, produced on the basis of verified scientific evidence and on the basis of the state of scientific and experimental knowledge acquired through the national and international bodies and organisations appointed for this purpose, must allow guidelines to be drawn up but cannot exclude the assessments made by the doctor in "science and conscience", which in turn cannot escape the control and guideline activity envisaged in the exercise of medical practice.

[268] Guidelines are consensus documents resulting from a careful review of scientific literature and established clinical practice that must be validated by a scientific technical body or organisation the functions of which include the production of technical rules in the field of health. They are an effective tool for clinical governance and SSN organisation and can be defined as recommendations developed in a systematic way to assist clinicians in the management of specific clinical conditions. The guidelines are produced for a broad scope ranging from medical to clinical management. The type of guideline is, in fact, diversified: there are management, diagnostic, operational and therapeutic guidelines. The guidelines in the search of a balance in the relationship between quality and impact of medical services are intended to optimise diagnostic strategies, select therapeutic strategies, ensure that the quality of the services remains effective, and provide an indication of the rational use of

From the many areas in which the guidelines are applied, it is possible to reconstruct some of the basic functions they perform. The first is a health policy consisting of managing the provision of services in accordance with the logic of social justice, providing access for all citizens to the essential core of protection; the second is adapting clinical, therapeutic and care practice according to certain criteria that shape and direct the individual relationship between doctor and patient. These criteria relate to the respect of the individual as a person, the effectiveness of care and the cost-effectiveness of care[269].

The promotion of these is codified in the Ministerial Decree of 30 June 2004, by which the National Guidelines System was established, reorganised on the basis of Law no. 24 of 2017 with the Decree of the Minister of Health of 27 February 2018, and which, in compliance with the LEAs, coordinates the national and regional institutions and the so-called "scientific societies" in carrying out their activity of drafting, updating and verifying guidelines.

In the Italian legal system, the guidelines do not rise to the rank of a binding prescription of law, but constitute a support for professional practice (on a par with the code of ethics), and have the function of not so

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resources. See C. Borghi, *Linee guida e affidabilità delle prestazioni*, in La tutela della salute tra garanzie degli utenti ed esigenze di bilancio, edited by F. Roversi Monaco and C. Bottari. Bottari, Santarcangelo di Romagna, Maggioli, 2012, pp. 55 ff.

[269] The guidelines were therefore created to pursue a fundamental objective: to ensure the highest degree of appropriateness of interventions, reducing to a minimum the variability in clinical decisions linked to possible subjectivity in the definition of care strategies. Adherence to the guidelines, first by Law no. 189 of 2012 and then by Law no. 24 of 2017 repealing Article 3 of Law no. 189, allows for a limitation of professional liability. Article 5 of Law no. 24 of 8 March 2017 (Provisions on the safety of care and of the assisted person, as well as on the professional liability of healthcare professionals) provides that "healthcare professionals, when performing healthcare services for preventive, diagnostic, therapeutic, palliative, rehabilitative and forensic purposes, shall comply, without prejudice to the specificities of the case, with the Recommendations provided for in the Guidelines published pursuant to paragraph 3 and drawn up by public and private bodies and institutions, as well as by scientific societies and technical-scientific associations of the healthcare professions registered in the appropriate list". This list is established and regulated by the Decree of 2 August 2017 published in the Official Journal of the Italian Republic (Gazzetta Ufficiale della Repubblica Italiana), General Series no. 186 of 10 August 2017. The Guidelines can also be found on the Ministry's website at http://www.salute.gov.it/portale/sicurezzaCure/dettaglioContenutiSicurezzaCure.jsp?lingua=italiano&id=4835&area=qualita&menu=lineeguida (last accessed 29 April 2020). Article 6, first paragraph, third indent, provides that "If the event has occurred as a result of malpractice, culpability is excluded if the recommendations provided for in the guidelines as defined and published by law are complied with or, in the absence of these, the good clinical and care practices, provided that the recommendations provided for in the aforementioned guidelines are appropriate to the specifics of the case."

much proactively limiting the actions of the doctor, but rather of representing sources of precautionary rules and criteria aimed at facilitating the efficient use of the resources available and the assessment of the appropriateness of a certain service in relation to a certain pathology[270].

One of the tasks that the guidelines are supposed to perform in order to define the appropriateness and quality of medical services is to help direct choices according to a logic of rational and optimal use of resources[271]. From this point of view, an important aspect of the guidelines is that they can identify the appropriateness of services characterised by different costs but with similar parameters of disease, identifying as more advantageous those services that, because of the greater advantage from the clinical point of view, are also appropriate from the economic point of view. In any case, the ultimate decision in the process of identifying the services that can be provided in individual healthcare pathways depends on the evaluation carried out by the doctor: within the services declared essential by the regulatory system on the basis of the criteria of clinical efficacy and economic efficacy[272], the doctor is called upon to assess what is the best therapeutic-care choice in light of the patient's specific health conditions; whether or not they require the application of the indications contained in the guidelines[273]; and, if they do not, whether there may be a more effective therapeutic alternative in relation to the patient's specific condition.

Case law shows that the doctor, on the basis of his/her professional autonomy, has a duty to put the health of the patient before any other requirement, disregarding rules that respond exclusively to an econometric

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[270] *Programma nazionale delle linee guida, Manuale metodologico. Come produrre, diffondere e aggiornare raccomandazioni per la pratica clinica*, May 2002, updated in May 2004. The National Guidelines Programme, established on the basis of the National Health Plan 1998-2000 and Legislative Decree no. 229 of 1999, is coordinated by the ISS in collaboration with the National Agency for Regional Health Services.

[271] See M.J. Field and K.N. Lohr (ed.), *Guidelines for Clinical Practice: From development to use, Institute of Medicine*, National Academy Press, Washington DC, 1992. With regard to the functions performed, a distinction can be made between guidelines and other related instruments. "Protocols", for example, are predefined and binding patterns of behaviour used in the course of experiments. On the other hand, "care profiles" or "diagnostic and therapeutic pathways" are the results of adapting the guidelines to local situations, with their specific organisational and management characteristics.

[272] See Article 1 of Legislative Decree no. 502 of 1992 as amended in 1999.

[273] Guidelines may be a yardstick for assessing a doctor's conduct, but this does not prevent conduct that does not comply with the guidelines from being regarded as appropriate based on particular aspects of the case in question that made it necessary to disregard them. On this see Civil Court of Cassation., section III, 30 November 2018, no. 30998.

logic[274]. This is because of the basic principles of health consisting, on the one hand, of the fundamental right of the patient to be treated with clinically and organisationally appropriate therapies, and, on the other, in the principles of the autonomy and responsibility of the doctor, who is the guarantor of that right through his/her professional choices[275].

7. *Resource allocation, professional ethics and bioethics*

Resource allocation is a question that, by its nature, unquestionably pertains to ethical and bioethical issues. The literature on this subject is extensive, and must necessarily be taken into account here[276]. Professional ethics requires a reflection on the appropriateness of allocation in clinical practice.

In the Italian Code of Medical Ethics (Article 6, paragraph 2 of the 2018 update) concerns the optimal use of resources, which must be balanced

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[274] Criminal Court of Cassation, section IV, 23 October 2010-2 March 2011, no. 8254. The Court's ruling undoubtedly reinforces the principle according to which economic considerations cannot diminish the irreducible core of the right to health protection enshrined in the Constitution, as an inviolable area of human dignity, placing itself in line with the established approaches of constitutional jurisprudence and doctrine within the more general framework of health protection. In Judgement no. 169 of 2017, in paragraph 8 on the legitimacy of the indications of appropriateness non-compliance with which could have led to penalties against doctors, the Constitutional Court determined: "This hermeneutic meaning must also be understood to contain the provisions on monitoring compliance with the indications of the ministerial decree: they absolutely cannot prescribe the free exercise of the medical profession, but constitute a simple invitation to argue any significant deviations from the protocols. The prescriptions are absolutely incompatible with political or purely financial considerations, since legislative discretion is limited by 'the scientific and experimental findings, which are constantly evolving and on which the medical art is based: so that, in the field of therapeutic practice, the basic rule must be the autonomy and responsibility of the doctor, who, with the consent of the patient, makes the necessary professional choices (judgments no. 338 of 2003 and no. 282 of 2002)' (Judgement no. 151 of 2009)".

[275] See S. Marzot and F. Negri, *Le regole cautelari sottese alla colpa medica: il valore delle Linee Guida*, in La tutela della salute tra garanzie degli utenti ed esigenze di bilancio, edited by F. Roversi Monaco and C. Bottari, Santarcangelo Romagna, Maggioli, 2012, pp. 175 ff. Bottari, Santarcangelo di Romagna, Maggioli, 2012, pp. 175 ss.; L. Dimasi, *Responsabilità medica e ruolo delle linee guida*, in La tutela della salute tra garanzie degli utenti ed esigenze di bilancio, edited by F. Roversi Monaco, C. Bottari, cit., pp. 193 ss.

[276] G. Berlinguer, *Le priorità della medicina e le priorità della salute*, in Bioetica, 1994, n. 2; Id., *Etica della salute*, Milano, Il Saggiatore, 1994; L. Palazzani, *Teorie della giustizia e allocazione delle risorse sanitarie*, in Medicina e Morale, 1996, no. 5; Id., *Teorie della giustizia e bioetica: la questione della allocazione delle risorse sanitarie*, in Verità e metodo in giurisprudenza, edited by G. Dalla Torre and C. Mirabelli, Vatican City, Libreria Editrice Vaticana, 2014; L. Forni, *La sfida della giustizia in sanità. Salute, equità, risorse*, Turin, Giappichelli, 2016.

with ensuring the effectiveness, safety and humanity of health services while avoiding any form of discrimination in access to care. Similarly, articles 13 (Prescription for prevention purposes), 20 (Care relationship) and 21 (Professional competence) have to do with the appropriate use of health care resources.

These rules of ethics stipulate that prescriptions must be based on the optimal use of resources, that time for communication is part of a patient's treatment time, and that doctors may not take on tasks that they are unable or unwilling to perform. On this aspect, the specific emphasis that Law no. 219 of 2017 places on "Rules on informed consent and advance treatment dispositions", on the relationship of care and trust between doctor and patient, which must be based on informed consent and on the enhancement of communication as a time of care (respectively paragraphs 2 and 8 of Article 1 of Law no. 219), constitutes a specific transposition of the provisions contained in the code of ethics, as well as of the fundamental guidelines of international law and the case law that has been established on the subject[277].

The 2019 Code of Practice for Nurses, which amended the 2009 version, also contains a number of rules concerning the optimal use of resources. Article 30 (Organisational responsibility) states that the nurse participates in the fair allocation of resources within the organisation; article 17 (Relationship with the person assisted in the care pathway) refers to the resources for the person assisted that the nurse has to consider whether or not to activate in order to ensure the best care pathway.

In terms of bioethical reflection, a number of fundamental aspects have been outlined above with reference to bioethical models that envisage specific criteria for the distribution of resources at both the macro (programming) and micro (distribution) levels.[278] The European Union has already made a number of proposals for the distribution of resources at the macro (programming) and micro (distribution) levels. Here we should

[277] Law no. 219/2017 was published in the Official Journal on 16 January 2018 and entered into force on 31 January 2018. On Law 219, see the dedicated monographic issue of Rivista di Biodiritto, 2018, no. 1; G. Baldini, *Prime riflessioni a margine della legge 219*, in Rivista di Biodiritto, 2018, n. 2; R. Pescatore, *Appunti di analisi linguistica per l'uso della legge 22 dicembre 2017, n. 219. Norme in materia di consenso informato e di disposizioni anticipate di trattamento*, in Rivista di Biodiritto, 2018, no. 2; S. Canestrari, *"Una buona legge buona": la legge 219 del 2017 e la relazione medico-paziente*, in Diritto e Salute. Rivista di Sanità e Responsabilità Medica, 2018, no. 4; P. Borsellino, *Consenso informato e autodeterminazione terapeutica nella legge sul testamento biologico*, in Diritto e Salute. Rivista di Sanità e Responsabilità Medica, 2018, no. 4; D. Lenzi, *La legge 219/2017 e il difficile percorso parlamentare*, in Diritto e Salute. Rivista di Sanità e Responsabilità Medica, 2018, no. 4.

[278] On this, see chapter 1, section 4.2.

consider the contribution of the National Bioethics Committee (CNB), which has dealt with this issue on at least four occasions: “Ethics, the health system and resources” of 17 July 1998, “Bioethical guidelines for equity in health” of 25 May 2001, “On the communication by the National Health Service to patients of the costs of health care” of 28 September 2012, and “In Defence of the National Health Service” of 26 January 2017.

In its 1998 opinion, the CNB deals comprehensively and in depth with the problem of allocating scarce health resources, focusing in particular on issues such as scientific research, staff training and the importance of social assistance.

The 2001 CNB opinion devotes specific attention to clarifying the ethical principles of reference and, in the context of prioritisation, to highlighting the existing risks for the most fragile and the categories of people who can be held responsible for their state of health. In addition, the issue of the division of domains between prevention and treatment is highlighted for the purpose of resource allocation processes.

In its 2012 opinion, the CNB develops a number of reflections on the SSN's communication of the costs of healthcare services to patients. This opinion followed the question raised by the Minister for Health on the political and bioethical appropriateness of such communication, in consideration of the Lombardy Regional Council's decision IX/2633 of 2011 providing for this obligation.

In the foreword to the opinion, the CNB puts the question into context by first contextualising the global socio-economic situation of rising health costs driven by demographic, epidemiological, technological, anthropological and cultural factors and a decrease in available health resources. The regional resolution, therefore, raises the issue of the relationship between the individual's right to health and the public's interest in the stability of the health system, as well as the need to raise users' awareness of this problem.

Within the CNB, a number of different positions emerged. An initial majority asserted that mandatory and imposed communication to the patient of the charges for services received is not ethically justified. The argument here is that the provision of non-compulsory communication could be functional to the individual user's responsibility in the use of health resources, which would involve their participation in order to limit expenses and waste.

The CNB also considered the need to go beyond the pure logic of economic calculation as a guiding criterion for health policies, especially with regard to access to care for fragile and vulnerable people such as the chronically ill, terminally ill, patients with serious health conditions, and

patients whose prognosis is uncertain. Here, in order to protect the most fragile persons, the CNB determined that the communication of costs can be provided in a separate document from the medical record and only at the request of the mentally competent patient or, in the case of patient without competence, at the request of their legal representative. However, a minority of CNB members argued that mandatory disclosure of costs in a separate document from the medical record could be considered consistent with the principles of bioethics and also an important tool in the advancement of "liberal democracy."

In its 2017 opinion "In Defence of the SSN" the CNB sets out some firm points given the premise of scarcity of health resources. This CNB opinion focuses on the issue of the sustainability of the health system. The crisis impacting the system is linked to a number of factors, including European constraints on the budgets of the Member States and the demographic changes that began in 1992, as a result of which an ageing population is affected by a variety of diseases and in need of increasingly expensive treatments and more pharmaceuticals. In this critical scenario in terms of health demand, the CNB recalls the relevance of specific factors such as the very low investment in prevention that sees Italy in last place among OECD countries for health expenditure in this sector while the share of general expenditure allocated is equal to that of countries such as Spain, Portugal and Greece[279]. The recommendations of the CNB, therefore, to protect the sustainability of the SSN, concern the promotion of prevention, the homogenisation in all regions of the process of digitalisation of healthcare, the review of organisational methods (favouring primary care over hospital care), the protection of the most fragile patients suffering from dementia, cognitive impairment, chronic and/or serious diseases, the revitalisation of professional and inter-professional training, the advancement of healthcare research and the protection of the healthcare sector against fraud and corruption. Moreover, the CNB recommends a periodic and planned review of the LEAs, based on scientific evidence and cost-effectiveness criteria, in order to avoid any wasteage of health resources. Lastly, it recommends that action be taken to reduce the high costs borne by citizens and families to cover services that are provided by private or "intra-moenia" bodies and that contribute to widening the gap between the affluent and those without financial means who are faced with long waiting times or who ultimately choose to forego health care for economic reasons.

[279] See CNB, *In difesa del Servizio sanitario nazionale*, 26 January 2017, p. 5.

8. *Health service resilience in the face of high-cost innovative drugs and the COVID-19 pandemic*

On two recent occasions, the resilience of the Italian health service was put to the test[280]. Though fundamentally of a different nature, both were critical: one arose following the marketing of innovative drugs against hepatitis C and the other came in the wake of the spread of the SARS-COV-2 virus.

Anticipating a possible conclusion on the management of issues concerning the definition of health priorities that emerged in the two cases, it must be said that the problem of a selective access to pharmaceutical and intensive care was solved by referring to solutions of price negotiation in the case of drugs against hepatitis C[281], and in the case of access to intensive care for patients having contracted SARS-COV-2 the preparation of an effective health response, both in terms of organisation of the service and containment of the spread of contagion.

In the first case, after decades in which the only available treatment was interferon, in November 2014 AIFA approved a new drug for the treatment of hepatitis C, a direct-acting antiviral drug. The name of the drug's active ingredient is Sofosbuvir, while Sovaldi is the trade name of the product patented by the multinational Gilead Sciences[282]. The drug is characterised by very high efficacy, broad tolerability and a cost that, at least initially, made it unacceptable to the SSN and not affordable for the entire hepatitis C population in Italy (about one million people). Given the high cost, access to the drug was rationed on the basis of parameters decided by AIFA, these derived in essence from the severity of the disease. On the basis of these criteria, free treatment was only possible if the elasticity of the liver was severely impaired and the patient had fibrosis (F3) or cirrhosis (F4). For other patients in different stages of the disease, only two alternatives remained: to wait for the condition to worsen or pay for the medication out of pocket.

The costs of the therapy, however, were estimated at €50,000 per treatment cycle at the time of its launch in 2015.

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[280] On the notion of health system resilience, please refer to the relevant EU documents noted in chapter 1, paragraph 3.2.

[281] A CORIPE study on innovative hepatitis C drugs was carried out in 2015-2016 under the supervision of Prof. Nerina Dirindin, entitled "Diritto individuale alla salute e risorse disponibili".

[282] The anti-Hepatitis C drug was discovered in 1998 by Pharmasset, a small US bio-tech company, which was bought in 2011 by Gilead for $11 billion, almost four times its market value at the time.

The first months of 2015 were dominated by a heated debate focusing primarily on finding ways to reconcile the protection of the individual right to health with the interests of the community, because the high cost of these drugs had a direct impact on universalism and equal access to treatment.

On the other hand, the price set by the multinational company marketing the drug could not be reconciled with the low production costs of the drug and the fact that the generic version of the active ingredient of the drug was available at a low price in other countries[283]. Moreover, in Italy, the incidence of the disease was such that it further highlighted the tensions in the relationship between the high demand for treatment, the high cost of drugs and access to treatment in a situation of scarcity of resources[284].

The access protocols, based on the criteria established by AIFA, provide for the stratification of patients according to the need for treatment and the severity of the disease, guaranteeing immediate access to new therapies only for patients with the most serious conditions.

The scientific societies estimated that there were about 80,000 patients to be treated within 2 years, while the rest were asked to wait.

From the outset, and throughout the period of limited access to treatment, AIFA entered into price negotiations. This negotiation resulted in a price reduction from the initial approximately €50,000 to around €6,000-7,000 per treatment cycle.

As a result of this cost reduction, on 30 March 2017 AIFA published a decision modifying the criteria for access to treatment[285]. The change saw the previous selective access transformed into universal access, with only a few adjustments, such as the criterion of co-morbidity (e.g., treatment for patients with low fibrosis only if affected by diabetes). The 12 criteria, identified on the basis of the opinions expressed by the technical-scientific commission and in agreement with the regions, scientific societies and patient associations, currently allow universal access to innovative therapies, treating all patients for whom the therapy is deemed appropriate[286].

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[283] In India, for example, Gilead had entered into licensing agreements with manufacturers marketing generic versions of the active ingredient at low prices.

[284] The CNB also commented on fair access to innovative medicines in a motion. See CNB, *Per una politica di accesso equo a farmaci innovativi ad alta efficacia per patologie gravi: riduzione dei prezzi e contenimento dei costi a carico del SSN e dei cittadini*, 23 February 2017.

[285] See AIFA, *Ridefinizione dei criteri di trattamento per la terapia dell'epatite C cronica*, Determination of 24 March no. 500/2017.

[286] One criterion was added to the 11 criteria in Determination no. 500 of 2017 by AIFA

The second case that put the resilience of the health service to the test was the emergency created by the spread of COVID-19 caused by the SARS-COV-2 virus. The virus, of the SARS (Severe Acute Respiratory Syndrome) strain, has highlighted some sustainability issues for the healthcare system. In particular, the characteristics of the virus, such as its high contagiousness, lethality due to respiratory crises in the event of age-related health problems and the presence of comorbidity, quickly led to an emergency situation before there was a specific treatment or an effective vaccine. This emergency has highlighted the impact that cuts in health service funding have had in terms of reducing healthcare resources.

Within a short time from when the virus spread across Europe, it became clear that the most critical situation was in hospital intensive care units. ICUs, suffering from limited availability of beds, few ventilators and few specially trained intensive care staff, were faced with a disproportionate demand for access due to the respiratory and oxygen saturation problems that the virus caused. This emergency situation raised a number of disruptive questions: in the emergency context of scarce resources as described, who has access to intensive care and who should be excluded from it? On the basis of what criteria?

Determination no. 1454 of 2019. The following are the 12 treatment criteria: Criterion 1: Patients with cirrhosis in Child A or B class and/or HCC with complete response to surgical or loco-regional resective therapy who are not candidates for liver transplantation and in whom liver disease is a determining factor for prognosis; Criterion 2: HCV-RNA positive recurrent hepatitis of the transplanted liver in a clinically stable patient with optimal levels of immunosuppression; Criterion 3: Chronic hepatitis with severe extra-hepatic HCV-related manifestations (cryoglobulinemic syndrome with organ damage, B-cell lymphoproliferative syndromes, renal failure); Criterion 4: Chronic hepatitis with METAVIR F3 (or corresponding Ishak) fibrosis; Criterion 5: On the liver transplant list with cirrhosis MELD <25 and/or with HCC within the Milan criteria with the possibility of a wait on the list of at least 2 months; Criterion 6: Chronic hepatitis after solid organ (non-liver) or marrow transplantation in a clinically stable patient with optimal levels of immunosuppression; Criterion 7: Chronic hepatitis with METAVIR F2 fibrosis (or corresponding Ishak) and/or comorbidities at risk for progression of liver damage [HBV co-infection, HIV co-infection, chronic non-viral liver disease, diabetes mellitus under drug treatment, obesity (body mass index ≥30 kg/m2), hemoglobinopathies and congenital coagulopathies]; Criterion 8: Chronic hepatitis with METAVIR F0-F1 fibrosis (or corresponding Ishak) and/or comorbidities at risk for progression of liver damage [HBV co-infection, HIV co-infection, chronic non-viral liver disease, pharmacologically treated diabetes mellitus, obesity (body mass index ≥30 kg/m2), hemoglobinopathies and congenital coagulopathies]; Criterion 9: Infected health care workers; Criterion 10: Chronic hepatitis or cirrhosis of the liver in patient with chronic renal failure undergoing dialysis treatment; Criterion 11: Chronic hepatitis in patient on the waiting list for solid organ (non-liver) or marrow transplantation; Criterion 12: Chronic hepatitis or cirrhosis of the liver in patients who cannot access liver biopsy and/or fibroscan for social welfare reasons.

It must be noted that addressing these questions has led to the identification of issues on two levels: on the one hand, there are considerations about general decisions concerning the annual state budget and, on the other, there is the dramatic and urgent problem of identifying available resources at a certain time and place.

The imbalance between existing resources and the high demand for access to intensive care sparked a lively debate on the possible criteria to be used in solving dilemmas concerning access to and discontinuation of intensive care.

The responses were manifold. These included, for example, the Spanish document produced by the Sociedad Española de Medicina Intensiva Crítica y Unidades Coronarias (SEMICYUC) and the Sociedad Española de Enfermería Intensiva y Unidades Coronarias (SEEIUC) entitled "Plan de Contingencia para los Servicios de Medicina Intensiva frente a la pandemia COVID-19"; the Belgian Society of Intensive Care Medicine document "Ethical principles concerning proportionality of critical care during the 2020 COVID-19 pandemic in Belgium: advice" (2020); the Hastings Centre document of 17 March 2020 entitled "Ethical Framework for Health Care Institutions Responding to Novel Coronavirus SARS-CoV-2 (COVID-19) Guidelines for Institutional Ethics Services Responding to COVID-19 Managing Uncertainty, Safeguarding Communities, Guiding Practice"; the Comité Consultative National d'Etique document of 13 March 2020 entitled "Enjeux éthiques face à une pandémie"; and the Nuffield Council on Bioethics document entitled "Ethical considerations in responding to the COVID-19 pandemic" (2020).

In Italy, the issue has also been addressed in a CNB opinion entitled "COVID-19: clinical decision-making in conditions of scarce resources and the triage criterion in pandemic emergencies", published on 15 April 2020[287].

[287] The CNB declares that the clinical criterion, which must be assessed on a case-by-case basis, is the most appropriate reference, considering any other selection criterion (such as age, sex, social status and role, ethnicity, disability, responsibility for behaviour that induced the pathology, costs, etc.) to be discriminatory and therefore ethically unacceptable. The Committee also analyses the function of triage in a pandemic emergency situation. Triage must be based on certain prerequisites: preparedness (preparation of action strategies in the public health field, in view of exceptional conditions, with a transparent chain of responsibilities), clinical appropriateness (medical assessment of the effectiveness of the treatment in relation to the clinical need of each individual patient, clinical appropriateness (medical assessment of the effectiveness of the treatment in relation to the clinical need of each individual patient, with reference to the urgency and seriousness of the onset of the pathology and to the prognostic possibility of recovery, taking into account the proportionality of the treatment), and topicality (which places the individual assessment of the patient physically present in the emergency department in the broader perspective of

All these documents (with the exception of the Spanish one) refer to the need to use criteria of justice that are not likely to establish discrimination in the access to intensive care, asking in some cases to refer the possible allocative conflict, determined by the situation of disproportionality between people who require access to care and the available health resources, to a clinical bioethics committee (this is the position expressed in the French document and in the document of the Hastings Centre), and in other cases to refer to criteria that guarantee greater impartiality and objectivity, such as the criterion of medical urgency (this is the position expressed in the Belgian document) and the clinical criterion (this is the main position that can be deduced from the aforementioned CNB opinion).

The publication on 6 March 2020 by the working group of the Italian Society of Anaesthesia, Analgesia, Resuscitation and Intensive Care (SIAARTI) of the Clinical Ethics Recommendations for admission to and discharge from intensive care in exceptional conditions of imbalance between need and available resources has raised a number of questions on the issue of access to intensive care in the context of viral emergencies.

The document summarises, in 15 points, the guidelines for anaesthetists and resuscitators who are in the front line of an unprecedented emergency situation. The purpose of the recommendations is twofold: to "relieve clinicians of some of the responsibility for the choices, which can be emotionally burdensome, made in individual cases" and "to provide explicit criteria for allocating healthcare resources in a situation of extraordinary scarcity".

The identification of the criteria for access to and discharge from intensive care could, in the reasoning of the SIAARTI, be based not only on the use of clinical appropriateness and proportionality of care, but also on the application of the criterion of distributive justice and the appropriate allocation of healthcare resources. From these principles the document derives the identification of "criteria of maximum utility", i.e., prioritising access to treatment for those who have a greater probability of therapeutic success or greater life expectancy.

There are two operational criteria that derive from the search for maximum utility. The first refers to the age of the person at the time of admission in intensive care, which can be an objective criterion for assessing the probability of survival and the number of years of life saved from the perspective of maximising the benefits for the greatest number of people.

The second operational criterion refers to the presence of comorbidity and the overall health status in addition to age. Elderly, frail or multi-

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the "community of patients", with a periodic review of waiting lists).

disease patients are likely to face a longer stay in an intensive care unit, which is therefore more costly for the health service, and possibly less effective.

It is envisaged that the "criteria of maximum benefit" should be supplemented by other aspects concerning the appropriateness of intensive care such as the severity of the illness, the presence of other illnesses, the impairment of organs and systems and the potential for recovery. It is specified that access to intensive care can only be excluded where all the existing organisational and resource management possibilities of the regional and national health system have been exhausted.

On the substantive content of the document, it must be noted that the development of operational criteria is derived from the principles of clinical appropriateness, distributive justice and appropriateness of the distribution of resources. This logical reasoning may not be entirely straightforward because the principles of clinical appropriateness, allocative appropriateness and distributive justice are multidimensional and not unambiguous and need to be further specified, including by considering other relevant factors, which we have seen to be of a legal and ethical nature in the specific context of reference. On the one hand, the possible constitutional configurations of health protection play a special role in the problem of resource allocation. On the other, in the field of bioethics, as we have seen, there are multiple approaches to the issue of resource allocation, with each reference model offering the possible application of specific allocation criteria.

In view of the severity of the situation that arose during the pandemic, we believe that the SIAARTI document has undoubtedly had the merit of identifying and clarifying the fundamental questions that arise in the definition of clinical priorities, highlighting the need to further investigate, with a public discussion that is as inclusive and open as possible, the dilemma and the problems that arise in emergency situations concerning the use of available resources.

Chapter Four

Fieldwork: resource allocation strategies in Tuscany and Piedmont
by Caterina Di Costanzo

1. *Introduction*

This final section of the research report is the result of fieldwork conducted in the course of 2017 with the cooperation of various actors in the medical, scientific and institutional fields in Tuscany and Piedmont. The aim of the research was to compare the specific processes of allocation of health care resources in the two regions in light of the analysis of the Italian allocation system presented in the previous chapter. Additionally, an attempt was made to identify some regulatory, social and economic markers that have characterised the period of interest (2011-2016) and to use them to interpret the data relating to the volumes of activity recorded in the two regional health systems[1].

The reference period for this fieldwork (2011-2016) was selected both for the availability of data from the bodies that collect them for their respective SSRs (the Regional Health Authority - ARS for Tuscany and CSI - *Consorzio per il sistema informativo* for Piedmont), and because of the representative nature of this period, which coincided with a significant contraction of healthcare resources associated with a series of interventions to reorganise Italian healthcare[2]. Indeed, it was a period in which the effects of the economic crisis had a considerable impact on social rights in general and on the right of access to health services in particular.

The analysis of the trend of health expenditure at the national and regional levels in the last decades points to a number of interesting aspects. The trend, which had been on the rise due to the factors mentioned above[3], slowed down considerably during the period in question. The average annual growth rate in the four-year period 2003-2006 was 6.4%, but

[1] The term *marker*, which is typical of biomedical language, is used in this context to refer to the use of regulatory, organisational, economic and social tools which are likely to be indicators of a mode of operating and developing the health system or of possible dysfunctions.

[2] On this aspect, see chapter 3, section 6 above.

[3] See general introduction, section 2.

dropped in the following five-year period to 1.8%, and this trend was further consolidated in the period 2012-2018, where health expenditure registered an average annual variation rate of 0.4%[4]. With this in mind, comparing ordinary SSN funding and current health expenditure serves to illustrate the progressive reduction of funding and expenditure over the period considered.

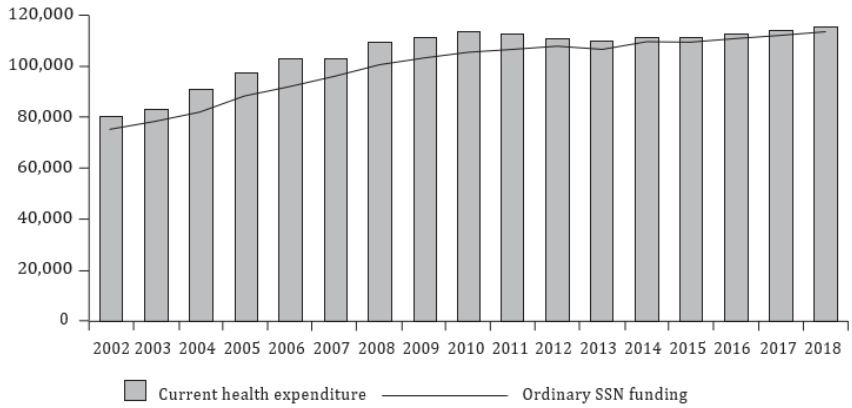

Fig. 1. Current health expenditure and ordinary SSN funding. Years 2002-2018 (figures in million euros).

Source: Ministry of Economy and Finance, *Monitoraggio della spesa sanitaria*, July 2019.

In this context, the research on these specific regional contexts aims at, on the one hand, establishing whether there is a link between the defunding dynamic and the reorganisation measures undertaken, and on the other, investigating the access to services as an implementation of the individual right to health.

In particular, it should be noted that the work on regional data did not consider primary care and general practitioners and that the focus was on the volume of activity of the public system (public facilities and accredited private sector) only. Therefore, this work does not set out to establish a connection between the reduction in the activities in the public system and a greater recourse to the purely private sector, to which the increase in co-payments may be a contributing factor, as some studies have shown[5].

[4] See Ministry of Economy and Finance, *Monitoraggio della spesa sanitaria*, July 2019, pp. 7 ff.

[5] See, for example, *IX Rapporto Sanità. Crisi economica e sanità: come cambiare le politiche*

As regards the quantitative analysis of the trend in the volumes of activity in the years considered, the collection of data concerning the services considered (accesses to the ER, hospital admissions, outpatient specialist services) and the elaboration of graphs and summary tables (included partly in the text of the report and partly in the appendix) represented a specific phase within the research, which benefited greatly from discussions with some members of the Quality Department of ARS in Tuscany and with the research group of SEPI led by Prof. Giuseppe Costa in Piedmont[6].

The project also focused specifically on the Città della Salute e della Scienza di Torino, given its relevance in the area of Turin. the authors would like to thank Dr. Giulio Fornero, Director of Quality and Risk Management of the University Hospital for the data concerning the trend of hospital admissions and for the comparison between the trend of waiting lists for some outpatient specialist services at the regional level and at the health authority level[7], which are illustrated in full in the graphs and tables found in the appendix of this report.

Lastly, several meetings with the CORIPE research group, coordinated by Prof. Nerina Dirindin, focused on the discussion of the fieldwork and the study of access to drugs against hepatitis C in a context of scarcity of resources, which CORIPE carried out in greater detail as part of an economic analysis research project.

2. The organisation of the Regional Health Service

The decentralised nature of the SSN and the way its organisational structure impacts how resources are allocated require some preliminary explanation in reference to the peculiarities of the two regional health systems in this regard.

2.1. Tuscany

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pubbliche, edited by F. Spandonaro, Rome, Health Communication, 2013, esp. pp. 47-48, available (in Italian) at https://www.creasanita.it/images/rapportosanita/9/IX_Rapporto_Sanita_CREA.pdf.

[6] See Introduction, section 3 for a comprehensive list of contributors.

[7] As regards the data relating to waiting times in particular, the decision was made to include them despite the many factors influencing trends in them because waiting lists have a significant impact on the perception of users in relation to the accessibility of health services (A. Pizzimenti, F. Ierardi and A. Vannucci, *Gli indicatori e la prospettiva dei cittadini*, in "Salute e Territorio", 2005, no. 205).

The Tuscan health system is governed by Regional Law no. 40 of 2005, entitled "Regulation of the Regional Health Service" and subsequent amendments.[8] Since the 2008 reform, this Law has provided for an integrated health and social plan[9] and assigns to the Regional Council the tasks of controlling, supervising, promoting and supporting health services, as well as assessing the quality of services and care pathways.

The organisational characteristics of the operational structure of the Regional Cabinet are provided for and regulated by Regional Law no. 1 of 2009 and subsequent amendments "Consolidated text on the organisation and regulation of personnel", which assigns to the Departments (which already exercise significant powers in guiding and governing the Region) a series of additional functions. The Resolution of the Regional Council no. 706 of 1 July 2015 identified the Departments which, together with the General Directorate of the Regional Cabinet and the Regional Attorney's Office, constitute the top management structures supporting the governing bodies of the Region of Tuscany.

The Directorate for Citizens Rights and Social Cohesion is responsible for health and socio-healthcare matters, more specifically in the following areas: policies for the protection of the right to health; socio-healthcare integration; sport; coordination of youth policies; coordination of relations with the third sector; welfare policies; management of relations with dependent bodies and organisations operating in the areas for which the Directorate is responsible, in accordance with the guidelines provided by the Director General of the Council.

2.2. Piedmont

In the first phase of health reforms in 1992-1993, the Piedmont Region chose to organise its health service separately from its social service, implementing the reform that had substantially deprived the municipalities of their health functions (which they would recover in 1999 in the framework of social and health integration). This set-up is reflected in the structure of the administrative organisation of the Regional Council, which provides for two separate directorates for health and social services.

The regional organisational infrastructure was recently modified by the Regional Council Decision (DGR) no. 4-439 of 2019 "Partial reorganisation of the structures of the Regional Council role. Art. 5 of R. Law 28 July 2008,

[8] Among the legislative measures to reform Law no. 40 is Regional Law no. 84 of 2015, on which see elsewhere in this chapter.

[9] See Regional Law no 60. of 2008 "Amendments to Regional Law no. 40 of 24 February 2005 (Regulation of the regional health service)".

no. 23, as amended. Modification of the organisational provisions approved by DGR no. 20-318 of 15 September 2014 and subsequent amendments and DGR no. 11-1409 of 11 May 2015 and subsequent amendments". Specifically, it modified all sectors related to the Region's health and social policy within the Health and Welfare Directorate.[10]

The Piedmontese health system is governed by Regional Law no. 18 of 2007 "Regulations for social and health planning and the reorganisation of the regional health service" and subsequent amendments.[11] This law led, on the one hand, to the reform of regional planning and, on the other, to the reorganisation of health authorities through an initial process of territorial and organisational aggregation[12], which has been fully implemented in recent years.

The Plan for the reorganisation and economic rebalancing (Deficit Recovery Plan) of the SSR in Piedmont was signed by the parties on 29 July 2010 and approved by DGR no. 1-415 of 2010 [13]. On 30 September 2010, the relevant implementation programme referred to in Article 1, paragraph 3, was submitted to the Ministry of Economy and the Ministry of Health. With DGR no. 44-1615 of February 28, 2011, the Regional Council adopted

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[10] The Health and Welfare Directorate is currently divided into the following sectors: pharmaceutical, supplementary and prosthetic medicine; organisational systems and human resources of the SSR; economic and financial planning; prevention and veterinary medicine; planning of health and social-health services; SSR rules for relations with providers; investment policy; management control, information systems, health logistics and procurement; anti-corruption and supervision of public and private contracts and structures; housing welfare policies; policies for children, families, minors and young people, support for situations of social fragility; policies for equal opportunities, rights and inclusion; social welfare and health programming, service standards and quality.

[11] See in particular Regional Law no. 3 of 28 March 2012 "Provisions on the organisation of the Regional Health System".

[12] Article 23 of Regional Law no. 18 of 6 August 2008 on the reorganisation of the Regional Health Service provides for supra-zonal coordination areas within which certain functions, including health functions, can be carried out in a coordinated manner, and delegates the identification of these health functions to be carried out at the area level to the Regional Council.

[13] The operational programmes for the reorganisation, requalification and strengthening of the Regional Health Service (later called Deficit Recovery Plans) were created by the 2005 Budget Law (Law 311/2004) and are attached to agreements signed by the Ministers of Health and Economy and Finance with the individual Regions. Piedmont has been in financial difficulty since 2007, the year in which the MEF formally notified the Region of the deficit, which had already been ascertained at Technical Board level. In 2010 this situation led to the signing of a healthcare debt reduction plan and the subsequent launch of the complex process of intervention on the financials of the Piedmontese healthcare system, which ended on 21 March 2017 with the signing of the agreement with the Government that sanctioned ending the phase, potentially leading to the SSR going into administration under an external receiver.

the Addendum to the Deficit Recovery Plan and to the Implementation Program, with which the Region outlined the objectives of intervention in the various health and social-health macro-areas for the period 2010-2012. It also identified, among the various measures provided for in the implementation program, those relating to the reorganisation of the hospital, emergency, local, laboratory analysis and radiodiagnostic care networks.

In the second phase of the recovery plan, with DGR no. 25-699 of December 30, 2013, the Piedmont Region approved the 2013-2015 Operating Programmes pursuant to art. 15, par. 20, of Legislative Decree no. 95 of 2012 converted, with amendments, by Law no. 135 of 2012, with the aim of continuing and strengthening the action of controlling health spending, while protecting the LEAs.

Following the positive evaluation of the actions undertaken by officials from the Ministry of Health and the Ministry of Economy, the Piedmont Region's recovery plan was officially concluded on 21 March 2017.

2.3. Ongoing reorganisation processes: Tuscany

In recent years, the Regional Health System in Tuscany has undergone a profound reorganisation, approved by the Regional Council with Regional Law no. 84 of 28 December 2015 "Reorganisation of the institutional and organisational structure of the Regional Health System. Amendments to Law 40/2005"[14].

As of 1 January 2016, three new USLs were established, one for each "Area Vasta" (wide area - AV)[15], merging the previous 12. In addition to these, four University Hospitals (AOU) – including Careggi and Meyer in Florence, Pisa and Siena, as well as an ESTAR (*Ente di sostegno tecnico-amministrativo regionale* - Regional technical-administrative support body)[16], remain in place and are fully autonomous. The reform envisaged

[14] Regional Law no. 84 of 2015 repeals Regional Law no. 28 of 2015 "Urgent provisions for the reorganisation of the institutional and organisational structure of the Regional Health Service". Regional Law no. 84 was subsequently amended by Regional Law no. 58 of 2016 "2016 Law for the Maintenance of the Regional System".

[15] Article 1 of Regional Law no. 84 defines the *area vasta* ("Wide Area" - AV) as "the area in which regional strategic planning is implemented, in which the planning of local health unit and the university hospital unit are integrated". The three AVs are as follows: Azienda USL Toscana centro (former ASL 3 of Pistoia, 4 of Prato, 10 of Florence, 11 of Empoli); Azienda USL Toscana nord ovest (former ASL 1 of Massa e Carrara, 2 of Lucca, 5 of Pisa, 6 of Livorno, 12 of Viareggio); and Azienda USL Toscana sud est (former ASL 7 of Siena, 8 of Arezzo, 9 of Grosseto).

[16] Prior to the 2015 health system reform, public services were provided through 12 ASLs, 4 AOUs (including one paediatric one), other bodies such as ISPO and Fondazione Monasterio,

more coordinated planning for the AV through greater synergy between the AUSLs and the AOUs, through the implementation of integrated planning across the AV with the involvement of inter-health authority departments[17].

Improving the organisation of local (outpatient) services required the overall redefinition of the functions of the District Area and the conference system, especially in order to maximise the effectiveness of the local response of social-health integration. In this sense, the Regional Council approved the "Provisions on the revision of the territorial scope of District Zones (*Zone Distretto* – ZD)" (Regional Law no. 11 of 2017). This regional law defined the adequate size of the District Zones, reduced them from 34 to 26, introduced greater autonomy for the ZDs, and pointed towards a directly managed "Health Society" (*Società della salute*)[18].

2.4. Ongoing reorganisation processes: Piedmont

The need to implement the Operational Programmes led to an intensification of reorganisation processes in the health sector.

The reorganisation process started with the identification of six *Area Vasta* bodies called "supra-zonal federations" (*federazioni sovrazonali*)[19], which were then eliminated in the second phase of the implementation of the Deficit Recovery Plan, and continued with the reorganisation of the healthcare services. The process was completed in 2012 with the reorganisation of the Turin health system AOU "Città della Salute e della Scienza"[20], and in 2016 with regard to the ASL of Turin, which was reorganized through internal mergers.

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which remain unchanged, and 3 support bodies defined as ESTAVs organised at AV level, which merged into ESTAR pursuant to Regional Law no. 26/2015.

[17] On AV programming, see Article 7 of Regional Law no. 84 of 2015 and DGR no. 391/2016.

[18] Health Societies (*Società della Salute,* "SdSs") are public non-profit organisations set up on a voluntary basis by the municipalities of the same district-area and the competent local health authority, for the joint management of integrated local health, social-healthcare and welfare activities. Two regional laws of 2014, no. 44 and no. 45, identify the instruments to regulate these integrated local structures in each district area: the continuation of the Health Society or the creation of a social and health agreement between all the municipalities of the district area and the reference USL. In Tuscany, there are currently 15 Health Societies and 11 district areas without SdSs and that have to sign the social-health agreement as per article 70-bis of Regional Law no. 40 of 2005.

[19] Art. 2, par. 3 of Regional Law no. 3 of 2012, amending Regional Law no. 18 of 2007.

[20] See Regional Council Resolution no. 167-14087 of 3 April 2012 "Approval of the 2012-2015 Regional Health and Social Plan and identification of the new hospital authority Città della Salute e della Scienza di Torino and of the supra-zonal Federations". The DCR identifies the new hospital authority Città della Salute e della Scienza di Torino and the hospital authorities attached to it (AOU San Giovanni Battista di Torino; AO CTO/Maria Adelaide di

Some of the key nodes of the reorganisation process pertained to, above all, the overall rethinking of "regional health networks", dehospitalisation and the implementation of community-based care.

As regards the local network, the objectives set out in the Regional Addendum to the Deficit Recovery Plan (par. 1.4) included "Improving appropriateness and healthcare service delivery at the local level", which required the Region to identify a series of actions to improve the care of patients with special attention to the proper management of individual care provided in the "care chain"[21]. The actions put in place in the 33 districts of Piedmont led to the establishment of a network of "Care Homes" (*Case della Salute*) in 2017 and, in 2018, to the development of regional indications for the establishment of Practice Communities in each district as a regional model for the management of chronic conditions[22].

3. Emergency services

Following the Presidential Decree of 27 March 1992, the need emerged for a connection between emergency services and the broader "emergency system" through the integration of various intervention levels in a coordinated plan involving all the relevant players. The Ministerial Decree no. 70 of 2 April 2015 "Regulation defining qualitative, structural, technological and quantitative standards for hospital care" provided for an integrated organisation of emergency services and the emergency system through a locally-based response to minor emergencies, hospital emergency rooms and Emergency Admission Departments (*Dipartimenti di emergenza-urgenza accettazione,* "DEA"). These last are made up of functional groupings of operational units and, depending on the operational units they are composed of, are divided into level I DEAs and level II DEAs.

3.1. Tuscany

The emergency area has been the subject of careful restructuring and reorganisation for years. DGR no. 1117 of 2013 marked an intermediate step providing for the reduction of operation centres from 12 to 6, on the way to ultimately decreasing their number to 3. To do this, the centres of

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Torino; AO OIRM/S. Anna di Torino), stating that the new authority will take effect on 1 July 2012.

[21] See DGR no. 27-3628 of 28 March 2012 "Implementation of the Deficit Recovery Plan - DGR no. 44-1615 of 28 February 2011, as amended. The local healthcare network: criteria and strategy for the improvement of appropriateness and outpatient care".

[22] See the 2018 Regional Chronicity Plan.

Florence and Prato were unified in 2014, followed by those of Pistoia and Empoli, and Viareggio and Massa in 2015; later, in 2016, Lucca was merged with Viareggio-Massa, and Grosseto with Siena.

Alongside the need to unify the operation centres and maximise the efficiency of the emergency services, over the years the need emerged to focus on the quality of care provided and the effectiveness of the actions undertaken through the experimentation of innovative organisational and management models. This ultimately led to the strengthening of Tuscan emergency rooms (*Pronto Soccorso*)[23]. Through DGR no. 806 of 2017, Tuscany was able to reform and reorganise its ERs to reduce waiting times and to ensure greater attention to the most fragile patients. The ER system was restructured into high, medium and low levels of complexity of activity. The transition to this new model comes from years of experimentation carried out at the AOU of Careggi and at the ER of Prato and Empoli. DGR no. 974 of 2017 introduced plans for the management of overcrowding in emergency rooms, requiring each local authority to draw up a detailed action plan to be followed in the event of overcrowding in the emergency room.

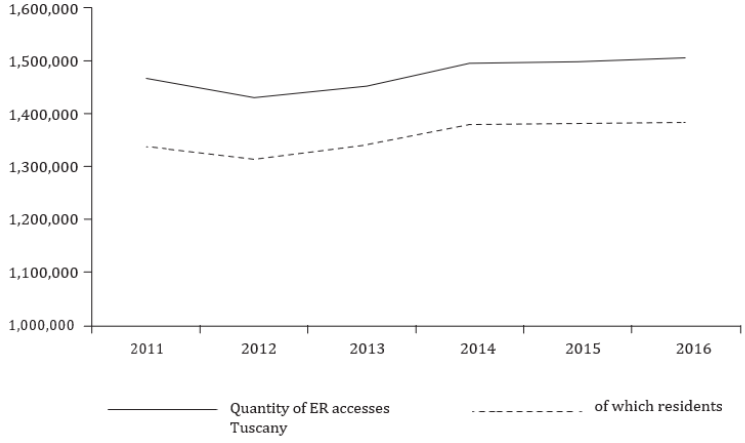

Fig. 2a. Trend in the volume of accesses to the emergency room in Tuscany by resident and non-resident population. Years 2011-2016.

Source: Calculations based on ARS Toscana data (RFC 106 flow).

[23] See the experimental proposals and organisational innovations contained in the following DGRs: no. 958 of 2007; no. 1015 of 2007; no. 140 of 2008; no. 1010 of 2008; no. 360 of 2009; no. 601 of 2009; no. 449 of 2010; no. 693 of 2011; no. 210 of 2012.

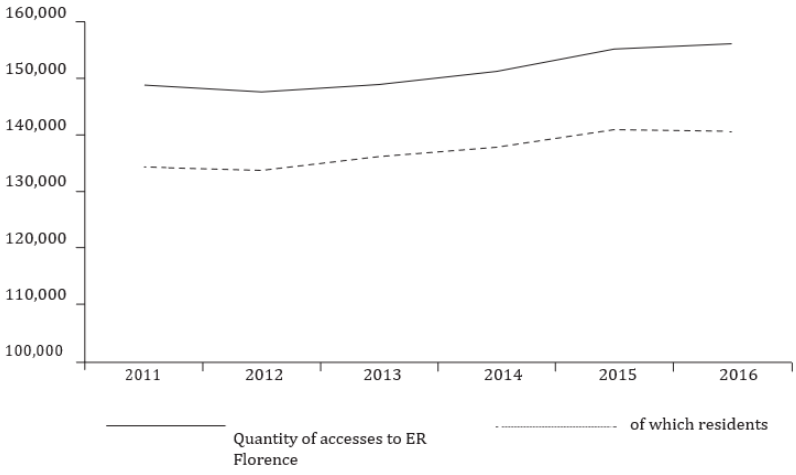

Fig. 2b. Trend in the volume of accesses to the emergency room in Florence by resident and non-resident population. Years 2011-2016.

Source: Calculations based on ARS Toscana data (RFC 106 flow).

Despite regulatory measures aimed at rationalising the emergency sector, services in this sector exhibited an increase in the volume of activity in the years 2014-2016, both at the regional level and at the level of the Florence Health Authority (figs. 2a and 2b).

3.2. Piedmont

The emergency area can be described as an area of functional intersection between outpatient and hospital services, which should operate in concert.

DGR n. 48-8609 of April 14, 2008 "Guidelines for the revision of health emergency systems" pursues the objectives of providing regional coordination for DEAs and integration with the local Emergency Services (118 - *Servizio di emergenza territoriale* (SET)) at the regional and local levels, and ensuring cooperation between the emergency system, the local district system and hospital facilities and services, with the goal of preventing overcrowding of emergency rooms, reducing waiting times for services and limiting emergency admissions. One of the fundamental objectives of the DEA network is, first and foremost, its integration with the local emergency system. To this end, lines of action have been defined both at the regional and local levels (including both ASR and supra-zonal

coordination areas) as a necessary condition for ensuring broader forms of coordination with district services, as well as with hospital structures and services.

DGR no. 59-13644 of 22 March 2010 provided for the establishment of the regional and supra-zonal coordination of the Emergency Network of the Piedmont Region, according to the supra-zonal reference areas defined in the table attached to the DGR[24]. Moreover, in application of DGR no. 1-415 of 2 August 2010 and subsequent amendments, the Regional Council defined the criteria for reorganising the "118" (emergency) system with Measure no. 44-1980 of 29 April 2011: this reduced the number of Operation Centres from 8 to 4. Regional Council Decrees no. 3-2249 of 27 June 2011 and no. 16-2348 of 22 July 2011 set out further interventions and reorganisation measures redefining the organisation of operation centres for the coordination of emergency services[25]. This merged the eight "118" operation centres into four. As regards the reorganisation of the operation centres, the reference criterion for defining the number of centres was population density (with an expected reference catchment area of between half a million to one million inhabitants). For the 118 operation centre in Turin, in light of the complexity and size of the area in question, the provincial catchment area was maintained at 2.2 million inhabitants[26].

[24] See also DGR no. 18-1831 of 7 April 2011 reorganising the emergency network on the basis of the hub-and-spoke model and DGR no. 44-1980 of 29 April 2011.

[25] DGR no. 16-2348 of 22 July 2011 provided for the establishment of the "Inter-departmental 118" emergency operation service, consisting of the following Regional Health Authorities: AO SS. Antonio e Biagio e Cesare Arrigo of Alessandria, ASL Cuneo 1, AOU Maggiore della Carità of Novara, AOU San Luigi Gonzaga of Orbassano.

[26] Considering the orographic and strategic positioning of the 118 operation centres, and taking into account the investments made in technological support at some of them, the emergency coordination system was reorganised into four 118 operation centres, as follows: Area 1 TO: Operation Centre Turin; Area 2 AL-AT: Alessandria Operation Centre at AO SS. Antonio e Biagio and Cesare Arrigo of Alessandria; Area 3 CN: Cuneo Operation Centre at ASL CN1; Area 4 NO-BI-VC-VCO: Novara Operation Centre at AO Maggiore della Carità in Novara.

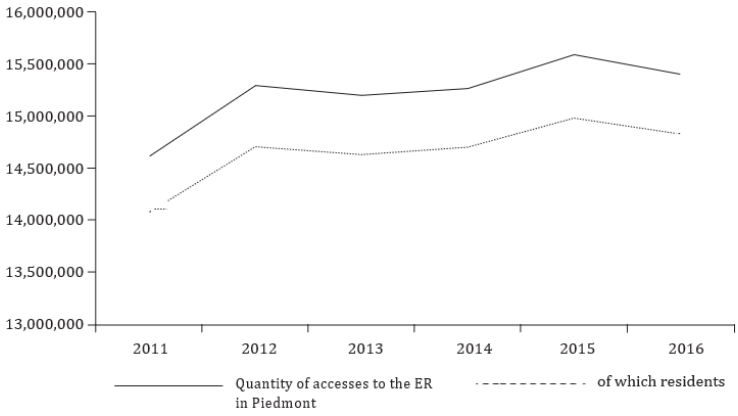

Fig. 3a. Trend in the volume of accesses to the emergency room in Piedmont by resident and non-resident population. Years 2011-2016.

Source: Calculations based on CSI Piemonte data (EMUR-PS/C2 flow).

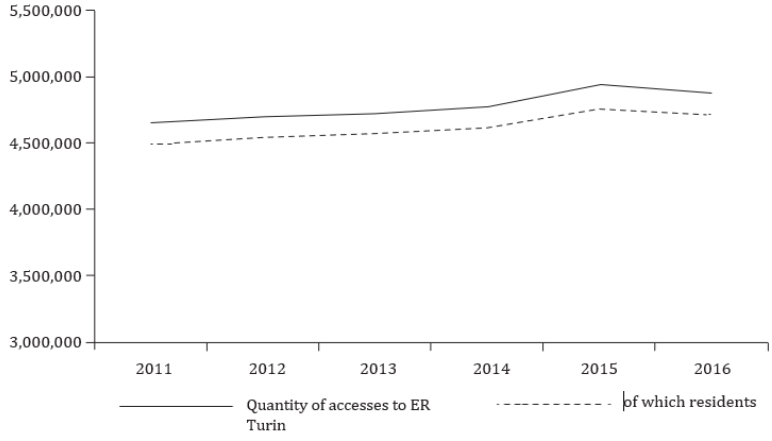

Fig. 3b. Trend in the volume of accesses to the emergency room in Turin by the resident and non-resident population. Years 2011-2016.

Source: Calculations based on CSI Piemonte data (EMUR-PS/C2 flow).

Given the management complexity and the relevance of the resources to be managed, the coordination function of the operation centres is guaranteed by a complex structure for each local area.

The reorganisation of the system can therefore be described as significant. Nevertheless, the graphs of the trend in access to those services in the years under consideration indicate an overall increase in the volume of activity at the level of both the regional and local health authorities (Figures 3a and 3b).

4. Hospital care

The agreement between the State and the Regions of 23 March 2005 required the Regions to fulfil a series of obligations concerning the rationalisation and use of the hospital network. In particular, Article 4 envisaged the progressive integration between hospital and district care, and Article 7 committed the Regions to defining the relations between hospital and non-hospital care, through the constant and permanent involvement of general practitioners and family paediatricians to promote real and essential integration between primary and hospital care, also extending to diagnostic, therapeutic and rehabilitation paths and the sharing of prevention measures.

Article 6 of the 2010-2012 Health Pact envisaged the rationalisation of the hospital network by increasing the appropriateness of hospital admissions and promoting a shift from ordinary to day hospitalisations, from day hospitalisations care to outpatient care and, in general, from inpatient to residential and home care.

Article 15, par. 13(c) of Legislative Decree no. 95 of 6 July 2012, implemented (with amendments) by Law no. 135 of 7 August 2012, concerning the revision of public spending, provided for the reduction in the standard number of accredited hospital beds charged to the Regional Health Service to a level no greater than 3.7 beds per 1,000 inhabitants, including 0.7 beds per 1,000 inhabitants for rehabilitation and post-acute long-term care, and providing for the consistent adjustment of the staffing levels of public hospitals; as a result, the assumption is a hospitalisation rate of 160 per 1,000 inhabitants, of which 25% refers to day hospitalisations.

Section 8 of Annex 1 to Ministerial Decree no. 70 of 2015, concerning hospital networks, required that hospital networks be organised in pathology networks, so as to integrate hospital activity for acute and post-acute cases with outpatient activities. It also required the adoption by the Regions of specific provisions taking into account the organisational guidelines and the recommendations contained in the specific agreements sanctioned by the State-Regions Conference on the respective matters[27].

[27] Ministry of Health Decree no. 70 of 2015 was issued in implementation of Article 15, par.

From 2010 to 2018, the overall number of beds fell by an average of 1.8%, continuing the trend observed since the mid-1990s.

From 2010 to 2018, hospital beds in public or accredited private facilities for the treatment of infectious diseases, pneumology and intensive care decreased on average by 1.2%. It can also be observed that while beds for infectious diseases decreased by 2.9% and those for pneumology by 2.6%, intensive care beds increased by 1.2%[28].

With regard to the trend in intensive care beds (a matter of particular relevance during the COVID-19 pandemic), according to the 1997 statistical yearbook of the SSN, there were 3,119 intensive care beds in use, equal to 79% utilisation rate.

The statistical yearbook published on 18 September 2019 presented data for 2017 and indicated an increase in ICU beds, as well as a decrease in their utilisation: 44,600,600 beds used; 57,870 inpatients; 790,128 inpatient days; 13.7 average bed days; 48.4 utilisation rate (per 100).

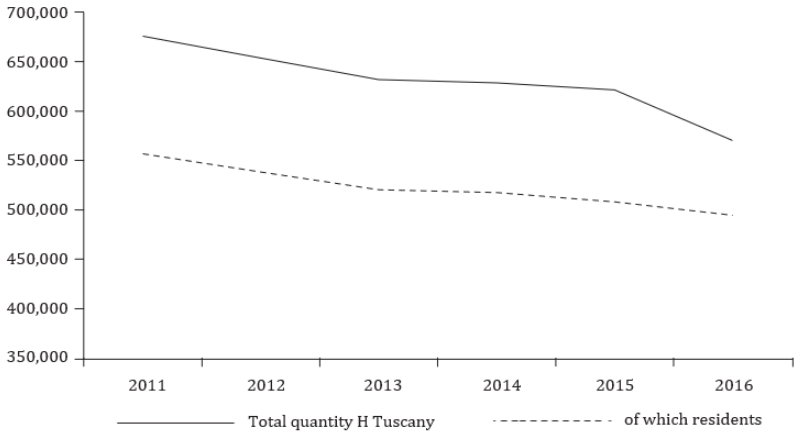

Fig. 4a. Trend in the volume of accesses to hospital services in Tuscany by resident and non-resident population. Years 2011-2016.

Source: Calculations based on ARS Toscana data (SDO flow).

13(c) of Legislative Decree no. 95 of 2012, implemented with amendments by Law no. 135 of 2012. On the basis of this legislation, hospital beds in Italy have decreased by at least 7,389.

[28] See ISTAT's written submission to the 5th Commission for Economic Planning and Budget of the Senate of the Republic, Rome, 26 March 2020, p. 15, in the context of the examination of the bill converting Legislative Decree no. 18 of 2020.

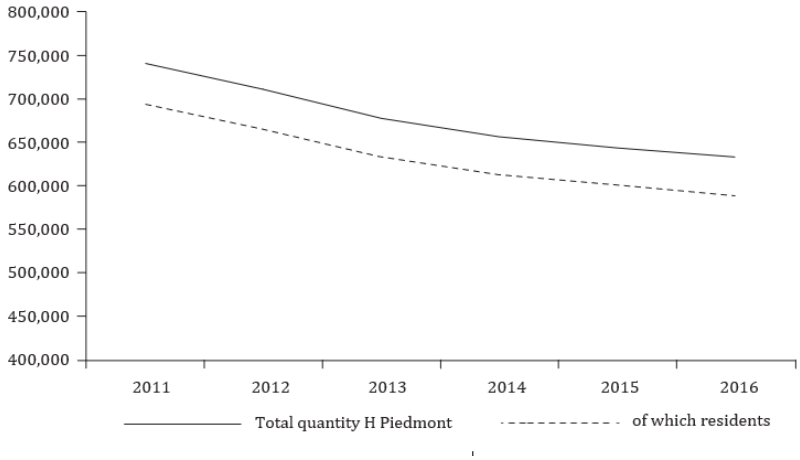

Fig. 4b| Trend in the volume of accesses to hospital services in Piedmont by the resident and non-resident population. Years 2011-2016.
Source: Calculations based on CSI Piemonte data (SDO flow).

As figures 4a and 4b indicate, the volume of activity of hospital services (which include ordinary hospitalisation and day hospitalisations) decreased both in Piedmont and in Tuscany, as a consequence of the economic-regulatory measures illustrated above.

4.1. Tuscany

Hospital care has undergone significant changes at both the national and the regional levels. De-hospitalisation, with the consequent reduction in the rate of hospitalisation and beds, and greater emphasis on primary care have been the constant reference points for health policies in recent years. Alongside these actions, local services should also have been redefined, but contrary to expectations they have not received the desired attention.

In Tuscany, DGR no. 145 of 2016 in addition to the provisions of Ministerial Decree no. 70 of 2015 provided for the reduction of beds to 3.7 per 1,000 inhabitants. As a consequence of these normative acts, in the years of reference a decrease can be observed in the volume of

hospitalisation services both at a regional level and in the Florence area (figs. 5a and 5b).

The decrease in volumes of activity also affected day-hospital services, and this is reflected in the significant variations seen (fig. 6).

In Tuscany, from 2010 to 2018 beds in intensive care increased by 1.8%, while beds in infectious diseases and pneumology decreased by 2.5% and 4.4%, respectively (average annual variation).

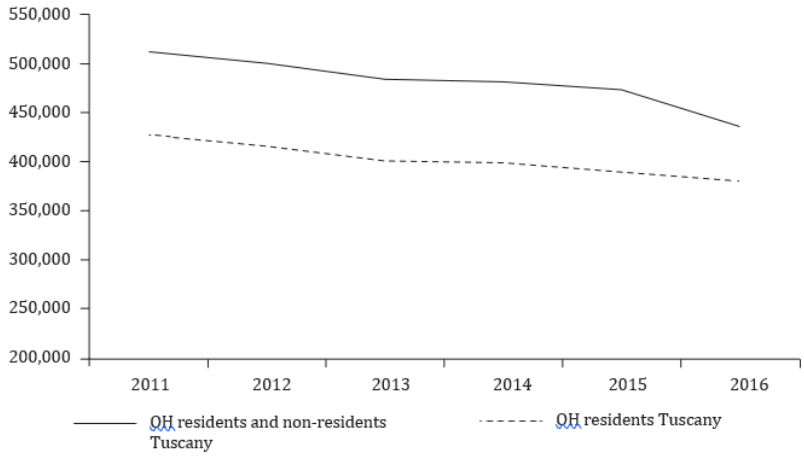

Fig. 5a. Trend in the volume of ordinary hospitalisations in Tuscany by resident and non-resident population. Years 2011-2016.

Source: Calculations based on ARS Toscana data (SDO flow).

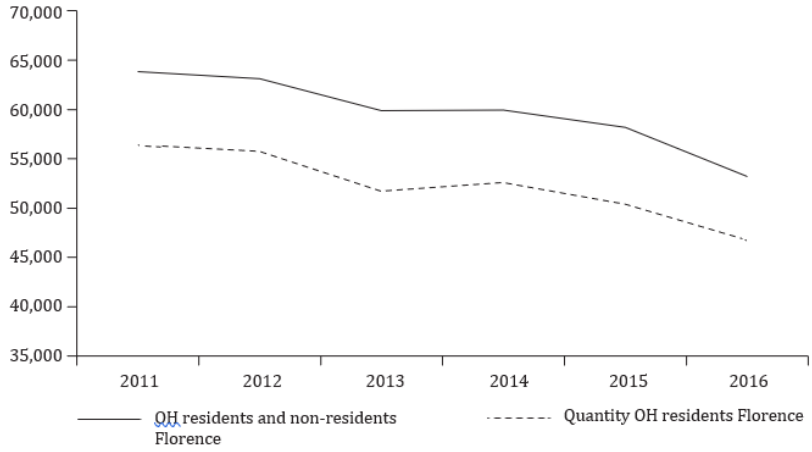

Fig. 5b. Trend in the volume of ordinary hospitalisations in Florence by resident and non-resident population. Years 2011-2016.

Source: Calculations based on ARS Toscana data (SDO flow).

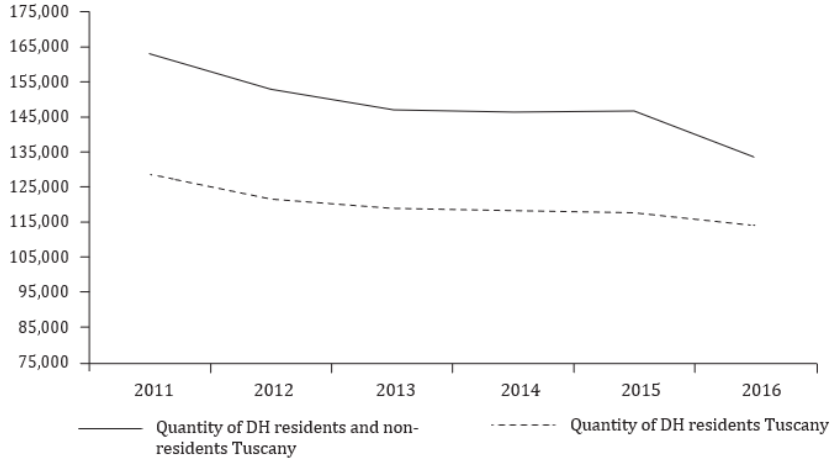

Fig. 6. Trend in the volume of accesses to Day Hospital services in Tuscany by resident and non-resident population. Years 2011-2016.

Source: Calculations based on ARS Toscana data (SDO flow).

Table 1. Trend in OH beds in Tuscany for infectious diseases, pneumology, intensive care. Years 2010-2018 (absolute values and rates per 10,000 inhabitants)

	2010	2011	2012	2013	2014	2015	2016	2017	2018	2018 (rate per 10,000 inhabitants)	Average annual variation (%)
Tuscany	**848**	**827**	**828**	**806**	**783**	**766**	**785**	**785**	**775**	**2.1**	**-1.1**
Infectious and	277	268	273	257	235	231	233	231	227	0.6	-2.5
Pneumology	245	233	219	214	178	171	165	170	171	0.5	-4.4
Intensive care	326	326	336	335	370	364	387	384	377	1.0	1.8

Source: Calculations by ISTAT based on Italian Ministry of Health data contained in the Memorandum presented to the Senate on 26 March 2020.

In Infectious Diseases, 277 beds were available in 2010 and 227 in 2018; in 2010; in pneumology, 252 beds were available in 2010 and 171 in 2018; in intensive care, there were 326 beds in 2010 while there were 377 in 2018[29].

4.2. Piedmont

The role of the hospital in the regional legislative framework has changed significantly. Regional policies have opted essentially for de-hospitalisation and a reduction in the hospitalisation rate, aiming explicitly, in line with national objectives, at: converting ordinary hospitalisation into day hospitalisation; transforming day hospitalisation into outpatient care; and increasing residential and home care. As a result, between 2012 and 2018 twelve hospitals were closed in Piedmont. The 2013-2015 Operating Programme that implemented the Deficit Recovery Plan selected them primarily from among the smaller facilities (i.e., with fewer than 120 beds, which represent the optimal standard) of the existing hospital network[30]: the Valdese hospital of Turin; the hospital of Castellamonte of ASL TO 4; the hospitals of Giaveno, Avigliana, Venaria, Torre Pellice, Pomaretto of ASL TO

[29] See ISTAT's written submission to the 5th Economic Planning and Budget Committee of the Senate of the Republic - Rome, 26 March 2020, p. 15, in the context of the examination of the bill converting Legislative Decree no. 18 of 2020.

[30] Cfr. Regione Piemonte, *Programmi Operativi per il triennio 2013-2015*, *allegato alla DGR del 30 dicembre 2013, n. 25-6992,* and particularly *Programma 14: Riequilibrio ospedale-territorio*, pp. 189 ff.

3; the hospital of Arona of ASL NO; the hospital of Caraglio of ASL CN 1; the hospital of Valenza of ASL AL. In addition, the staff and equipment of the Ophthalmic Hospital and the Amedeo di Savoia Hospital in Turin were transferred to other AOs, with a parallel reorganisation and rationalisation of specialist functions.

The considerations underlying the process of reorganising the hospital network are set out in Regional Decree no. 17-1830 of 7 April 2011 "Implementation of the Reduction Plan. Regional criteria for the identification of facilities and bed allocations within the hospital network". This Decree underscored that the reorganisation of the hospital network was meant to lead to services being provided in facilities capable of guaranteeing adequate safety and quality of care, as well as to the conversion of smaller hospital facilities into local outpatient facilities and additionally to reassigning certain disciplines. In particular, with DGR no. 6-5519 of 14 March 2013, the network of neonatology and birth departments was restructured (reduction from 32 to 24 birth departments, of which 7 with neonatal intensive care units (NICUs)). This was done in order to address pre-existing critical issues consisting in a shortage of beds in NICUs and the difficulty in ensuring adequate neonatal care due to the fragmentation of small birth centres, which do not allow for an adequate number of neonatologists to be present on a 24-hour basis. On the other hand, the gradual amalgamation of smaller centres has brought the birth centres down to an adequate size according to national standards (i.e., centres with approximately 1,000 births a year, with the possibility of further decreasing to the mandatory limit of 500 births a year only for particularly remote geographical areas). As a result, eight birth centres were closed: Cuorgnè, Carmagnola, Susa, Borgosesia, Domodossola, Bra, Tortona and Acqui Terme.

The 2012-2015 Regional Social and Health Plan (*Piano socio-sanitario regionale*, PSSR), which defined the role of each regional hospital, imposed a reorganisation of the hospital network and the network of non-hospital facilities[31]. The two processes, which began in 2014 and 2015 respectively,

[31] The PSSR (2012-2015) was approved by DGR no. 167-14087 of 3 April 2012. Its Annex B also provided for the establishment of the new AO Città della Salute e della Scienza, resulting from the merger of AOU San Giovanni Battista di Torino, and AO CTO-Maria Adelaide and AO OIRM-Sant'Anna, as well as the identification of the supra-zonal areas. Paragraph 5.3.5 identified, as an implementation tool, the contextual revision of the care network leading to progressive de-hospitalisation (decentralised provision of care and strengthening of alternative forms of care compared to hospitalisation), while ensuring the pursuit of continuity and integration of care, as well as the interaction between hospital and non-hospital services, between the public network and the accredited private network for post-acute services, and between hospital and emergency networks, in part in relation to the

in the wake of the 2012-2015 PSSR, are aimed at rethinking places of care to organise them as a system divided by phase and intensity of care. In this phase of reorganisation, hospitals were viewed as specialised centres for the treatment of the acute phase of disease and advanced diagnostics[32].

The main guidelines of regional legislation on the subject concern the enhancement of the appropriateness of hospitalisation[33], the reduction of hospital beds[34], the organisation of the hospital network[35] and the organisation of continuity of care[36].

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need to treat chronic diseases caused by the ageing of the population. The indications of the PSSR underscored the need for the reorganisation of the regional hospital network towards a functional reorganisation of the hospital structures, including by converting some of them into primary care structures, and strengthening the home care infrastructure, with particular reference to integrated home care, as well as continuity of welfare and health care. The dismantling of hospitalisation services was to be accompanied in parallel with the activation of those pertaining to the local level of care, in order to continue to guarantee, to the Piedmontese population, the essential levels of care.

[32] This role emerges clearly with respect to the organisational solutions adopted at the Parco della Salute e della Scienza di Torino and the Città della Salute e della Scienza of Novara, the new, single hospital of ASL VCO. Paragraph 5.3.3 of the Regional Healthcare Plan provides for the classification of hospital centres in the public network into three levels: local hospitals, "ospedale cardine" (hospitals providing frequent acute care services) and reference hospitals. It also provides for the organisation of the Piedmontese hospital network into six supra-zonal areas, within which all the hospitals (including hospitals falling into the three categories above, private IRCCSs and accredited nursing homes, including those with a complementary role in the network) must be functionally integrated, regardless of their legal-administrative nature.

[33] DGR no. 15-1828 of 7 April 2011 "Implementation of the Deficit Recovery Plan - Appropriateness of inpatient activity and redetermination of acute beds in the hospital network. Implementation of the indications of the Addendum to the Deficit Recovery Plan approved by DGR no. 1-415 of 2 August 2010 and its implementation programme" approves the guidelines for improving the organisational appropriateness of hospital activities. In particular, DGR 4-2495 of 3 August 2011 specified the appropriateness criteria for inpatient activity, in line with the indications of the addendum and the guidelines of the 2010-2012 Health Pact of 3 December 2009.

[34] With DGR n. 1-4117 of 5 July 2012, the reduction of beds in the hospital network was programmed in relation to the indication of the recovery plan, adopting the following criteria: increase of efficiency in the use of available hospital resources; evaluation of the decrease of cases and days of hospitalization determined by the application of regional guidelines on appropriateness, in particular with DGR n. 15-1828 of April 7, 2011, n. 4-2495 of August 3, 2011 (acute admissions) and DGR n. 13-14349 of January 28, 2011 (post-acute admissions); evaluation of the impact of extra-regional mobility; reorganisation according to a hub-and-spoke model with strong integration of the hospital centres by basins corresponding to the supra-zonal areas; revision of bed allocations starting with the hospitals that, in the social-health plan, are scheduled for reconversion. DGR no. 6-5519 of 14 March 2013 "Regional health planning. Interventions for revising the Piedmont hospital network..." and its corresponding implementing measures (*Determinazione dirigenziale* (Departmental Decision – D.D.) no. 532 of 4 July 2013, subsequently amended by D.D. no. 651 of 29 August 2013 and D.D. no. 816 of 18 October 2013) defined the need for beds and

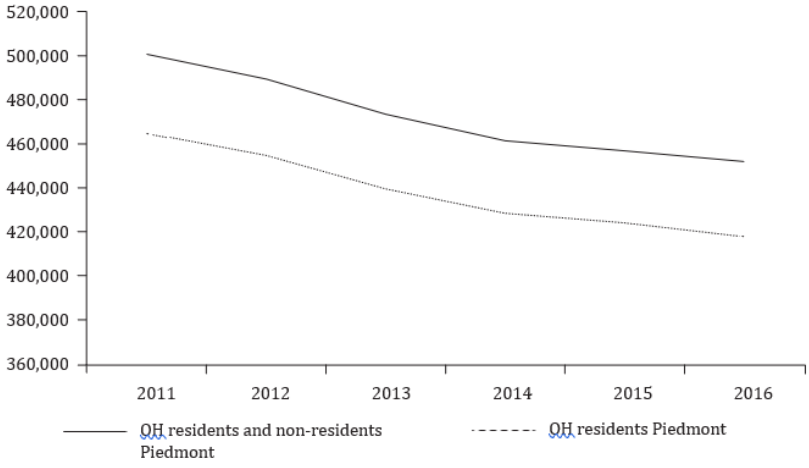

Fig. 7a. Trend in the volume of ordinary hospitalisations in Piedmont by resident and non-resident population. Years 2011-2016.

Source: Calculations based on CSI Piemonte data (SDO flow).

organisational structures, broken down by area and discipline, in implementation of the national legislation and the Deficit Recovery Plan. DGR n. 1-600 of 19 November 2014 on "Adjustment of the hospital network to the standards of Law 135/2012 and the Health Pact 2014-2016 and guidelines for the development of the territorial network", as integrated with DGR n. 1-924 of 23 January 2015, envisaged a reshaping of the hospital network in terms of the number of beds as well as the organisation of hospital disciplines and the related complex structures, in line with the Ministerial Regulation "Definition of qualitative, structural, technological and quantitative standards relating to hospital care" (subsequently approved by Ministerial Decree no. 70 of 2015).

[35] DGR no. 6-5519 of 14 March 2013 "Regional health programming. Interventions for the revision of the Piedmont hospital network..." envisages the need for the hub-and-spoke model and the need for an overall and integrated vision of the three networks: the hospital network, the emergency network, and the local network.

[36] See the following resolutions of the Regional Council: DGR no. 46-233 of 4 August 2014 and DGR no. 1-600 of 19 November 2014 "Modifications and integrations on the subject of continuity of care with a health value with which the programme for the conversion of RSA health structures is approved"; DGR no. 30-3016 of 7 March 2016 "Modifications and integrations to DGR no. 77-2775 of 29 December 2015 on the definition of the requirements of the extra-hospital function of continuity of care with a health value. Amendments to DGR no. 6-5519/2013. Modifications and integrations to annexes A), B) and C) to DGR no. 13-2022 of 5 August 2015"; DGR no. 12-3730 of 27 July 2016 "Modifications and integrations to annex A to DGR no. 6-5519 of 14 March 2013: paragraph 'Continuity of care with healthcare value'. Amendments and integrations to Annexes A), B) and C) to DGR no. 30-3016 of 7 March 2016"; DGR no. 30-7568 of 21 September 2018 "Redefinition of the need for beds for continuity of care with a health value (CAVS). Update of Annex A to DGR no. 12-3730 of 27 July 2016".

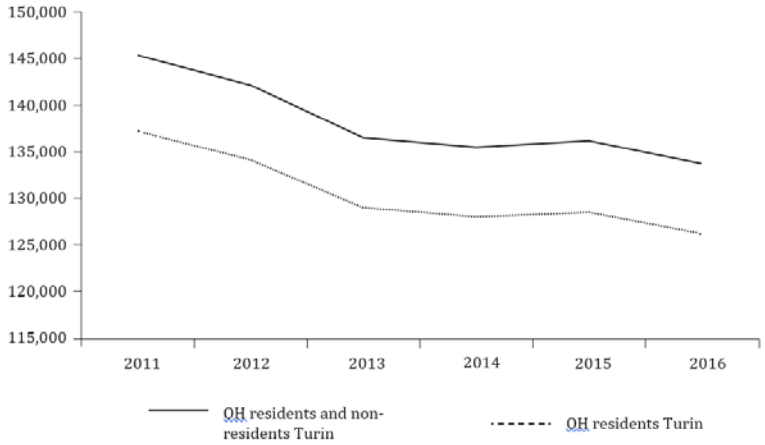

Fig. 7b. Trend in the volume of ordinary hospitalisations in Turin by resident and non-resident population. Years 2011-2016.

Source: Calculations based on CSI Piemonte data (SDO flow).

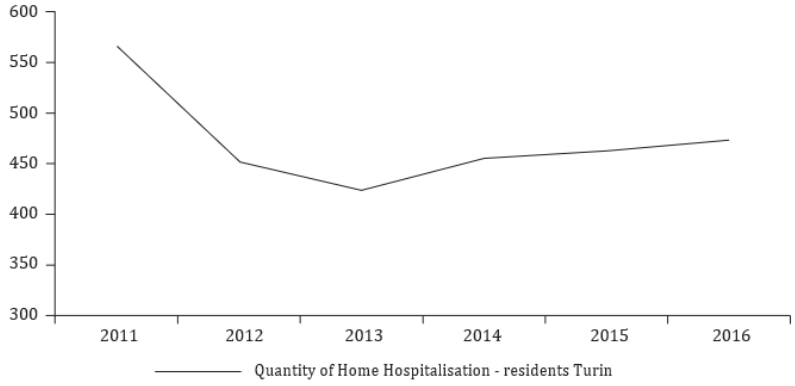

Fig. 7c. Trend in the volume of accesses to home hospitalisation services in Turin by resident population. Years 2011-2016.

Source: Calculations based on CSI Piemonte data (SDO flow).

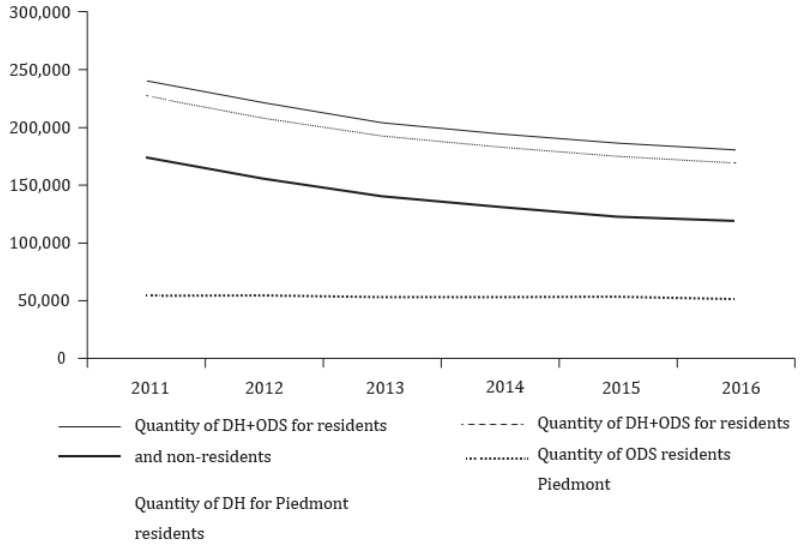

Fig. 8. Trend in the volume of accesses to Day Hospital services in Piedmont by resident and non-resident population. Years 2011-2016.

Source: Calculations based on CSI Piemonte data (SDO flow).

Table 2. Trend in OH beds in Piedmont for infectious diseases, pneumology, intensive care. Years 2010-2018 (absolute values and rates per 10,000 inhabitants)

	2010	2011	2012	2013	2014	2015	2016	2017	2018	2018 (rate per 10,000 inhabitants)	Average annual variation (%)
Piedmont	**826**	**798**	**757**	**772**	**750**	**747**	**726**	**687**	**697**	**1.6**	**-2.1**
Infectious and	238	232	231	233	227	235	218	188	195	0.4	-2.5
Pneumology	249	233	191	199	196	193	188	183	185	0.4	-3.6
Intensive care	339	333	335	340	327	319	320	316	317	0.7	-0.8

Source: ISTAT calculations based on calculations derived from Italian Ministry of Health data contained in the Memorandum presented to the Senate on 26 March 2020.

In the years of reference, the volume of hospitalisation services decreased both at the regional level and in the Turin area (figs. 7a, 7b and 7c).

The decrease in volumes of activity also affected day hospital services and one-day surgery (fig. 8).

In Piedmont, the number of beds per 10,000 inhabitants decreased from 2010 to 2018 in infectious diseases, pneumology and intensive care, by 2.5%, 3.6% and 0.8% respectively (average annual variation).

In Infectious Diseases, 238 beds were available in 2010 as compared to 195 beds in 2018. In pneumology, 249 beds were available in 2010 and 185 in 2018. In ICU there were 339 beds available in 2010 and 317 in 2018[37] (table 2).

5. Specialist outpatient services

The reorganisation affecting the hospital setting has led to related organisational changes for the outpatient setting, especially in terms of a more active involvement of the sector. The reduction in hospitalisation should lead to the assumption that specialist, hospital inpatient and outpatient services provided by both public and accredited private operators should have increased to better respond to centres the health needs of the population from an organisational point of view.

The volumes of specialist outpatient activity can be analysed by dividing them into 5 main areas:

- clinical (specialist medical examinations)
- diagnostic imaging (ultrasound, scintigraphy, magnetic resonance imaging, tomography, nuclear medicine)
- laboratory diagnostics (blood and urine tests)
- instrumental diagnostics (endoscopies, echo Doppler, echocardiography, electroencephalograms, electromyography, fluorangiography)
- procedures (biopsies, outpatient surgery, medically assisted procreation, etc.)

5.1. Tuscany

[37] See Table 10 of ISTAT's written submission to the 5th Committee for Economic Planning and Budget of the Senate of the Republic - Rome, 26 March 2020, p. 33, in the context of the examination of the bill converting Legislative Decree no. 18 of 2020.

Observing the graphs illustrating the data provided by the Regional Health Authority (ARS) in Tuscany from 2011 onwards, the variation in the services provided can be considered minimal, but this requires some clarification. The trend across the region and in Florence concerning the volumes of specialist activities appears stable in the years considered (figs. 9a and 9b).

While in the field of diagnostic imaging there is a decrease in services at the regional level[38], laboratory diagnostics exhibits stable levels of service volumes in the years under consideration[39].

The ARS Health Reports exhibit substantial correspondence with these analyses of activity volumes. These reports show a decrease in the percentage of diagnostic imaging from 2013 to 2016, while the number of clinical, instrumental diagnostic and procedural activities remained substantially stable in the years under consideration[40].

In the ARS health report, the decrease in diagnostic imaging services is attributed to additional co-payments, which had an impact on the cost of these services, especially for higher incomes (from 70,000 euros and up)[41].

The data in the health reports produced by ARS Toscana show, for the period of 2014-2018, that the greatest contraction occurred between 2015 and 2016 (-4.6%). Benefits paid in 2018 are 7.6% lower than in 2014. 2018 shows a contraction of 1.2% compared to 2017, consolidating the downward trend since 2014[42].

In the field of specialist services with a high risk of lack of appropriateness, there is a decrease in the volume of activity for ultrasound of the upper abdomen and nuclear magnetic resonance of the spine[43], while there has been an increase in computerised tomography of the spine and vertebral canal[44].

[38] See figure E.2 Tuscany in the appendix.
[39] See figure E.3 Tuscany in the appendix.
[40] See ARS Toscana, *Relazione sanitaria*, 2016, p. 101.
[41] See ARS Toscana, *Welfare e salute in Toscana*, 2017, p. 179.
[42] Data taken from ARS Toscana, *Welfare e salute in Toscana*, 2019, p. 159.
[43] See figures F.1 Tuscany and F.2 Tuscany in the appendix.
[44] See figure F.3 Tuscany in the appendix.

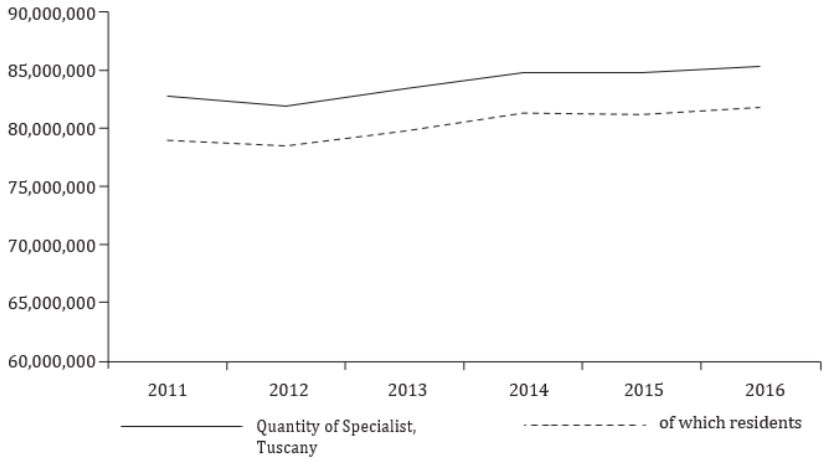

Fig. 9a. Trend in the volume of accesses to outpatient specialist services in Tuscany by resident and non-resident population. Years 2011-2016.

Source: Calculations based on ARS Toscana data (SPA flow).

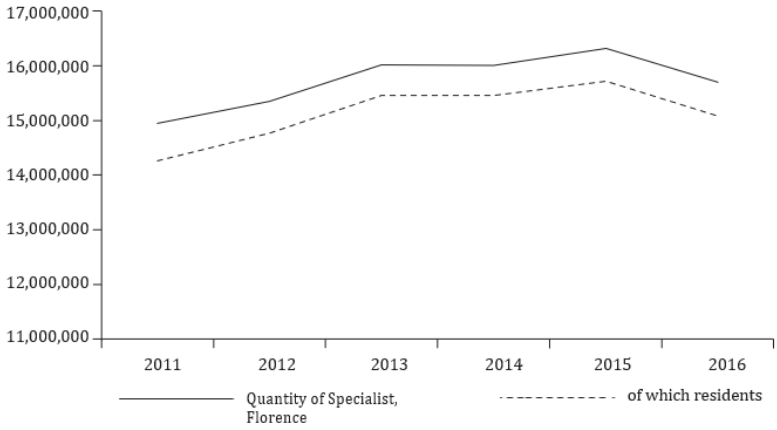

Fig. 9b. Trend in the volume of accesses to outpatient specialist services in Florence by resident and non-resident population. Years 2011-2016.

Source: Calculations based on ARS Toscana data (SPA flow).

In relation to specialist services with a medium risk of lack of appropriateness, the volume of activity of computed tomography of the upper abdomen decreases[45], as does that of computed tomography of the lower abdomen[46].

In the field of specialist services with a low risk of lack of appropriateness, the trend in the volume of neurological examinations has remained stable over the years (but it has increased at local health authority level)[47], while the volumes of simple electro-myography and psychiatric interviews have decreased[48].

One figure worth mentioning is the volume of psychiatric check-ups, which is increasing both at the regional and local authority levels[49].

5.2. Piedmont

The data contained in the graphs indicate that the volumes of specialist care in Piedmont have modestly decreased from 2012 onwards, with a decrease of about 2 million services in the regional area and a smaller decrease in the Turin area (TO1 and TO2) (Figures 10a and 10b).

Instrumental and imaging diagnostic services have also steadily decreased since 2011, as have laboratory diagnostics, both at the regional and local authority levels[50].

The trends for specialist services in the selected services are different.: in the area of services with a high risk of lack of appropriateness, the volumes of ultrasound of the upper abdomen and computed tomography of the spine and vertebral canal are rising, both at the regional and local authority levels[51].

In the category of services with a medium risk of low appropriateness, the volumes of computed tomography of the upper abdomen are lower at the regional level, while at the local authority level the trend varies[52].

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[45] See figure G.1 Tuscany in the appendix.
[46] See figure G.2 Tuscany in the appendix.
[47] See figures H.1 Tuscany and H.1 Florence in the appendix.
[48] See figures H.2 Tuscany and H.4 Tuscany in the appendix.
[49] See figures H.3 Tuscany and H.3 Florence in the appendix.
[50] See figures E.2 Piedmont and E.3 Piedmont; Figures E.2 Turin and E.3 Turin in the appendix.
[51] See figures F.1 Piemonte and F.3 Piemonte; Figures F.1 Torino and F.3 Torino in the appendix.
[52] See figures G.1 Piemonte and G.1 Torino in the appendix.

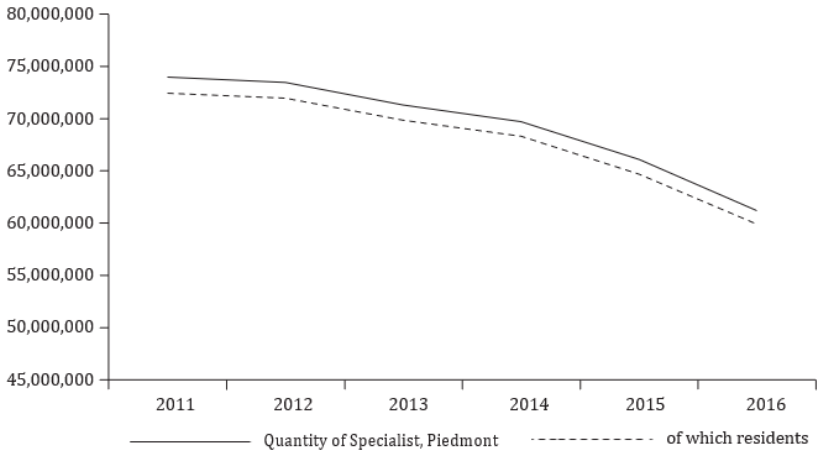

Fig. 10a. Trend in the volume of accesses to outpatient specialist services in Piedmont by resident and non-resident population. Years 2011-2016.

Source: Calculations based on CSI Piemonte data (C flow).

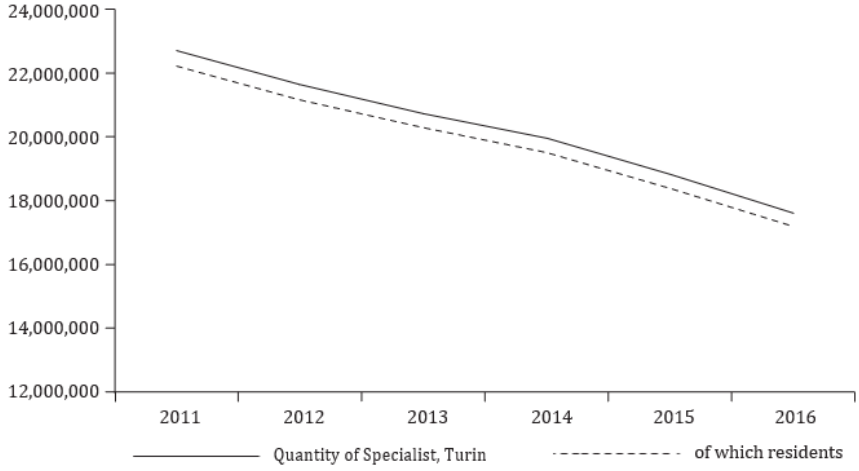

Fig. 10b. Trend in the volume of accesses to outpatient specialist services in Turin by resident and non-resident population. Years 2011-2016.

Source: Calculations based on CSI Piemonte data (C flow).

Within the category of services at low risk of low appropriateness, in particular the volumes of activity of the services of neurological

examination and simple electromyography (both at the regional and local authority levels), psychiatric interviews (at the regional and local authority levels) decrease, while the volumes of the services related to psychiatric check-ups can be said to be constant, except for the years 2013 and 2014 in which they decreased at the regional level[53].

6. The role of the third sector

Third-sector organisations pursue non-profit, civic, solidarity and socially useful objectives, and the recent reform introduced by Legislative Decrees no. 117/2017 and 112/2017 has recognised the key role and strategic function of voluntary organisations and social promotion associations.

In fact, the new legislation on the third sector envisages more interaction between public bodies and private social actors. Article 55 of Legislative Decree no. 117 (Code of the third sector), 3 July 2017, identifies the "Involvement of third sector entities" as a way to implement the principles of subsidiarity, cooperation, effectiveness, efficiency and economy, financial and asset homogeneity, responsibility and unity of administration, and enables public administration bodies to ensure the active involvement of third sector entities in local policies through co-planning (joint actions for the identification of needs) and co-design (joint actions for the identification of implementation methods).

The number of third sector organisations in Italy has increased quite significantly, from 235,232 in 2001 to 343,432 in 2016[54].

In 2016, there were 343,432 not-for-profit institutions active in Italy and, as of 31 December 2016, they employed a total of 812,706 people. This represents a growth in these organisations from 2015 by 2.1% in terms of number of organisations, and3.1% in terms of employees; this is therefore a sector that continues to expand over time with average annual growth rates in line with the trends outlined in traditional censuses.

In 2015-2016, the number of non-profit institutions in almost all legal forms increased, but it was foundations that grew the most (+16.4%), while social cooperatives exhibited a slight decrease (-3.3%). The association is the most popular legal form (85.1%), followed by other legal forms (8.2%), social cooperatives (4.5%) and foundations (2.2%).

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[53] See figures H.1 Piedmont and H.1 Turin; figures H.2 Piedmont and H.2 Turin H.2 Turin; figure H.3 Piedmont; figures H.4 Piedmont and H.4 Turin in the appendix.

[54] See ISTAT, *Struttura e profili del settore no profit*, 11 October 2018, published at https://www.istat.it/it/files/2018/10/non-profit.pdf.

The geographical distribution of non-profit organisations exhibits a high concentration in Northern Italy (171,419 units, equal to 51% of the national total) compared to Central Italy (75,751 units, equal to 22.5%) and Southern Italy (89,105 units, equal to 26.5%). Lombardy and Lazio are still the regions with the largest presence of non-profit organisations (with shares of 15.7% and 9.2%, respectively), followed by Veneto (8.9%), Piedmont (8.5%), Emilia-Romagna (8%) and Tuscany (7.9%). The regions with the lowest presence of non-profit organisations are Valle d'Aosta (0.4%), Molise (0.5%) and Basilicata (1%)[55].

6.1. The Florence experience

Voluntary work, social cooperation and other third sector actors are well established in Tuscany[56]. The recent reform of the third sector has further contributed to the consolidation of their presence in areas where they represent a deep-rooted tradition[57].

The landscape of organisations carrying out activities in the health and social care sector in Tuscany is remarkably vast and varied[58]. It should be pointed out that, in the framework of this research, only a few interesting and relevant experiences in the Florence area have been surveyed and analysed from a structural and functional point of view. In order to identify the type of organisations working in this field, we referred first of all to those organisations which are affiliated with Caritas. These are Associazione Niccolò Stenone, Casa Stenone and Casa Vittoria.

Associazione Niccolò Stenone has been running a specialist outpatient clinic since 1990, which provides social and health services for immigrants and all those who live in a state of indigence and are in need of general and

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[55] See ISTAT, *Censimento permanente delle istituzioni no profit. Primi risultati*, 20 December 2017, published at https://www.istat.it/it/files/2017/12/Nota-stampa-censimen- to-non-profit.pdf.

[56] For an analysis of the subject concerning Tuscany, see E. Stradella, *Le forme di partecipazione e il ruolo del Terzo settore*, in M. Campedelli, P. Carrozza and E. Rossi (Rossi (ed.), *Il nuovo welfare toscana: un modello? La sanità che cambia e le prospettive future*, Bologna, Il Mulino, 2009; as well as E. Rossi, *La partecipazione degli enti privati all'organizzazione dei servizi socio-sanitari in Toscana*, in Istituzioni del federalismo, 2016, no. 3.

[57] After the reform, Article 14, par. 2 of Regional Law no. 58 of 2018 makes reference to the institution of co-planning as a way of promoting the participation of third sector actors in the planning and delivery of services. See D. Caldirola, *Stato, mercato e Terzo settore nel decreto legislativo n. 117/2017: per una «nuova» governance della solidarietà*, in Federalismi, 2018, No 3.

[58] See ARS Toscana, *Welfare e salute in Toscana*, 2019, p. 129.

specialist care, dental examinations and treatment[59]. Associazione Niccolò Stenone and the activities of its affiliated outpatient clinic are targeted at those who are not registered with the SSN because they have been removed from the registry of the municipality of their last residence, and those who find themselves in a state of economic hardship. The aim is to protect their health by means of a personalised care project, which is not intended to be an alternative to the SSN but rather a supplement to the services provided by the public health system on the basis of the legal status of the patients. This service is possible thanks to the voluntary and completely pro bono activity of doctors and health professionals who offer general medical examinations and specialist consultations every day of the week (except holidays and Saturdays).

Casa Stenone is a low-threshold continuity of care residential facility for homeless Italians and immigrants. It was launched in 2011 on the basis of a project presented by the Florentine health authority (ASF) and financed by the Region: the project covers all hospitals in the Florence area, i.e., the hospitals dependent on ASF and those dependent on AOU Careggi. Casa Stenone operates under an agreement signed by the Health Society of Florence and Caritas Fiorentina. Casa Stenone can accommodate up to 12 people who are discharged from hospital and risk losing continuity of care[60].

Lastly, since 1998 Casa Vittoria has provided social and health care for people with a number of unresolved social problems (lack of a family network, lack of housing, etc.). The most commonly treated diseases are related to cancer, psychiatric and cognitive conditions (dementia, etc.). The interview carried out in February 2018 with one of the managers of Casa Vittoria revealed that "the psychiatric service in Florence only engages with the most serious cases. Bipolar and depressed people are not treated here, except when they become acute."

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[59] Specifically, the outpatient medical and dental clinic identifies the following as targets for its activities: "all those who, in a condition of socio-economic marginality, are excluded from any assistance from the SSN; STP (foreigners temporarily present in the territory) or ENI (non-registered Europeans) who need continuity of care for multiple chronic pathologies or conditions of such seriousness as to require continuous care or, conversely, evaluation of emergencies that cannot be referred to the district service provided by the ASL; Italians no longer registered with the SSN, in financial difficulty or facing difficulties of a different nature in accessing the public system (cognitive-behavioural difficulties)."

[60] The violation of the continuity of care can occur in a wide range of cases: from the need to control the adherence to anti-tubercular therapy, to patients with serious vascular diseases, to the consequences of traumas (even serious ones) with significant problems requiring orthopaedic treatment (open fracture of the tibia with external fixation for a period of several months), to Italian patients without a fixed abode, to patients coming from long imprisonment, without family members or reference figures.

Other specific organisations provide basic services aimed at supporting people experiencing deep personal and social distress. These are Centro Porte Aperte (of Associazione Insieme onlus) and Centro la Fenice.

Centro Porte Aperte is a low-threshold reception centre for marginalised individuals that provides support and orientation services[61]. Centro Porte Aperte has been working since 1997 in the Florence area pursuing damage reduction and health protection interventions aimed at promoting the social integration of drug and alcohol abusers living in extreme and marginal situations. The centre aims to intercept social and health needs and to facilitate access to existing services by defining individual pathways in cooperation with the competent services.

La Fenice is a low-threshold day centre that has been operating since May 2014. The centre frequently works with homeless people with psychiatric problems, for which they rely on the Stenone Outpatient Clinic. An interview conducted in February 2018 with one of the managers highlighted that "Psychiatric care is more complex: it requires continuity and attention to related needs. This is why homeless people with mental problems cannot access emergency care."

In this sense, the threshold on access to the emergency room is very high: the regulation of access and relational patterns acts as a filter limiting access for people with very complex needs. This is the case, for example, with the homeless, who after years of living on the streets find it very difficult to sit in a chair and wait in an enclosed space or to interact with an operator. In patients suffering from chronic deprivation, the access threshold is very high.

Lastly, important work is being carried out by voluntary associations that provide specialist examinations for those who are usually excluded from access to the SSR. Examples include the medical outpatient clinic set up at the Health Care Centre of the Church of Santa Maria al Pignone, and the Foundation Institute for Virological Research Bartolomei Corsi which provides free specialist examinations for people referred by their general practitioner or by a welfare association that acts as a facilitator to access the services.

6.2. The Turin experience

[61] The "low threshold" is defined in the Centre's reports in the context of the applied methodology. The methodology is characterised by the recognition of needs in order to build a relationship that can be a stimulus to adhere to a project to improve the person's condition. The working method is based on unconditional admission (except for the ban on substance use in the centre), empathetic listening to the person, and mediation of relational dynamics.

In Piedmont, too, there are several well-established third-sector organisations operating in the social and health fields. The authors' discussions with representatives of some of the best-known organisations based in Turin (Camminare insieme, Caritas, Centro medico del Servizio missionario giovani - SERMIG, Cottolengo, Ufficio Pio) helped to highlight the relevance of these experiences for the communities and the area of reference. In particular, these organisations provide medical care, services and medicines that are not included in the essential levels of care to people who are excluded from access to the SSN for various reasons or who are socio-economically disadvantaged.

The association Camminare insieme[62] was founded in April 1993 with the aim of providing free medical care to all those who cannot access the services of the SSN. Through the voluntary contributions of its members, the association provides free outpatient medical and dental care, health education, and socio-economic assistance when illness is exacerbated by poverty. At first, the beneficiaries were mainly (legal and irregular) foreigners, but since 2000, the problem of access to care has been affecting a growing segment of the Italian population: according to the data provided by the association, in the years 2010-2016 the Italians who have benefited from the association's services were 3.9% of the total, while from the start of the association's activity up to 2010 the percentage of Italians was 2.1% (table 3). Also significant is the proportion of patients who turn to the association despite having a regular registration with the SSN (about 25.6% between 2010 and 2016). Interviews with the operators indicate that these are mostly accesses aimed at obtaining non-reimbursable drugs or are foreign users who experience language and/or relational barriers with the general practitioner or with the SSN services.

As can be seen from the data provided by the association and shown in table 4, the volume of activity almost doubled from 2010 to 2016. As is to be expected considering the association's specific mission, the services most in demand consisted of general medicine (about 61.2% of the services provided in the period indicated), followed by dentistry (about 13.5%), paediatrics (about 5.5%) and gynaecology (about 5.3%).

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62 See the association's webpage https://www.camminare-insieme.it/index.php/lenostreoriginimenu. Since 1998, Compagnia di San Paolo has been the main financial backer of the Association's activities, which in recent years has provided health care for more than 45,000 patients.

Table 3. *Patients admitted by the association Camminare insieme from 1994 to 2016*

	2010-2016	1994-2009	1994-2016
No. of admitted patients	13,425	31,852	45,277
No. of Italian patients	535	690	1,225
Share of Italians over total	39%	2.1%	2.7%
No. of patients registered with the SSN	3,433		
Share of SSN registered patients over total patients	25.6%		

Source: Calculations derived from data provided by Associazione Camminare insieme.

Table 4. *Services provided by Associazione Camminare insieme from 2010 to 2016*

Service	2010	2011	2012	2013	2014	2015	2016	Total	%
General medicine	3,864	4,582	4,896	5,709	6,649	7,387	7,823	40,910	61.2
Dentistry	1,055	1,329	1,228	1,514	1,227	1,304	1,360	9,017	13.5
Paediatrics	153	129	317	702	958	893	517	3,669	5.5
Gynaecology	448	405	415	525	686	664	418	3,561	5.3
Ultrasound	107	169	161	251	253	249	194	1,384	2.1
Orthopaedics	0	129	132	113	132	270	292	1,068	1.6
Dermatology	84	78	86	154	235	143	115	895	1.3
Ophthalmology	153	160	46	39	130	137	186	851	1.3
Surgery	55	82	52	135	108	158	210	800	1.2
Pneumology	21	81	135	115	163	113	113	741	1.1
Gynaecological ultrasound	72	86	84	123	95	86	95	641	1.0
Physiotherapy	0	0	58	194	181	112	87	632	0.9
Cardiology	40	97	69	69	86	134	139	634	0.9
Neurology	19	34	63	53	83	108	92	452	0.7
Physiatrics	63	74	72	79	91	61	0	440	0.7
Optometry	35	60	66	19	30	17	52	279	0.4
Otolaryngology	95	78	35	0	0	2	39	249	0.4
Urology	0	0	18	36	42	44	45	185	0.3
Doppler ultrasonography	0	8	20	33	18	23	45	147	0.2
Oral hygiene	0	0	0	0	0	61	13	74	0.1
Rheumatology	0	0	0	0	11	10	34	55	0.1
Cardiac ultrasound	0	0	0	6	11	15	20	52	0.1
Angiology	7	5	1	1	3	10	17	44	0.1
Nephrology	0	0	0	0	0	0	13	13	0.0
Total	6,271	7,586	7,954	9,870	11,192	12,001	11,919	66,793	

Source: Calculations derived from data provided by Associazione Camminare insieme.

The Giovanni Paolo II Medical Centre of SERMIG[63], which has been operating at the Arsenale della Pace in Turin since 1989, is also a voluntary

[63] See the centre's webpage https://en.sermig.org/our-arsenals/arsenal-of-peace-turin-italy/hospitality/medical-service.html

medical service, set up to provide treatment for all those who cannot access the public health service. In the 1990s, it provided primarily general medical and paediatric care, but later expanded its services to include the provision of specialist examinations, ophthalmology, osteopathic treatments for children, dental care (which is in great demand also among Italian patients or legal residents with financial difficulties), and other forms of care.

The data provided by the SERMIG Medical Centre (table 5) show significant medical activity and an increase in the percentage of Italians who requested a health service, especially dental services, in the years considered.

Table 5. *Services provided by Giovanni Paolo II Medical Centre from 2011 to 2016*

Year	No. medical examinations	No. dental care visits	No. optical services	Share of Italians - medical examinations (%)	Share of Italians - dental care visits (%) (%)
2011	6,268	461	236	2.34	7.97
2012	5,486	692	203	2.29	13.4
2013	5,290	810	191	3.87	22.1
2014	5,439	1,000	223	4.29	20.0
2015	5,329	1,063	300	4.45	22.4
2016	6,275	1,200	35	6.07	18.0

Source: Data provided and processed by SERMIG.

The share of Italian patients who have requested access to treatment at the SERMIG Medical Centre has increased over the years: in 2000 Italians represented 0.76% of the total, but in 2010 the figure had increased to 1.81%, and in 2016 it reached 6.07%. As far as dental services are concerned (which provide a specific indicator, since they are important services for health but are not included, except in specific cases, in the essential levels[64]) the percentage of Italians asking to access the service at SERMIG was 4.79% in 2000, 6.95% in 2010 and 18% in 2016.

[64] The dental services covered by the SSN are indicated in the text containing the updated criteria of the essential levels of care, which is limited to the following cases: dental health protection programmes for children aged 0 to 14 years; specific categories of people in particularly vulnerable conditions.

Regarding the support provided to the health sector by the Italian Caritas facilities operating in Turin, consultation with the responsible person indicates that the requests received by the diocesan centres mainly concern access to non-reimbursable drugs (mostly psychopharmaceuticals prescribed to people undergoing treatment at mental health service facilities or supplements prescribed to oncological patients) or to medical devices to be paid by the patient (such as bed aids for invalids, walkers while awaiting the recognition of disability, nebuliser for children, and various types of orthopaedic devices). Sometimes the financial support provided by Caritas takes the form of covering the cost of co-payments for specialist visits.

This need is also addressed by a specific initiative of the Cottolengo hospital, an established private hospital now accredited with the SSN and run by the Piccola casa della divina provvidenza[65]. Following repeated requests from users, in 2015 the organisation developed a project called "SOS Ticket" specific for co-payments, and raised funds to cover the cost of co-payments for Cottolengo patients in economic distress, particularly after the economic crisis. The interviews conducted indicate that this financial support was particularly needed by destitute patients mainly with reference to specialist examinations and diagnostic services more specifically for eye and dental care services (not covered by the SSN), for minor health problems (e.g. dermatological visits, blood tests) that are not considered urgent and that are postponed for economic reasons, as well as for the purchase of devices included in the equipment provided to people exempt for pathology by the National Health Service. in particular, for ophthalmology and dental care (not covered by the SSN) for health problems that are not serious (e.g., dermatological examinations, blood tests), for which there is no urgency and which people choose to postpone for economic reasons, as well as for the purchase of additional devices that are included in the equipment provided free of charge by the SSN but the supply of which is inadequate to meet the needs of the patients (for example, reactive strips to measure blood sugar).

Lastly, the interviews conducted with the individuals in charge at Ufficio Pio[66], an operating body of Compagnia di San Paolo that supports vulnerable people and families facing socio-economic hardship in Turin and the surrounding area, reveal that it is very difficult for the elderly (over 65) to access non-reimbursable medicines.

7. Regional health expenditure

[65] See the relevant page on http://www.ospedalecottolengo.it/
[66] See the relevant page on http://www.ufficiopio.it/

In Italy, the SSN provides a quantitatively large basket of services at a cost per citizen that is among the lowest in Europe.

The data concerning the 2000-2017 period show, especially from 2009, a decrease in public health expenditure as a percentage of GDP and an increase in out-of-pocket expenditure (costs paid directly by families) compared to other major European countries. In 2000, France and Germany spent two percentage points of GDP more than Italy on their health service (7.5, 7.7 and 5.5% respectively); in 2017 the gap grew to Italy's disadvantage by three percentage points[67].

The per-capita expenditure indicator shows a similar trend: in the period 2000-2017, the gap between Italian public and private expenditure (expressed in dollars) increased compared to France and Germany, by 10 and 15 percentage points respectively[68].

The progressive defunding of the SSN, especially as regards the relationship between the level of resources allocated to healthcare and the level of inflation, has been highlighted recently by a number of specific reports on the subject[69]. The Health Fund exhibited growth until 2008, followed by a period of slower growth and then a decline between 2011 and 2013. For the three-year period 2014-2016, the resources earmarked for the health service as specified in the 2014-2016 Health Pact (State-Regions Agreement no. 82/CSR of 10 July 2014), set at 110 billion euros in 2014, 112 billion euros in 2015 and 115 billion euros in 2016, were redetermined by Legislative Decree no. 78/2015 and the 2016 Stability Law at 110 billion for 2015 and 111 billion for 2016. For 2017, the level of funding for the SSN was set at 113 billion euros, and 114 billion euros for 2018.

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[67] In 2017, public health expenditure in Italy amounted to 6.6% of GDP, about three percentage points lower than in Germany (9.6%) and France (9.5%), one percentage point lower than in the United Kingdom, and slightly higher than in Spain (6.3%), Portugal (6.0%) and the Czech Republic (5.8%). See Corte dei Conti, *Referto al Parlamento sulla gestione finanziaria dei servizi sanitari regionali (esercizio del 2017)*, Resolution no. 13/sezaut/2019/frg, p. 3.

[68] In 2017, per-capita Italian public expenditure (expressed in dollars at purchasing power parity) was USD 2,622, 35% lower than in France (USD 4,068) and 45% lower than in Germany (USD 4,869). See Corte dei Conti, *Referto al Parlamento sulla gestione finanziaria dei servizi sanitari regionali (esercizio del 2017)*, Resolution no. 13/sezaut/2019/frg, p. 3.

[69] In the period 2010-2019, some 37 billion euro were "deallocated" from the SSN. The overall increase in the national need for health (*fabbisogno sanitario nazionale*) was 8.8 billion euros, an average of 0.9% per year, which is lower than the average annual inflation (+1.07%). See Fondazione Gimbe, *4 Rapporto sulla sostenibilità del Servizio sanitario nazionale*, Bologna, June 2019, available in Italian at www.rapportogimbe.it, pp. 75 ff.

These amounts were subsequently adjusted downwards and, net of the Fund for Reimbursement to the Regions for the purchase of innovative medicines and the Fund for Reimbursement to the Regions for the purchase of innovative cancer medicines, the level of funding to which the State ordinarily contributes amounts to 111.7 billion euros for 2017 (+0.7 billion compared to 2016, +0.7%) and 112.7 billion for 2018 (+0.9 billion compared to 2017, +0.8%)[70].

Regional health expenditure increased from 79 billion euros to 116 billion euros in the period 2002-2018, with an average annual growth rate of 2.4%[71].

The analysis of the development of health expenditure (table 7) seems to point to a pattern of different phases. From 2002 to 2006, health expenditure increased in absolute value by 20 billion, with an average annual increase of 5.8%. Over the following five years, growth amounted to 11.5 billion euro in absolute terms, with an average annual rate of 2.2%. From 2011 to 2018, expenditure growth slowed down further (+5.5 billion euros), with an average annual growth rate of 0.7%, thus confirming the effectiveness of the measures to rationalise expenditure, including the adoption of the recovery plans.

[70] See Corte dei Conti, *Referto al Parlamento sulla gestione finanziaria dei servizi sanitari regionali (esercizio del 2017)*, Resolution no. 13/sezaut/2019/frg, pp. 7 ff.

[71] See data contained in the report by the Ministry of Economy and Finance *Monitoraggio della spesa sanitaria*, July 2019, pp. 20 ff.

Table 6. *Financing trends and per capita expenditure*

	2010	2011	2012	2013	2014	2015	2016	2017	2018
Ordinary SSN funding**	105,398	106,905	107,961	107,005	109,928	109,715	111,002	112,577*	113.400*
SSN expenditure**	113,131	112,255	110,461	109,614	110,938	111,224	112,504	113,611	115.410
Population***	59,364,690	59,394,207	59,685,227	60,782,668	60,795,612	60,665,551	60,589,445	60,483,973	60.391.000
Funding per capita***	1,775	1,798	1,808	1,760	1,808	1,808	1,832	1,861	1.878
Per capita expenditure****	1,906	1,890	1,851	1,803	1,825	1,834	1,855	1,878	1.911

* Including quotas for the Fund for the purchase of Innovative Medicines and the Fund for the purchase of innovative oncological medicines. Amounts in million euros.

** Including 223 million for the Fund for the purchase of innovative medicines and 500 million for the Fund for the purchase of innovative oncological medicines; net of these Funds, the financing distributed among the Regions amounted to 112 billion.

*** Population: source ISTAT.

**** Amounts in euro.

Source: Data processed by Court of Auditors, *Report to Parliament on the financial management of regional health services.*

Table 7. *Current health expenditure by region. Years 2008-2018 (values in millions of euros)*

Regions	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
Piedmont	8.074,5	8.345,9	8.467,1	8.418,4	8.393,7	8.192,1	8.188,6	8.097,2	8.241,7	8.304,3	8.441,7
Valle d'Aosta	260,3	263,8	277,8	278,5	278,8	271,2	260,5	261,8	256,5	254,5	259,0
Lombardy	16.723,2	17.200,8	17.816,6	18.123,6	18.154,1	18.293,4	18.789,9	18.847,7	18.936,4	19.437,6	19.866,2
Autonomous province of Bolzano	1.108,0	1.064,6	1.099,0	1.108,8	1.152,0	1.160,9	1.145,4	1.174,8	1.199,1	1.249,7	1.278,4
Autonomous province of Trento	994,9	1.062,5	1.096,1	1.131,6	1.157,8	1.150,7	1.152,7	1.128,4	1.148,4	1.194,2	1.220,3
Veneto	8.387,1	8.641,2	8.784,0	8.748,1	8.713,3	8.699,2	8.777,2	8.834,5	8.980,1	9.244,9	9.400,3
Friuli-V.G.	2.311,4	2.410,3	2.442,8	2.494,2	2.511,6	2.468,9	2.374,0	2.333,7	2.368,0	2.434,2	2.504,4
Liguria	3.175,8	3.270,8	3.240,4	3.232,3	3.147,4	3.122,4	3.159,0	3.175,6	3.184,7	3.209,8	3.232,5
Emilia-Rom.	7.946,7	8.269,1	8.440,9	8.494,3	8.801,3	8.617,6	8.654,5	8.748,1	8.854,3	9.035,0	9.176,0
Tuscany	6.658,9	7.115,5	7.082,0	7.131,2	7.120,1	6.948,1	7.113,8	7.197,8	7.277,8	7.446,9	7.512,5
Umbria	1.560,8	1.612,3	1.623,5	1.634,0	1.643,8	1.645,6	1.637,9	1.651,7	1.672,6	1.716,3	1.750,8
Marche	2.617,1	2.735,6	2.799,1	2.794,7	2.749,3	2.713,3	2.736,0	2.739,2	2.791,9	2.825,5	2.853,6
Lazio	10.943,4	11.175,3	11.054,7	10.892,6	10.853,6	10.628,2	10.662,3	10.712,7	10.701,6	10.698,3	10.744,0
Abruzzo	2.351,6	2.339,6	2.331,2	2.303,1	2.348,6	2.316,0	2.374,2	2.347,4	2.411,1	2.463,6	2.474,3
Molise	649,3	662,7	660,6	648,1	663,5	696,4	662,8	642,5	660,7	650,3	632,3
Campania	10.005,0	10.142,3	9.995,6	9.819,0	9.710,6	9.579,9	9.796,8	9.872,1	10.011,2	10.158,7	10.249,7
Apulia	7.074,6	7.135,2	7.227,2	7.051,2	6.906,3	6.931,0	7.047,7	7.092,6	7.231,0	7.262,7	7.380,3
Basilicata	1.014,2	1.033,5	1.056,4	1.059,6	1.030,3	1.022,1	1.029,0	1.033,6	1.035,4	1.069,2	1.050,5
Calabria	3.365,4	3.491,3	3.447,1	3.371,3	3.360,4	3.312,3	3.369,2	3.358,9	3.427,2	3.416,4	3.450,5
Sicily	8.273,6	8.389,4	8.506,2	8.499,9	8.514,8	8.530,4	8.644,9	8.658,1	8.842,5	9.052,0	9.241,9
Sardinia	2.903,4	3.048,5	3.125,7	3.179,6	3.225,3	3.183,7	3.238,0	3.238,6	3.293,2	3.215,4	3.280,7
Italy	106.399,2	109.409,9	110.573,9	110.414,2	110.436,6	109.483,3	110.814,5	111.147,2	112.525,5	114.339,5	115.999,8

Source: Ministry of Economy and Finance, Monitoraggio della spesa sanitaria, July 2019. Figures are net of depreciation and the balance of revaluations and write-downs to compensate for the various classification criteria used by the Regions prior to the definition of homogeneous accounting principles, pursuant to Legislative Decree no.118/2011.

7.1. Staff expenditure

The item that most influences health expenditure is represented by the purchase of goods and services (services and technical equipment), followed by the item "Personnel costs", which represents the fundamental resource for the functioning of the health system: at the national level, in 2017 total costs of personnel amounted to 33.85 billion euro, down by 2.22% compared to 2013.

Between 2010 and 2017 (the latest year with available data), there was a reduction in SSN personnel of 42,861 units (-6.7%). In 2017, the SSN employed 603,375, of which 101,100 doctors (-5.9% compared to 2010) and 253,430 nurses (-3.9%)[72].

In Piedmont, the workforce decreased by 4.4% over the whole period, while the national average decreased by 6%. The standardised data per 1,000 inhabitants indicate some variability among the regions, which can be attributed to possible differences in service outsourcing. On the basis of this index, Tuscany had 13.7 employees per 1,000 inhabitants and Piedmont 12.6 employees per 1,000 inhabitants, both exceeding the national average of 10.7 (table 8).

From 2010 to 2017, there was an overall decrease of 6.7% in the number of SSN employees nationally for every 10,000 residents, with a 6% decrease in physicians and 4% decrease in nurses.

In Tuscany there was an overall 3.7% decrease, a 0.2% increase in medical staff and a 1.9% decrease in nursing staff.

In Piedmont, there was an overall 5.2% decrease, a 3.4% decrease in medical staff and a 1.2% decrease in nursing staff (table 9).

As regards doctors, the share of over-60s rose from 4% to 21% in 10 years, which translates into 1,796 doctors who will reach retirement age within a few years. Among nurses, the share of staff aged over 45 increased from 31% in 2007 to 62% in 2017.

With regard to turnover, the situation between the two regions is different. In the years under consideration, Tuscany largely replaced its retiring staff, while Piedmont achieved a replacement rate of 87% in the period 2007-2017, meaning that for every 100 employees who left, only 87 were replaced. This figure is below the national average of 90, and among

[72] See ISTAT's written submission to the 5th Economic Planning and Budget Committee of the Senate of the Republic - Rome, 26 March 2020, p. 14, in the context of the examination of the bill implementing Legislative Decree no. 18 of 2020. The turnover freeze, introduced by Legislative Decree no. 78 of 2010 and initially envisaged only for the 2010-2012 period, was extended until 31 December 2014 and further extended to 2015 by Law no. 190 of 2014 (Stability Act 2015).

the regions it represents one of the lowest rates in relation to turnover (Table 10).

Table no. 8: Staffing trends in the SSR between 2008 and 2017. Values in thousands

Region	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	no. employed per 1,000 inhabitants
Lombardy	103.302	103.455	103.417	104.338	103.650	103.368	102.595	100.970	100.067	100.176	10,0
Veneto	60.114	60.811	60.573	60.597	60.291	60.461	60.135	59.782	59.701	59.302	12,1
Emilia-Romagna	59.389	60.512	61.044	60.809	60.457	59.989	59.069	58.139	57.796	58.250	13,1
Piedmont	57.710	59.108	58.997	58.073	57.221	56.751	56.081	55.359	55.229	55.155	12,6
Tuscany	51.256	52.248	52.460	52.473	52.166	52.049	52.029	51.505	50.932	51.338	13,7
Lazio	53.728	52.563	51.014	49.578	48.094	47.385	46.378	45.008	44.266	43.639	7,4
Campania	54.181	52.318	50.928	49.139	47.093	46.037	45.060	43.947	43.354	42.815	7,3
Sicily	47.585	47.100	45.817	45.735	45.657	45.330	44.713	43.648	42.924	42.550	8,4
Italy	689.856	693.716	688.847	682.541	673.416	670.241	663.796	653.471	648.663	647.048	10,7

Source: Data processed by IRES Piemonte based on MEF Annual Report.

Table no. 9: Staff employed in the SSN by Region - Years 2010, 2017 (per 10,000 residents)

	Staff employed by the SSN			Dentists employed by the SSN			Nurses employed by the SSN		
Regions	2010	2017	Variation %	2010	2017	Variation %	2010	2017	Variation %
Piedmont	129.4	122.7	-5.2	19.9	19.3	-3.4	49.7	49.1	-1.2
Valle d'Aosta	154.3	169.1	9.6	23.4	24.6	5.3	51.8	57.3	10.6
Lombardy	91.7	87.0	-5.1	13.0	12.9	-0.6	35.9	34.6	-3.6
Trentino-Alto Adige/Südtirol	152.7	156.6	2.6	17.6	18.9	7.3	56.4	58.3	3.5
Bolzano	*166.4*	*165.6*	*-0.5*	*17.5*	*18.0*	*3.0*	*59.2*	*60.9*	*2.9*
Trento	*139.5*	*147.9*	*6.1*	*17.8*	*19.8*	*11.3*	*53.6*	*55.8*	*4.1*
Veneto	*119.4*	*117.0*	-1.9	*16.0*	*16.3*	2.2	*50.5*	*49.5*	-1.8
Friuli-Venezia Giulia	148.4	143.4	-3.3	19.5	19.6	0.6	60.7	58.7	-3.4
Liguria	132.8	96.7	-27.2	20.9	15.1	-27.8	56.4	40.2	-28.7
Emilia-Romagna	131.9	126.0	-4.5	19.1	18.2	-4.7	56.2	55.2	-1.9
Tuscany	135.7	130.7	-3.7	21.7	21.8	0.2	58.0	56.8	-1.9
Umbria	119.0	121.9	2.4	21.2	22.3	5.5	52.4	52.8	0.8
Marche	119.7	118.1	-1.3	18.7	18.5	-0.8	51.3	51.2	-0.1
Lazio	80.6	66.7	-17.2	15.6	12.2	-21.8	35.0	31.3	-10.5
Abruzzo	107.5	106.5	-0.9	19.6	20.4	4.3	46.6	44.8	-3.9
Molise	115.4	90.2	-21.9	20.9	13.8	-33.7	48.7	40.9	-15.9
Campania	87.1	70.6	-18.9	18.5	15.2	-17.9	35.9	31.1	-13.4
Apulia	93.2	85.4	-8.3	16.9	15.9	-5.9	38.3	36.1	-5.6
Basilicata	115.4	115.2	-0.2	19.7	19.2	-2.4	49.7	49.6	-0.1
Calabria	110.9	94.8	-14.5	22.4	19.1	-14.6	41.6	37.4	-10.1
Sicily	84.3	82.4	-2.2	18.6	17.6	-5.1	31.9	34.5	8.4
Sardinia	112.4	127.0	13.0	22.0	25.5	16.3	44.3	50.3	13.4
Italy	**106.9**	**99.7**	**-6.7**	**17.8**	**16.7**	**-6.0**	**43.6**	**41.9**	**-4.0**

Source: ISTAT calculations based on Ministry of Health data.

These data show a reduction in the number of staff in the health sector, particularly from 2010, the year in which the freeze on turnover became effective in Piedmont in the framework of the health deficit recovery plan.

It should be pointed out that the current situation presents considerable critical aspects due to the coexistence of a series of factors, including the progressive ageing of the staff, the reduced generational turnover resulting from a reduction in recruitment in the health sector, and the high rate of retirement expected in the years to come[73].

[73] See M. Bocci, *L'allarme dei medici: con la quota 100 si rischiano migliaia di uscite dagli ospedali*, in Economia & Finanza, 29 April 2019.

Table 10. *Turnover rate, average for the last 10 years (2007-2017)*

Region	Overall *turnover* rate	Turnover *rate* doctors	Turnover *rate* nurses
Tuscany	105	119	107
Veneto	103	109	98
Emilia-Romagna	101	100	104
Lombardy	95	98	101
Italy	90	93	94
Piedmont*	87	91	97
Sicily*	68	79	80
Campania*	57	75	58
Lazio*	55	61	59

Note: Only regions with more than 40,000 employees are included in the table. Regions affected by the Deficit Recovery Plan are indicated with an asterisk. In general, the regions with a recovery plan were: Abruzzo, Calabria, Campania, Lazio, Liguria, Molise, Piedmont, Apulia, Sardinia, Sicily.

Source: Calculations by IRES Piemonte based on data from the MEF Annual Report and OPESSAN regional database.

8. Resource allocation at regional level

As noted, the amount of resources allocated to healthcare is decided annually by CIPE, which, upon the proposal of the Minister of Health and in consultation with the State-Regions Conference, determines the annual allocation of the current portion of the National Health Fund to the Regions and Autonomous Provinces[74].

The criteria for the distribution, together with the distribution proposal, are set out in the relevant State-Regions Agreement. In all the Agreements for the years falling within the period of interest (i.e., 2012, 2013, 2014, 2015 and 2016) the resources are broken down by level of care as follows:

- prevention 5%;
- district 51%;
- hospital 44%.

District care has the following sub-levels:

- general medicine 7%;
- pharmaceutical 13.57%;
- specialist 13.30%;
- local 17.13%.

The distribution criteria used are:

- weighted population (for specialist care and 50% of hospital care);
- expenditure ceiling (for pharmaceuticals);

[74] See art. 39, par. 1, of Legislative Decree no. 446 of 15 December 1997, repealing paragraphs 15, 17 and 19 of Article 11 of Legislative Decree no. 502 of 30 December 1992.

– unweighted population (for the remaining items).

Over the years considered, some values in the table concerning the allocation of weights for specialist care and 50% of hospital care changed.

Regional distribution differs from region to region.

In some regions, the RHP establishes the programming objectives and the DGRs set both the amount of funds to be allocated and the related operational objectives to be pursued (e.g., in Piedmont and Emilia-Romagna). Other regions (including Tuscany) draw up a more detailed RHP that contains programming and operational objectives, while DGRs are focused on defining the corresponding amounts. In some regions (Tuscany, Piedmont, Veneto and Lombardy), this planning is outlined in the social and health plan, while in others there is a distinction between a health plan and a more specifically social plan. In the first case, in addition to "vertical" planning between different levels of government, there is a "horizontal" planning covering different areas of competence and focusing on defining the role of the municipality and identifying coordination between different actors (region, municipality, health authority)[75].

On this specific aspect, from the point of view of financing different models of socio-healthcare integration can be identified: in some cases, the provision of some socio-healthcare services is delegated to the local authority in the name and on behalf of the municipality; in others, third parties are designated to carry out the socio-healthcare integration activity on behalf of the ASL and the municipalities.

The timing of allocation acts plays a key role in the efficiency of allocation processes. Effective planning requires that the definition of resources in relation to the objectives to be pursued is carried out in advance of the respective actions. In practice, there are few Regions that approve the distribution resolutions at the beginning of the reference year, and in the years of economic crisis this has sometimes prevented the SSN bodies from balancing their budgets. This emerged, for example, from an analysis of the planning documents of the two former ASLs in Turin (ASL TO1 and ASL TO2, now merged into the single ASL City of Turin), where it is specifically noted that despite the efforts made to contain costs, an operating loss is inevitable for the years 2013 and 2014. In the first case, the loss was recorded "in view of the further reduction in the 2013 funding, which was communicated to the ASL at the end of the year"[76].

[75] The authority's planning envisages a well-defined division between health activities (by the ASL) and social-health activities (by the municipalities) with a precise identification of the coordination mechanisms between the two.

[76] See A.S.L. TO1, Deliberation of the Director General no. 898/C03/2013 of 24 December 2013, p. 1.

Here it should be noted that the relevant resolution of the Director General (on the approval of the 2013 budget) is dated 24 December 2013. The approval timeframe makes it clear that the interactions and delays accumulated at other decision-making levels have a negative impact on the operations of the final recipients of the funds to be allocated. Consequently, in such circumstances these recipients can only operate without regard to the budget constraints that will be set later and opt instead to operate according to the health demand of users. This seems to be explicitly acknowledged in the decision of the Director General approving the budget of the former ASL TO1 for 2014, whose accompanying note concludes with the following observation:

"The ASL wishes to draw attention to the fact that it is not possible, given the funding currently envisaged, to implement further actions in 2014 to recover all the emerging costs, since guaranteeing production levels in line with the regional planning is also considered essential."[77]

This trend, which is interesting to analyse here, shows how the needs expressed by the ASL do, at certain specific junctures, "exceed the budgets envisaged at the regional level", indicating a tangible sign of conflict between a political/managerial logic and a clinical logic; clearly in the concrete experience of healthcare structures, the need to guarantee access to services can collide with the realities of economic planning.

The Region of Tuscany is one of the few that manage to approve the allocation resolutions at the beginning of the relevant year, based essentially on a forecast of what will be decided in the CIPE resolutions. Once the resolution has been approved by CIPE (and therefore once the allocated resources have been clearly identified) the Region proceeds with the additional and final allocation of resources. Piedmont adopted a similar approach in 2015.

8.1. The process of allocating health resources in Tuscany

Pursuant to art. 25, paragraph 1, of Regional Law no. 40 of 2005 and subsequent amendments, the Regional Health Fund is divided into three parts: the ordinary management fund; funds aimed at the development of services; and funds directed towards the organisation of the system[78].

[77] See A.S.L. TO1, Deliberation of the Director General no. 164/C03/2014 of 25 February 2014, Annex 2 (Accompanying Note to the 2014 Provisional Technical Budget), p. 4.

[78] The purpose of the ordinary operating fund is to ensure the resources for the management of the budget of activities. These include both those provided directly and those managed by public and private providers operating on the basis of the regulations in force. The fund is distributed among the health authorities on the basis of the criterion of resident population weighted according to other equity criteria (age of the population and

The health authorities financing model provides for a series of parallel funds (ordinary management fund, geographical specificities fund, fund for maintaining economic and financial balance, fund for supporting healthcare activities, fund for non-remunerative activities, innovation fund) that finance the ASLs, the ESTAV/ESTAR, other SSN bodies and the AOU.

The various funds have different structures and purposes[79]. The ordinary management fund is intended to guarantee the resources for the ordinary management of the activities managed by the ASL or through public and private health providers. This fund is distributed among the local health authorities on the basis of the criterion of equity with respect to the resident population, appropriately weighted according to the needs identified.

The fund for maintaining economic and financial balance is intended to support the ASL's efficiency recovery processes[80]. It is divided among the health care authorities on the basis of the agreed identification of specific objectives and results.

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identified need). Funds for the development of services are intended to financially support regional programmes and operational actions for covering the costs of actions aimed at increasing the qualification of services or for interventions supporting activities targeting weaker population groups. The funds aimed at organising the system are intended to cover the costs of activities carried out by regional health bodies and institutions, as well as regional initiatives for innovation and development of the system, including activities carried out in the context of international cooperation in favour of particularly disadvantaged population groups.

[79] In order to understand the type of funds involved, a specific research project was carried out in 2011 and 2012. For 2011, reference should be made to DGR no. 96 of 2011 "Allocation of the ordinary management fund and fund for maintaining economic and financial balance"; DGR no. 110 of 2011 "Fund for the dissemination of innovation"; DGR no. 111 of 2011 "Fund for the support of welfare activities"; DGR no. 116 of 2011 "Special funds for specific purposes"; DGR no. 1223 of 2011 "Fund for the governance of geographical specificities"; DGR no. 615 of 2012 "Commitment to repay ASL debts"; and DGR no. 791 of 2012 "Repayment of ASL losses". For 2012: DGR no. 47 "Allocation of the ordinary management fund (ESTAV)"; DGR no. 69 of 2012 "Allocation of the ordinary management fund and the fund for maintaining economic and financial balance"; DGR no. 89 of 2012 "Fund for the support of welfare activities"; DGR no. 90 of 2012 "Fund for the dissemination of innovation"; DGR no. 91 of 2012 "Special funds for specific purposes"; DGR no. 839 of 2012 "Allocation of resources to other entities"; DGR no. 1106 of 2012 "Fund for the governance of geographical specificities"; and DGR no. 400 of 2013 "2012 Integration".

[80] On the basis of art. 25, par. 2 of Regional Law no. 40 of 2005, the Regional Council annually identifies a fund aimed at maintaining the economic and financial balance of the system. At the accounting level, it is defined, pursuant to art. 25, par. 2, of Regional Law no. 40 of 2005, as the difference between the available resources and the ordinary management fund. This fund is intended for the financial support of efficiency recovery processes and is distributed among the health authorities on the basis of the prior identification of specific objectives and expected results.

The geographical specificities fund is intended to cover projects agreed upon with the governing bodies of local institutions and health authorities. 82.5% of this fund is assigned to mountain areas and 17.5% to island areas. The fund is allocated on the basis of the criterion of the reference population, taking into account the morphometric intensity index and the number of inhabitants of the island municipalities.

The special funds, on the other hand, are intended to go towards organising the system by financing regional health bodies and institutions and initiatives of the Region in the field of innovation and development of the system, including the provision of care within the framework of international cooperation projects. These funds include the fund for the support of AOU activities, the fund for the dissemination of innovation, quality and productivity in AOUs, and the fund for the support of regional functions in relation to insufficiently remunerative AOU activities.

For Tuscany, ESTAVs are also included in the resource allocation. Since 1 October 2014, Regional Law no. 26/2014 has provided for the establishment of ESTAR which, through departments at regional level, provides technical, administrative and other support to the Health Authorities, the entities of the Regional Health Service and the Local Health Authorities. From that date onwards, the three ESTAV support bodies merged into a single regional support body, ESTAR.

The ordinary management fund is divided between the Health Authorities and the AOUs, of which there are four in Tuscany. The fund to support highly specialised activities and the fund for teaching, research and innovation are both divided between the AOUs and the Monasterio Foundation[81].

The total of the ordinary fund is determined annually by the Regional Cabinet on the basis of the available resources and divided by levels of care (90% of the fund). For each level, the allocation to the ASLs is determined on the basis of the resident population divided by age group, with different weights for each group in relation to the different and specific consumption recorded.

"Resident population" refers to the population officially recognised in the regional flows of the registry surveys of the Tuscan municipalities, as well as non-resident non-EU foreigners with or without a regular residence

[81] The Foundation constitutes a specialised public body of the Regional Health Service, in accordance with Law no. 85 of 2009. Its activities are carried out at the Pisa Hospital, at the CNR Research Area, and at the Massa Hospital (Ospedale del Cuore G. Pasquinucci, formerly Ospedale Pediatrico Apuano) in Montepepe. The Foundation is a highly specialised centre for the treatment of cardiopulmonary diseases, including rare diseases of specific interest, such as congenital heart disease, hereditary dyslipidaemia, haemochromatosis, pulmonary hypertension and amyloidosis.

permit, insofar as they are entitled to healthcare; the gypsy populations present in the regional territory are also taken into account.

The remaining 10% of the ordinary fund is allocated to ASLs on the basis of the resident population weighted in relation to the socio-environmental conditions of the territorial area of reference of the health authority.

Table no. 11 Trends in regional and national breakdowns for Tuscany. Values in euro

	DGR FOR INITIAL ALLOCATION (ASL AND AOU)			**State-Regions Agreement/CIPE resolution proposal**	**CIPE Resolution (indistinct fund)**	**DGR for final allocation**
		Ordinary management fund	**Rebalancing fund**			
2011	DGR n. 96 of 21.2.2011	5,270 b	550,177 m	6,615 b	6,739 b	DGR n. 382 del 7.5.2012
2012	DGR no. 69 of 6.2.2012	5,397 b	550,177 m	6,720 b	6,808 b	DGR n. 400 of 27.5.2013
2013	DGR n. 1266 of 28.12.2012	5,328 b	514,541 m	6,600 b	6,733 b	DGR n. 698 del 4.8.2014
2014	DGR n. 23 of 13.1.2014	5,480 b	514,541 m	6,657 b	6,815 b	DGR no. 1342 of 29.12.2015
2015	DGR no. 575 del 27.4.2015	6,028 b	106,551 m	6,761 b	6,903 b	DGR no.883 of 6.6.2016
2016	DGR no. 633 of 27.6.2016	5,836 b	213,515 m	6,832 b	6,968 b	DGR no. 1033 del 25.9.2017

Source: Calculations based on data from Regional Council resolutions, agreements between State and Regions, CIPE resolutions.

As regards the ordinary operating fund and the fund for maintaining economic and financial balance, we analyse the trends of the allocations at the national and regional levels. The purpose of Table 11 is to clarify the phases that occur in the annual allocations and their development.

Detailed analysis of the Regional Council resolutions

The first resolution of the Regional Council for the period under consideration is DGR no. 96 of 2011, dated 21 February 2011, which concerns the allocation of the ordinary management fund and the fund for maintaining economic and financial balance for 2011. Annex 1 of DGR no. 96 sets out the quotas allocated between the ASLs and AOUs, while Annex 2 sets out the criteria by which these allocations are made. For the purposes of distributing the fund, the Regional Council took into consideration the note of the Presidency of the Council of Ministers of 28 December 2010, which communicated the proposal of the Minister of Health for a resolution of CIPE concerning the distribution among the regions of the financial resources of the SSN for 2011, to be submitted for approval to the State-Regions Conference, whose approval on the ministerial proposal was obtained on 24 April 2011.

The Region of Tuscany took note of the proposed quota and determined the ordinary management fund as 5.27 billion euros. In addition, it prudentially evaluated the allocation to the ASLs of the resources corresponding to the amount that they were authorised to enter in the budgets for the 2010 financial year and specified that this initial allocation would be followed by a further act of distribution on the basis of the resources allocated at the national level. The final allocation of resources for the year 2011 was made through DGR no. 382 of 7 May 2012. For the purposes of the allocation of resources, this DGR referred to the resolution of CIPE adopted on 20 January 2012 following the agreement reached at the State-Regions Conference no. 226 of 21 December 2011, which provided for a quota allocated to the Region of Tuscany equal to 6.73 billion euros. Given that other CIPE resolutions allocate resources for the purposes of the health service, the DGR for the additional allocation of resources proceeded to distribute the resources among the ASLs, AOUs and ESTAVs, considering that part of the resources of the Health Fund had already been allocated in 2011.

In 2012, the resources were likewise allocated in the first few months of the year. Since the State-Regions Agreement on the Minister of Health's proposal for CIPE resolution is dated 22 November 2012, DGR no. 69 of 6 February 2012 refers this time to Regional Law no. 67 of 2011 approving the budget for the year 2012 and the multi-year budget for 2012/2014 and to DGR no. 2 of 2012 with which the Council approved the 2012 and multi-year budget for 2012/2014. DGR no. 400 of 27 May 2013 resolved the final allocation of resources for 2012. Considering that CIPE Resolutions nos. 141, 142 and 144 of 21 December 2012 allocate resources

for the coverage of healthcare activities, DGR no. 400 allocated the resources that were added to those already allocated among the healthcare service entities, setting aside a portion for the risk arising from the direct management of expected claim managements and keeping a portion available for the 2013 financial year.

For 2013, the reference DGR was no. 1266 of 28 December 2012. In this case, the allocation concerned both the ordinary operating fund, the fund for maintaining economic and financial balance, and the special funds provided for in the 2008-2010 Regional Health Plan. The decision of the Regional Council to allocate the resources was very timely this year, considering that the State-Regions Agreement on the proposal of the Minister of Health for the CIPE resolution on the distribution of the available SSN funds among the Regions was issued on 19 December 2013. Additional resources to allow the healthcare entities to close the 2013 financial statements in economic balance were allocated in DGR no. 698 of 4 August 2014.

For the year 2014, Decree no. 23 of 13 January 2014 distributed the ordinary management fund, the fund for maintaining economic and financial balance and the special funds.

The process was once again about allocating resources in the absence of the CIPE resolution, which was approved on 29 April 2015 following the State-Regions Agreement on the ministerial proposal reached on 4 December 2014, according to the criteria of prudence, based on the allocations of the previous year, with respect to which no reductions were expected. In relation to the special funds, resources were earmarked for ISPO (Institute for oncological study, prevention and network) and the Monasterio Foundation, and AOUs for "innovation" actions, "teaching and research", and "reference centres". The final allocation of the resources for the purpose of closing the budgets of the healthcare entities was made with Regional Decree no. 1342 of 29 December 2015, i.e., after CIPE Resolutions nos. 52, 53 and 54 of 29 April 2014. In the meantime, the newly approved Integrated Social and Health Plan had changed the criteria for allocating resources among the ASLs on a per-capita basis. The Regional Plan 2012-2015 approved by resolution of the Regional Council no. 91 of 14 November 2014 provided the criteria for quantifying the ordinary management fund and the rebalancing fund (paragraph 9.1.1), the criteria for distributing the ordinary management fund among the ASLs (paragraph 9.1.3(a)), and the criteria for distributing the funds to the AO, Monasterio and ISPO (paragraph 9.1.3(c)).

In 2015, DGR no. 575 of 27 April 2015 revoked the previous allocation by DGR no. 1269 of 2014. The revocation was necessary because in order to

compensate for the impact of the decrease in the resources available to the Regions, as provided for by Law no. 109/2014 (2015 Stability Law), the State-Regions Conference had, with the Agreement of 26 February 2015, reduced the National Health Fund for 2015 to 109.71 billion euros, compared to the sum provided for by the Stability Law of 112.06 billion euros, reducing it by 2.35 billion euros. For 2015, the CIPE resolution was approved on 3 March 2017 (CIPE Resolution no. 27/2017) after the State-Regions Conference reached an agreement on 23 December on the ministerial proposal for allocating the resources among the Regions.

Therefore, the amount due to the Region of Tuscany, initially calculated at 6.76 billion, had to be recalculated. Regional Decree no. 883 of 6 June 2016 provided for the final allocation of financial resources to the ASLs and other entities for the purpose of closing the 2015 financial statements. By then, Agreements no. 237/2015 and no. 236/2015 of 23 December 2015 and Agreement no. 15/2016 of 11 February 2016 concerning Prison Medicine had been reached.

In 2016, the agreement in the State-Regions Conference on the ministerial proposal concerning the allocation of resources was reached on 14 April 2016, while the corresponding CIPE resolution was issued on 3 March 2017. DGR no. 633 of 27 June 2016 provided for the initial allocation of the Regional Health Fund for the year 2016 to the ASLs and other entities of the Regional Health Service. In this year, an intermediate allocation of the resources was made (which, starting in 2016, became a regular practice to be followed by the Region in the following years as well) with Regional Council Decrees no. 1426 of 27 December 2016 and no. 635 of 12 June 2017, while the final allocation of the resources took place with Regional Council Decree no. 1033 of 25 September 2017.

8.2. The process of allocating health resources in Piedmont

The planning activity takes the form of the Regional Health and Social Plan, which identifies the general objectives of health and well-being for local planning, development strategies and the lines of government of the regional health and social services and also represents the instrument for defining the macro guidelines of health programming.

The allocation of resources in Piedmont over the period under consideration was heavily constrained by the objective of achieving a balanced budget.

Table no. 12 Trends in regional and national breakdowns for Piedmont. Values in euro

	Allocation DGR				State-Regions Agreement/CIPE resolution proposal	CIPE Resolution (indistinct fund)
		SSR Funding	Indistinct fund			
2011	DGR no. 3-2482 of 29.7.2011	8,116 b	8,026 b		7,862 b	7,877 b
2012	DGR no. 2-4474 of 6.8.2012	8,028 b	7,750 m		7,962 b	7,918 b
2013	DGR no. 59-6674 of 11.11.2013	7,856 b	7,676 b		7,824 b	7,808 b
2014	DGR no. 38-812 of 22.12.2014	7,979 b	7,690 b		7,857 b	7,824 b
	Provisional allocation DGR (indistinct fund)		**Final allocation DGR (indistinct fund)**			
2015	DGR no. 34-2054 of 1.9.2015	7,671 b	DGR no. 35-3152 of 11.4.2016	7,788 b	7,969 b	7,824 b
2016	DGR no. 35-3152 of 11.4.2016	7,773 b	DGR no. 42-4921 of 20.4.2017	7,872 b	8,014 b	8,043 b

Source: Calculations based on data from Regional Council resolutions, agreements between State and Regions, CIPE resolutions.

In particular, the regional government set a number of specific objectives for health care authorities in the period in question, such as achieving a balanced budget and maintaining service delivery levels.

The deliberations of the Regional Council on this subject outline the problem of maintaining a balance in the management of health resources, maintaining a level of quality in health care and gradually overcoming the allocation criterion based on historical expenditure through the transition from the determination of the regional need as the sum of the needs of individual ASLs to the determination of the overall regional need on the basis of levels of care.

The 2012-2015 Social and Health Plan reiterates that the main critical point to be overcome is the use of the criterion of historical expenditure within the processes of allocation of health resources. In order to overcome this critical point, the regional demographic and epidemiological specificities of the population had to be taken into account, but the needs had to be determined, above all, by referring to indicators of

appropriateness, quality, efficiency and effectiveness of the services provided[82].

As of 2015, the process of allocating healthcare resources changed. While in previous years the Regional Decree was issued at the end of the financial year, adopting the criterion of historical expenditure to allocate future resources, in 2015 the Piedmont Region decided to make an initial provisional allocation of resources while waiting for the national allocation acts, and then a final allocation of resources through a remodulation carried out on the basis of the allocation of the National Health Fund.

Detailed analysis of the Regional Council resolutions

The first decision of the Regional Council is DGR no. 3-2482 of 29 July 2011 "Economic and financial objectives of Regional Health Authorities for 2011". The resolution refers to DGR no. 44-1615 of 28 February 2011, which adopted the Addendum to the Deficit Recovery Plan and the implementation programme of Law no. 191 of 2009. The regional addendum provides for a series of actions in relation to the reorganisation of healthcare networks, personnel, hospital and non-hospital pharmaceuticals, the purchase of goods and services, and the purchase of services from the private sector. The DGR set the financing of the SSR for the year 2011 at 8,116,826,089 euros, of which 8,026,865,795 euros are indistinct funds to be distributed among the ASLs.

The resources for the year 2012 were allocated by DGR no. 2-4474 of 6 August 2012 "Determination of economic-financial objectives of Regional Health Authorities for the year 2012". The amount allocated was 8,028,486,941.00 euros, of which 7.750 billion was state funding and 200 million was planned regional resources.

DGR no. 59-6674 of 11 November 2013 "Determination of the economic-financial objectives of the Regional Health Authorities for the year 2013" set the financing of the health authorities at 7,708,350,000.00 euros, of which 7,676,350,000 euros came from the National Health Fund and 32 million from pay back (pharmaceutical companies' deductions). The DGR reiterated that the current portion of the NHF, for the purposes of determining the per capita quota, is divided by weighing the following factors: resident population; frequency of health consumption by age and sex; population mortality rates; indicators relating to particular territorial

[82] See the 2012-2015 Health and Social Plan of the Piedmont Region, approved by Regional Council Resolution no. 167 of 3 April 2012, pp. 14 ff.

situations considered useful for defining health needs; territorial epidemiological indicators.

Decree no. 38-812 of 22 December 2014 "Acknowledgement of the current financial availability for the Regional Health Service for the financial year 2014 and determination of the resources to be assigned to the Regional Health Service entities for the purpose of the economic-financial objectives for the year 2014" defined the indistinct fund prior to mobility as 7,690,362,325 euros. To this fund must be added the resources related to the tied fund, the bonus quotas, and extra-RHF funding, resulting in a total of 7,978,643,744 euros.

In 2015, the process of allocating regional resources was modified so that the Region first makes a provisional allocation on the basis of estimates of healthcare needs and then a final allocation when the distribution of the National Health at the national level has been determined (see DGR no. 34-2054 of 1 September 2015 "Acknowledgement of the provisional current financial resources for the Regional Health Service relating to the 2015 financial year and determination of the resources to be assigned to the entities of the Regional Health Service for the purposes of the economic-financial objectives for the year 2015"). The distribution criteria are set out in Table A.

DGR no. 35-3152 of 11 April 2016 "Remodulation of the 2015 financial year resources and allocation of the provisional 2016 financial year resources assigned to the Regional Healthcare Service Entities for the purposes of economic-financial objectives. Fulfilments as per art. 20, paragraph 2(a), and application of art. 30 of Legislative Decree no. 118/2011" reallocated resources for the 2015 financial year and provisionally allocated them for the 2016 financial year. The DGR set the indistinct health fund prior to mobility as 7,788,161,609 euros as compared to 7,671,473,618 euros of provisionally allocated resources. The allocation of the final resources for 2016 took place with DGR no. 42-4921 of 20 April 2017 "Re-allocation of the final 2016 financial year resources to the entities of the SSR in remodulation of the provisional resources allocated with DGR no. 35-3152 of 11 April 2016. Fulfilments of art. 20, par. 2(a) and application of article 30 of Legislative Decree no. 118/2011". The DGR identified the indistinct fund, prior to mobility, as 7,871,703,904 euros as compared to a provisional allocation of 7,772,813,284 euros.

9. Concluding remarks

The analysis conducted was aimed at identifying the allocation methods and criteria in the two selected regions and at highlighting the effects that

cuts in public health funding have had on the level of provision in a period particularly affected by the economic crisis and the contraction of economic resources.

Over the years, the two regions have adopted similar ways of allocating resources, with their programming documents being prepared at the beginning rather than at the end of the year. With regard to the case that emerged from the analysis of the programming documents of the two former ASLs of Turin for the years 2013 and 2014, the clinical criterion that underlies the need to respond appropriately to the demand for care appears to have prevailed over the managerial criteria of planning and managing services.

The regional health systems have substantially withstood the impact of the de-funding to which Italian health care has been subjected, even if in some cases there has been a drop in public service performance. A decrease in hospital services has been observed in both regions, consequent to the implementation of the progressive dehospitalisation policies adopted in other European countries, and a decrease in outpatient specialist services in Piedmont.

On the other hand, emergency room access has been stable or increasing in the years considered. This could be the sign of a sort of compensatory role played by the emergency services with respect to outpatient, local and hospital services, access to which has been made more difficult over the years by co-payments and longer waiting lists.

In addition, there is some interesting data with regard to the drilling-down in relation to the volumes of activity of the selected outpatient specialist services, classified in the macro-categories of low, medium and high risk of low appropriateness.

These include, within the category of services with a low risk of lack of appropriateness, the decrease in the volume of activity of the neurological examination services at the regional and ASL levels in Turin, simple electro-myography and psychiatric interviews at the regional level, while the volume of the services concerning psychiatric check-ups can be said to be increasing in Tuscany and unchanged in Piedmont, with the exception of the period 2013-2014.

In the category of services with a medium risk of lack of appropriateness, an interesting trend was the regional decrease in the volume of upper abdominal computed tomography services.

It should be added that within this framework, it is not yet possible to estimate the consequences of the lack of investment in personnel and in the upgrading of healthcare facilities, as the effects in these areas are only felt more clearly in the long term.

In any case, the reported data identify some critical aspects of the health system that have been further highlighted by the outbreak of the COVID-19 pandemic in the last months of 2019.

In particular, the pressure on hospital structures has clearly highlighted the fact that there has been excessive de-hospitalisation in Italy, which has led, in the current situation, to a risk of collapse in the management and organisation of services.

In recent years, the reorganisation of the healthcare network and the more appropriate use of hospital facilities have not been accompanied by an adequate provision of local healthcare targeted to cover the most vulnerable part of the population, particularly the elderly and the disabled, as well as those who cannot register with the SSN and those who are in particular financial difficulty.

For these last categories, it should be kept in mind that a fundamental role is played by third sector entities and associations, and their activities during the period under consideration is analysed in section 6 of this chapter, in reference to both Florence and Turin.

The lack of investment and the uneven regional organisation of primary care, among other factors, contributed to the crisis particularly in the early phases of the recent health emergency. In the regions in which the local health care system was organised more efficiently, the health service seems to have responded with corresponding efficiency, while in the regions where the organisation is more structured around the centrality of the hospital, the impact of the health emergency was more significant.

Lastly, the need for further technological innovation in the way in which care is provided has emerged extensively both in the national and European debate. This has been highlighted recently with reference to the need to implement care provision and monitoring remotely, through a wider use of new technologies in the field of health protection, the processes of digitalisation of health care and telemedicine, all of which also present opportunities to rationalize costs and improve the efficiency of care pathways so long as they can be regulated in such a way as to ensure the protection of the fundamental rights at stake.

Appendix

by Alessandra Cerruti

A. *Specialist visits trend (total volumes and volumes delivered within 30 days) 2011-2015; comparison between volumes in the Piedmont Region and the Città della Salute e della Scienza di Torino (CDSS)*

Type of visit		Total volume trend	Δ visits 2011-15	% 2015 over 2011	Δ > 30 days	% 2015 over 2011	Δ < 30 days	% 2015 over 2011	Trend of visits within 30 days
Allergology	Piedmont	↓	–15,801	74.1	–10,248	69.6	–5,553	79.6	↓
	CDSS	↑↑	28	100.4	–503	89.7	531	117.6	↑↑
Cardiology	Piedmont	↓	–46,897	81.0	–8,101	90.6	–38,796	75.9	↓
	CDSS	↓	–4,517	56.7	–1,773	59.5	–2,744	54.7	↓
General surgery	Piedmont	↓	–22,568	82.8	–2,556	86.7	–20,012	82.1	↓
	CDSS	↓	–6,294	67.7	–883	75.0	–5,411	66.1	↓
Vascular surgery	Piedmont	↓	–2,215	90.8	–1,618	74.9	–597	96.6	↓
	CDSS	↓	–927	32.4	–74	37.3	–853	32.0	↓
Plastic surgery	Piedmont	↓	–1,265	92.0	627	117.6	–1,892	84.5	↓
	CDSS	↑↑	691	115.9	216	176.0	475	111.7	↑↑
Dermatology	Piedmont	↓	–40,631	82.4	11,333	116.0	–51,964	67.7	↓
	CDSS	↓	–4,282	87.2	–1,900	87.4	–2,382	87.1	↓
Comprehensive eye/ocular examination	Piedmont	↓	–102,121	73.6	–49,789	75.7	–52,332	71.2	↓
	CDSS	↓	–523	44.0	–287	7.7	–236	62.1	↓
Gastroenterology	Piedmont	↓	–1,842	95.7	1,543	111.3	–3,385	88.4	↓
	CDSS	↑↑	412	107.7	–240	91.3	652	125.2	↑↑

Gynaecology	Piedmont	↓	−26,948	86.3	−2,628	91.3	−24,320	85.4	↓
	CDSS	↓	−4,760	69.9	−2,836	6.7	−1,924	84.9	↓
Endocrine, metabolic and nutritional diseases	Piedmont	↓	−62,771	48.4	−9,447	73.1	−53,324	38.3	↓
	CDSS	↓	−7,194	55.7	−3,278	55.2	−3,916	56.1	↓
Neurology	Piedmont	↓	−14,976	85.9	−2,278	92.7	−12,698	83.1	↓
	CDSS	↑↑	55	100.9	287	112.6	−232	93.6	↓
Neurosurgery	Piedmont	↑↑	319	103.1	1,141	130.7	−822	87.6	↓
	CDSS	↑↑	1,150	157.2	132	109.2	1,018	274.6	↑↑↑
Dentistry and stomatology	Piedmont	↓	−20,310	83.7	−6,381	79.9	−13,929	85.0	↓
	CDSS	↓	−2,095	89.9	−38	35.3	−2,057	90.1	↓
Orthopaedics and traumatology	Piedmont	↓	−49,636	77.8	−7,179	89.2	−42,457	73.0	↓
	CDSS	↓	−707	95.0	−847	88.0	140	102.0	↑↑
Otorhinolaryngology	Piedmont	↓	−33,169	85.3	−2,955	93.7	−30,214	83.1	↓
	CDSS	↓	−5,667	59.8	718	121.6	−6,385	40.7	↓
Pneumology	Piedmont	↓	−7,001	88.5	3,720	122.9	−10,721	76.1	↓
	CDSS	↑↑	170	106.1	−270	77.3	440	127.5	↑↑
Recovery and functional rehabilitation	Piedmont	↓	−43,340	84.8	−6,470	87.8	−36,870	84.1	↓
	CDSS	↓	−1,372	79.8	−272	68.9	−1,100	81.4	↓
Urology	Piedmont	↓	−1,433	98.6	1,871	105.9	−3,304	95.4	↓
	CDSS	↓	−209	97.8	−98	97.7	−111	97.9	↓

B. *Trend in diagnostic examinations (total volumes and volumes delivered within 60 days) 2011-2015; comparison between volumes in the Piedmont Region and in the Città della Salute e della Scienza di Torino (CDSS)*

Type of service		Trend total volumes	Δ visits 2011-15	% 2015 over 2011	Δ > 60 days	% 2015 over 2011	Δ < 60 days	% 2015 over 2011	Trend visits within 60 days
Colonoscopy with flexible endoscope	Piedmont	↑↑	4,424	110.9	3,816	144.2	608	101.9	↑↑
	CDSS	↑↑	338	107.2	157	109.4	181	106.0	↑↑
Colposcopy	Piedmont	↓	–3,422	77.4	–2,138	46.7	–1,284	88.4	↓
	CDSS	↓	–1,196	79.9	–2,584	0.8	1,388	141.6	↓↓
Head and neck ultrasound diagnostics	Piedmont	↓	–13,240	88.6	1,684	108.3	–14,924	84.5	↓
	CDSS	↓	–2,873	70.0	–1,087	73.9	–1,786	67.0	↓
Echocardiography	Piedmont	↓	–7,083	96.5	1,310	103.7	–8,393	95.0	↓
	CDSS	↓	–132	99.0	59	101.4	–191	98.0	↓
Supra-aortic trunk colour Doppler	Piedmont	↓	–10,378	93.2	–1,898	93.2	–8,480	93.2	↓
	CDSS	↑↑	268	105.4	586	136.1	–318	90.5	↓
Upper / lower limbs colour Doppler	Piedmont	↓	–25,908	83.7	–5,630	67.7	–20,278	85.6	↓
	CDSS	↓	–1,226	81.2	–289	47.6	–937	84.3	↓
Complete abdomen ultrasound	Piedmont	↓	–28,757	89.6	1,204	103.4	–29,961	87.5	↓
	CDSS	↓	–4,866	73.3	–3,223	47.6	–1,643	86.4	↓
Ultrasound of lower abdomen	Piedmont	↓	–9,284	59.9	34	101.6	–9,318	55.6	↓
	CDSS	↓	–817	36.6	–239	17.6	–578	42.1	↓
Ultrasound of upper abdomen	Piedmont	↓	–17,596	78.5	3,562	136.5	–21,158	70.6	↓
	CDSS	↓	–1,315	80.6	–86	96.1	–1,229	73.1	↓
Gynaecological ultrasound	Piedmont	↓	–1,902	66.1	86	165.0	–1,988	63.8	↓
	CDSS	↑↑	24	105.8	–18	14.2	42	110.7	↑↑

Unilateral breast ultrasound	Piedmont	↓	−2,104	53.7	−60	82.2	−2,044	51.4	↓
	CDSS	↓	−500	41.2	−33	5.7	−467	42.8	↓
Dynamic electrocardiography	Piedmont	↑↑	239	100.4	6,065	183.2	−5,826	93.4	↓
	CDSS	↓	−1,660	63.3	887	428.6	−2,547	47.0	↓
Standard and HP/SLI electroencephalography	Piedmont	↓	−2,816	90.2	97	105.0	−2,913	89.1	↓
	CDSS	↓	−446	81.6	−203	55.9	−243	87.6	↓
Simple electromyography	Piedmont	↓	−42,609	75.9	−8,819	56.6	−33,790	78.4	↓
	CDSS	↓	−1,112	90.2	−816	60.4	−296	96.8	↓
Esophagogastroduodenoscopy	Piedmont	↑↑	20,990	161.7	5,582	210.7	15,408	153.1	↑↑
	CDSS	↑↑	2,003	147.8	464	146.2	1,539	148.4	↑↑
Bilateral mammography	Piedmont	↓	−36,170	53.9	−4,689	69.2	−31,481	50.2	↓
	CDSS	↓	−3,754	35.4	−2,761	16.9	−993	60.1	↓
Continuous blood pressure monitoring	Piedmont	↓	−2,298	85.1	67	110.5	−2,365	84.0	↓
	CDSS	↓	−311	83.6	−6	92.0	−305	83.2	↓
Complete X-ray of the spine	Piedmont	↓	−1,546	83.2	22	112.0	−1,568	82.6	↓
	CDSS	↑↑	295	123.3	−14	69.6	309	125.3	↑↑
MRI lower abdomen (contrast)	Piedmont	↑↑↑	2,185	230.4	201	289.8	1,984	226.4	↑↑↑
	CDSS	↑↑	113	119.8	0	101.0	113	120.0	↑↑
MRI of the spine	Piedmont	↑↑	6,662	105.9	336	109.8	6,326	105.8	↑↑
	CDSS	↓	−304	92.9	198	180.1	−502	87.5	↓
Simple spirometry	Piedmont	↓	−11,983	80.1	878	106.3	−12,861	72.3	↓
	CDSS	↑↑	301	103.4	365	116.6	−64	99.0	↓
Cardio-vascular exercise test with treadmill	Piedmont	↓	−8,159	61.3	−2,533	56.6	−5,626	63.2	↓
	CDSS	↓	−1,418	46.0	−183	70.0	−1,235	38.8	↓

Type of service		Trend total volumes	Δ visits 2011-15	% 2015 over 2011	Δ > 60 days	% 2015 over 2011	Δ < 60 days	% 2015 over 2011	Trend visits within 60 days
CT maxillofacial	Piedmont	↓	−3,081	83.7	−78	83.3	−3,033	83.7	↓
	CDSS	↓	−627	65.6	−88	16.2	−539	68.7	↓
CT neck (contrast)	Piedmont	↑↑	3,853	163.2	666	197.2	3,187	158.9	↑↑
	CDSS	↑↑	529	134.5	53	129.4	476	135.2	↑↑
CT head	Piedmont	↓	−120	99.6	72	114.1	−192	99.3	↓
	CDSS	↓	−272	86.8	8	115.4	−280	86.0	↓
CT head (contrast)	Piedmont	↑↑	465	104.6	−106	85.1	571	106.1	↑↑
	CDSS	↑↑	447	130.4	−3	98.5	450	135.4	↑↑
CT chest (contrast)	Piedmont	↑↑	10,619	122.9	2,471	154.3	8,148	119.4	↑↑
	CDSS	↑↑	1,733	122.9	62	105.3	1,671	126.1	↑↑
CT full abdomen (contrast)	Piedmont	↑↑	10,088	118.5	2,031	139.0	8,057	116.3	↑↑
	CDSS	↑↑	1,139	113.3	−23	98.1	1,126	115.8	↑↑
CT upper abdomen (contrast)	Piedmont	↓	−1,117	72.9	109	146.2	−1,226	68.5	↓
	CDSS	↑↑	91	109.0	36	138.7	55	106.0	↑↑
CT lower limb	Piedmont	↓	−2,110	62.0	5	109.0	−2,115	61.5	↓
	CDSS	↓	−55	94.3	19	257.9	−74	92.3	↓
CT rachis and vertebral canal	Piedmont	↓	−775	94.4	247	232.9	−1,022	92.5	↓
	CDSS	↓	−402	81.0	74	311.1	−476	77.1	↓

C. *Data on emergency room accesses in Piedmont and Tuscany 2011-2016*

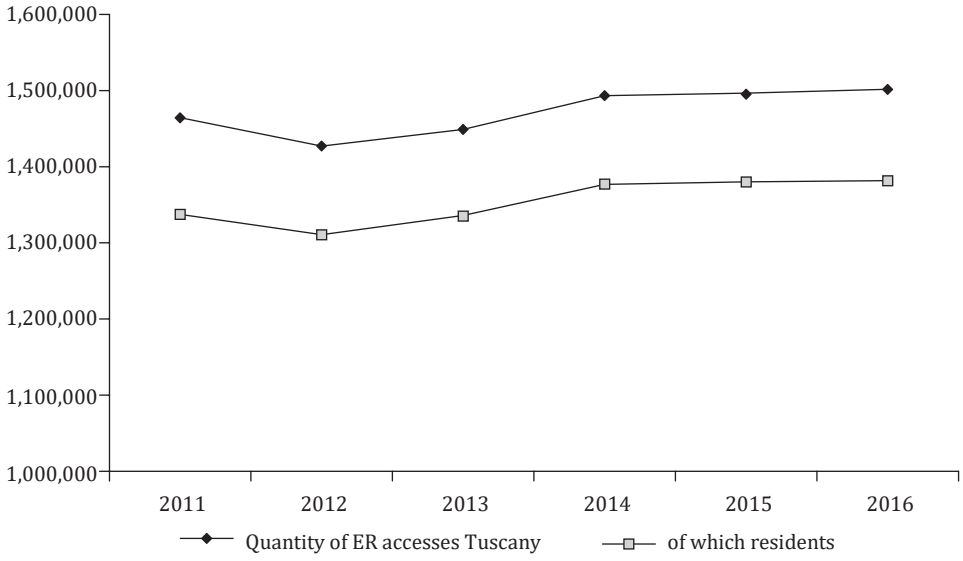

Fig. C_Tuscany. Trend in the volume of accesses to the emergency room in Tuscany by the resident and non-resident population - Years 2011-2016.

Source: Calculations based on ARS Toscana data (RFC 106 flow).

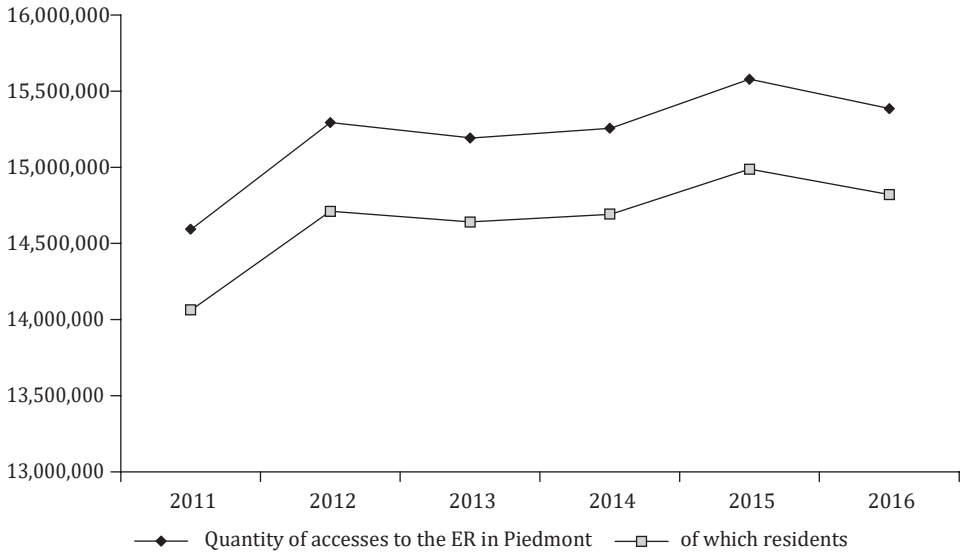

Fig. C_Piedmont. Trend in the volume of accesses to the emergency room in Piedmont by the resident and non-resident population - Years 2011-2016.

Source: Calculations based on CSI Piemonte data (EMUR-PS/C2 flow).

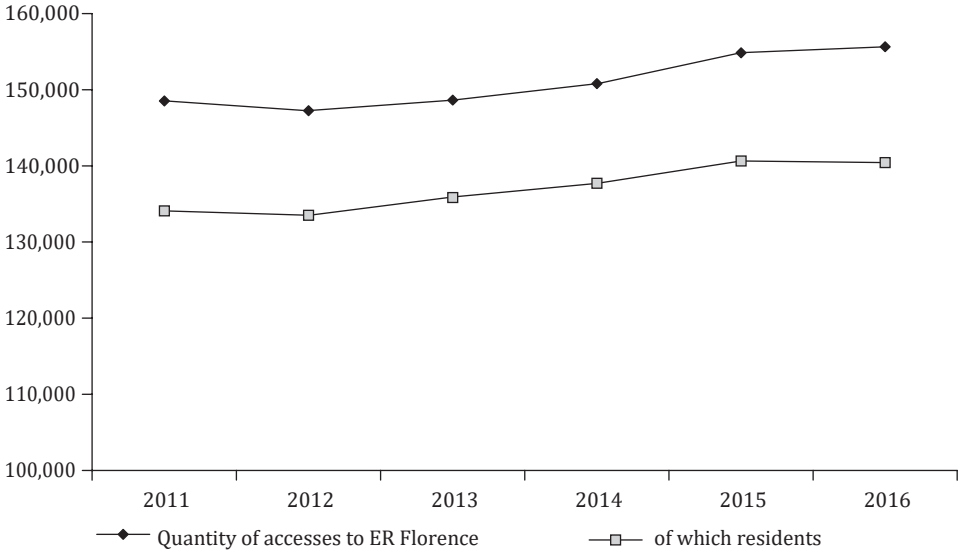

Fig. C-Florence. Trend in the volume of accesses to the emergency room in Florence by resident and non-resident population - Years 2011-2016.

Source: Calculations based on ARS Toscana data (RFC 106 flow).

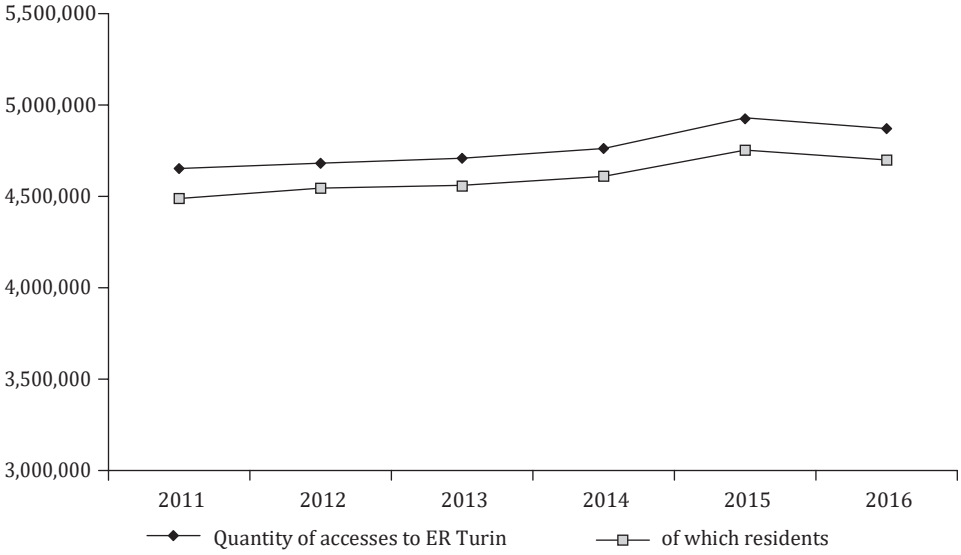

Fig. C_Turin. Trend in the volume of accesses to the emergency room in Turin by the resident and non-resident population - Years 2011-2016.

Source: Calculations based on CSI Piemonte data (EMUR-PS/C2 flow).

D. *Data on hospital services (total and broken down into admissions and day hospital/day surgery) provided in Piedmont and Tuscany in 2011-2016*

D.0. *Total hospital services*

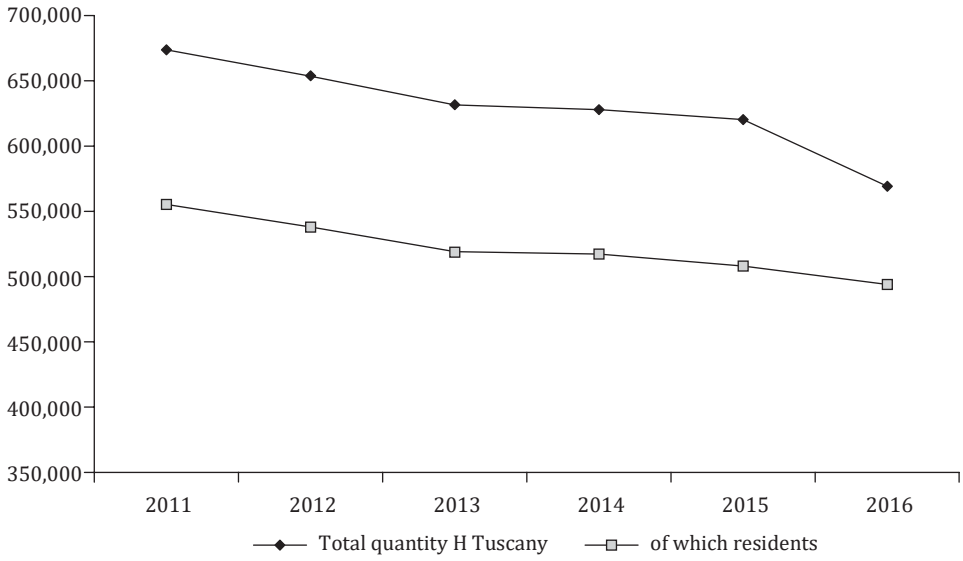

Fig. D.0_Tuscany. Trend in the volume of accesses to hospital services in Tuscany by the resident and non-resident population - Years 2011-2016.

Source: Calculations based on ARS Toscana data (SDO flow).

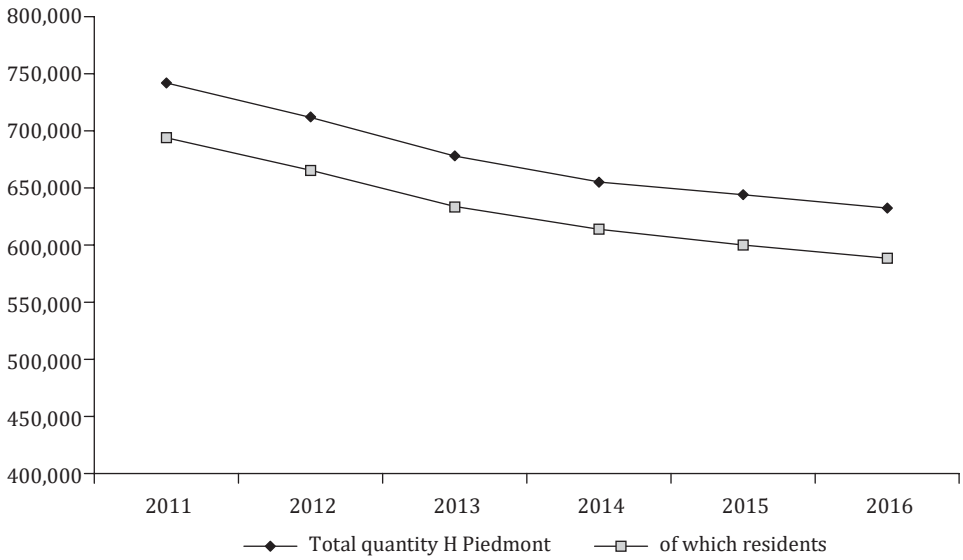

Fig. D.0_Piedmont. Trend in the volume of accesses to hospital services in Piedmont by the resident and non-resident population - Years 2011-2016.

Source: Calculations based on CSI Piemonte data (SDO flow).

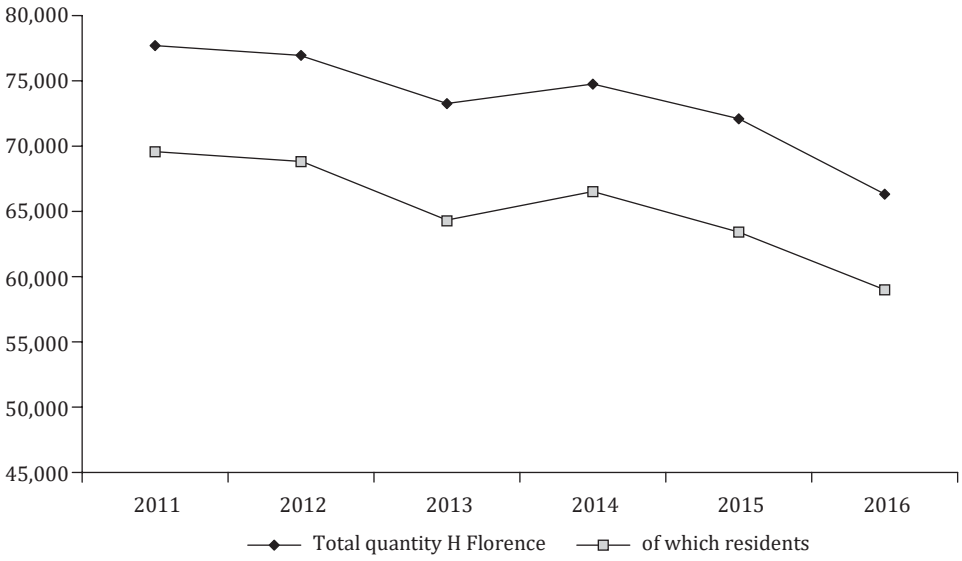

Fig. D.0_Florence. Trend in the volume of accesses to hospital services in Florence by the resident and non-resident population - Years 2011-2016.

Source: Calculations based on ARS Toscana data (SDO flow).

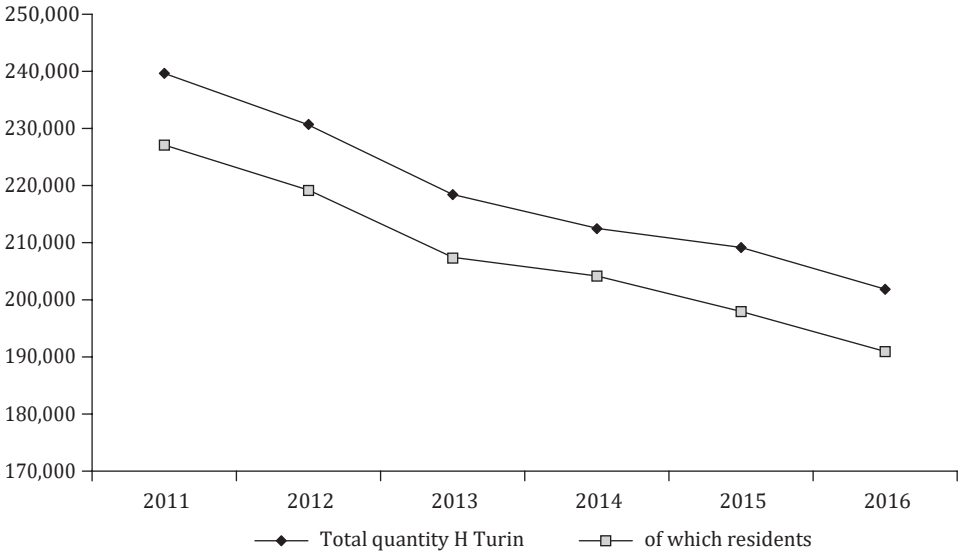

Fig. D.0_Turin. Trend in the volume of accesses to hospital services in Turin by the resident population - Years 2011-2016.

Source: Calculations based on CSI Piemonte data (SDO flow).

D.1. *Ordinary Hospitalization*

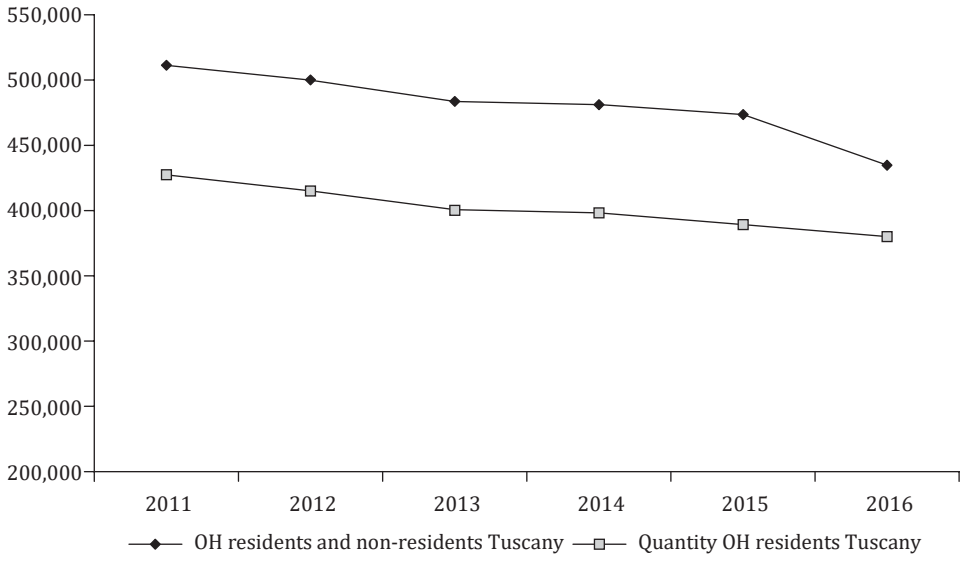

Fig. D.1_Tuscany. Trend in the volume of ordinary hospitalisations (OH) in Tuscany by the resident and non-resident population - Years 2011-2016.

Source: Calculations based on ARS Toscana data (SDO flow).

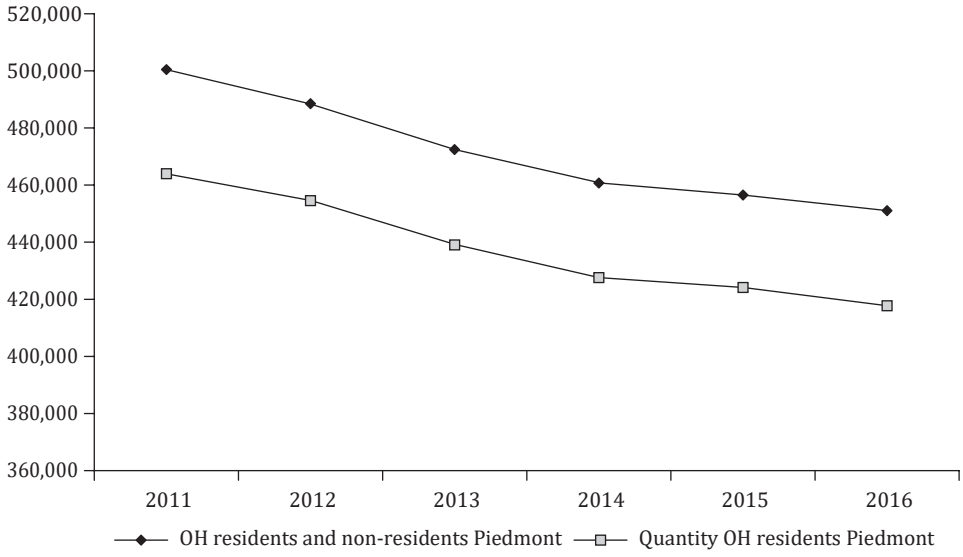

Fig. D.1_Piedmont. Trend in the volume of ordinary hospitalisations in Piedmont by the resident and non-resident population - Years 2011-2016.

Source: Calculations based on CSI Piemonte data (SDO flow).

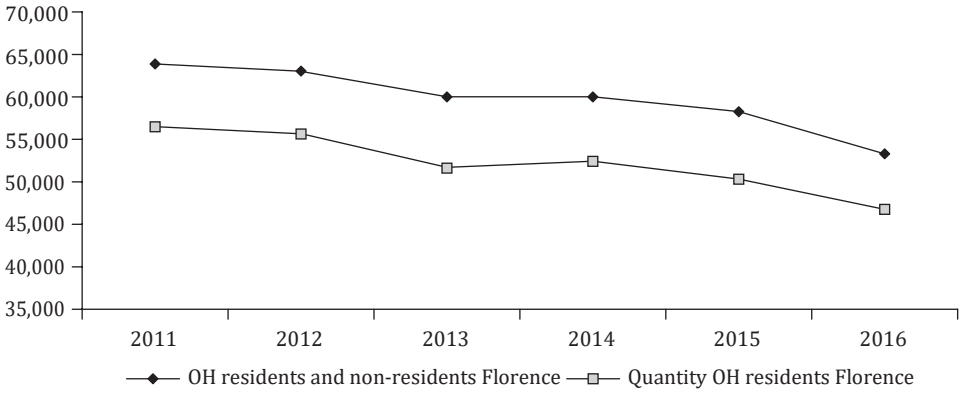

Fig. D.1_Florence. Trend in the volume of ordinary hospitalisations in Florence by the resident population - Years 2011-2016.

Source: Calculations based on ARS Toscana data (SDO flow).

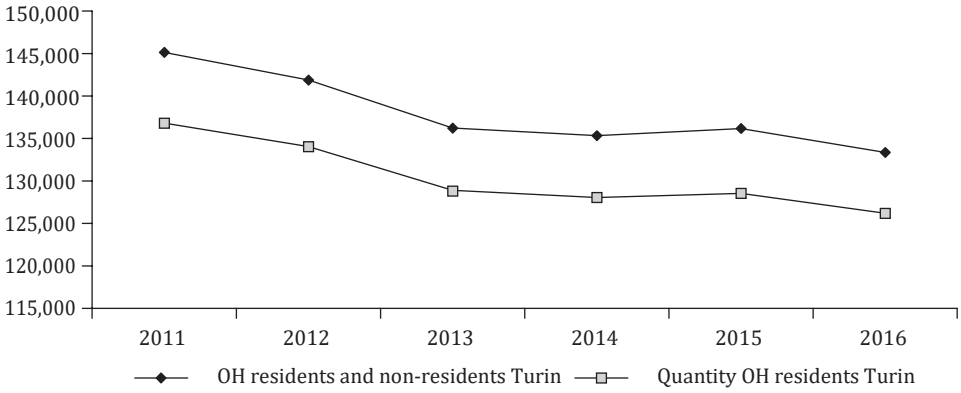

Fig. D.1_Turin. Trend in the volume of ordinary hospitalisations in Turin by the resident and non-resident population - Years 2011-2016.

Source: Calculations based on CSI Piemonte data (SDO flow).

Fig. D.1_Turin_bis. Trend in the volume of accesses to home hospitalisation in Turin by the resident population - Years 2011-2016.

Source: Calculations based on CSI Piemonte data (SDO flow).

D.2. *Day Hospital*

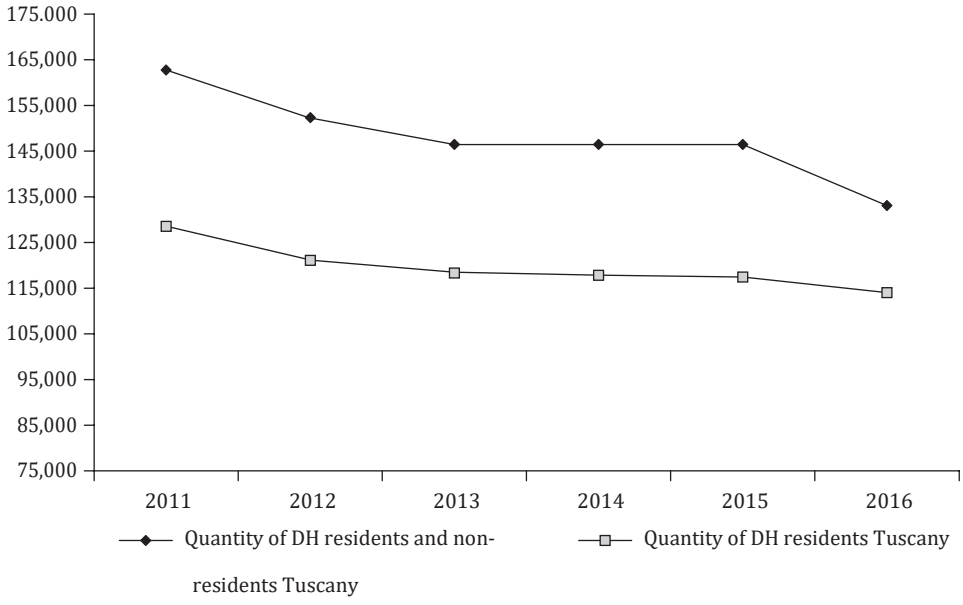

Fig. D.2_Tuscany. Trend in the volume of accesses to Day Hospital services in Tuscany by resident and non-resident population - Years 2011-2016.

Source: Calculations based on ARS Toscana data (SDO flow).

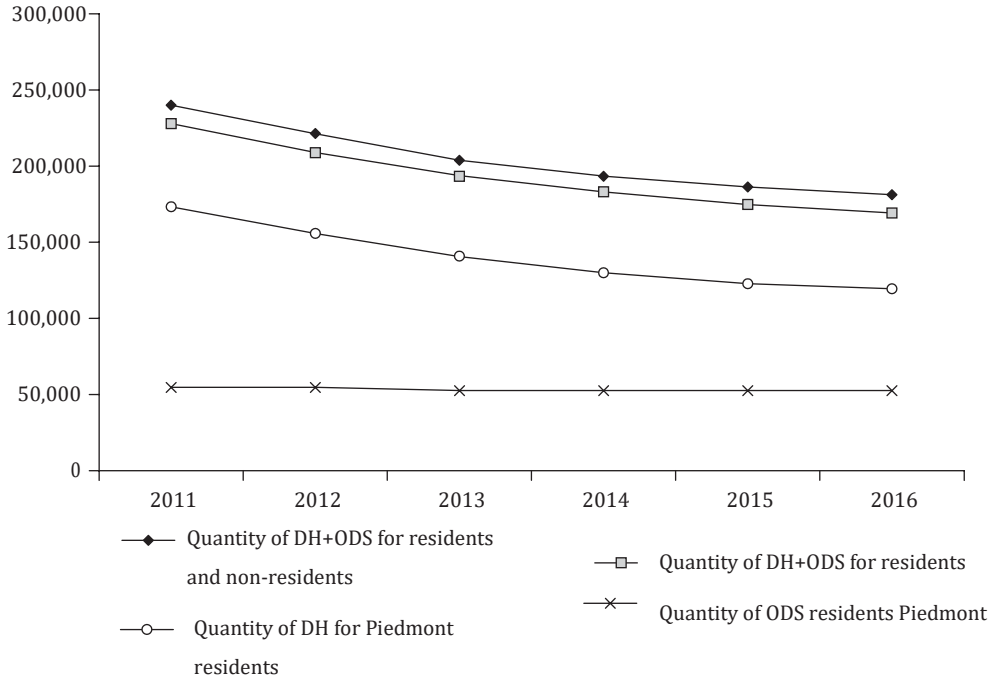

Fig. D.2_Piedmont. Trend in the volume of accesses to Day Hospital and One Day Surgery services in Piedmont by resident and non-resident population - Years 2011-2016.

Source: Calculations based on CSI Piemonte data (SDO flow).

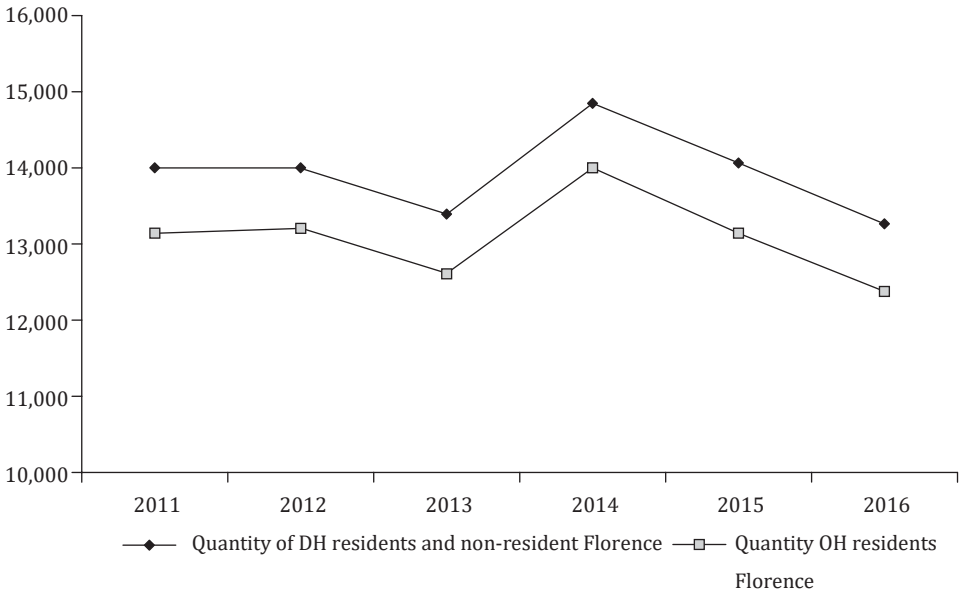

Fig. D.2_Florence. Trend in the volume of accesses to Day Hospital services in Florence by resident and non-resident population - Years 2011-2016.

Source: Calculations based on ARS Toscana data (SDO flow).

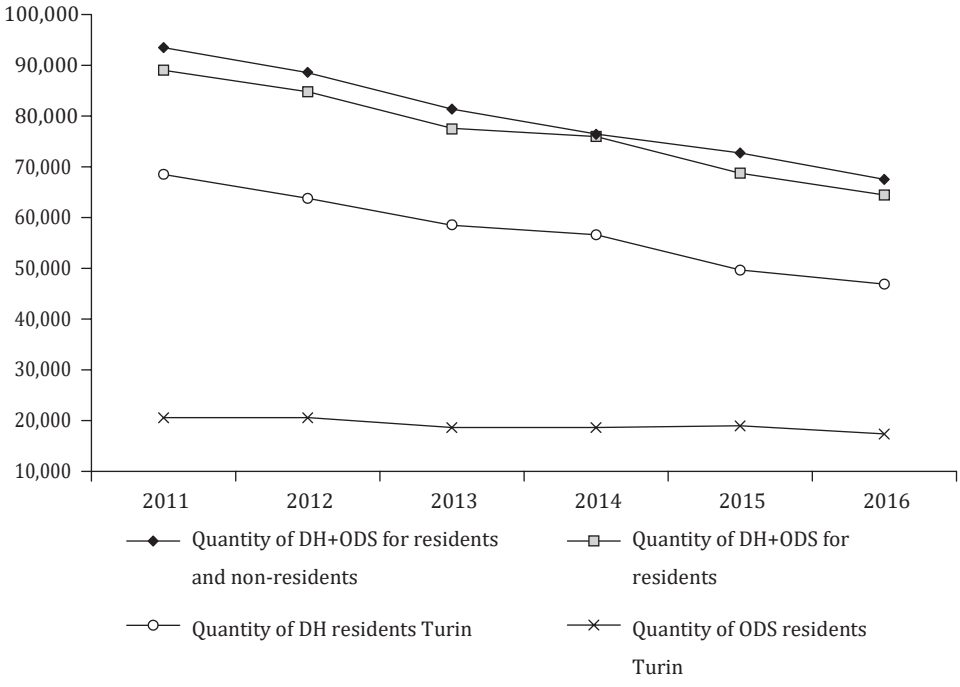

Fig. D.2_Turin. Trend in the volume of accesses to Day Hospital and One Day Surgery services in Turin by the resident and non-resident population - Years 2011-2016.

Source: Calculations based on CSI Piemonte data (SDO flow).

E. *Data on specialist outpatient services (total and broken down by type) provided in Piedmont and Tuscany in the period 2011-2016*

E.0. *Total SPA (first specialist visits + diagnostic imaging + laboratory diagnostics + instrumental diagnostics + procedures)*

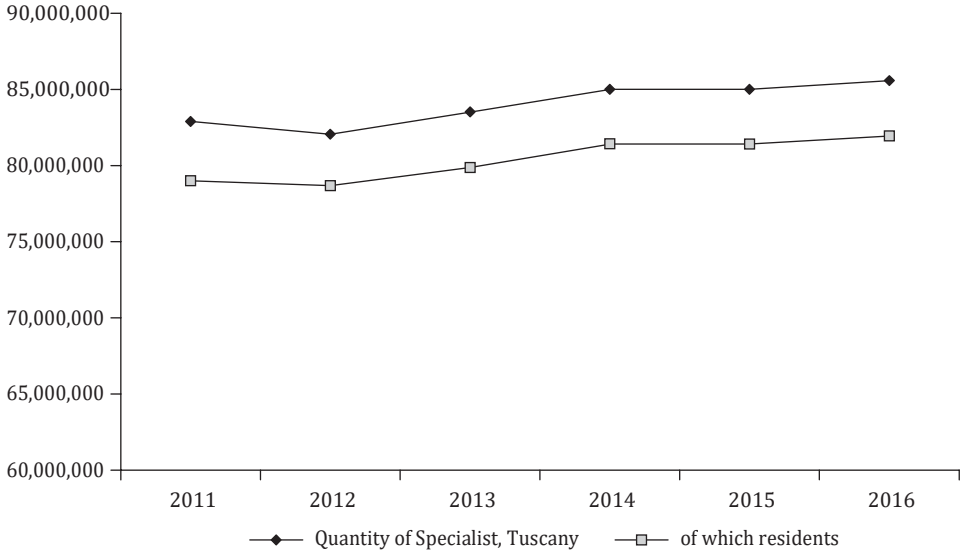

Fig. E.0_Tuscany. Trend in the volume of accesses to outpatient specialist services in Tuscany by the resident and non-resident population - Years 2011-2016.

Source: Calculations based on ARS Toscana data (SPA flow).

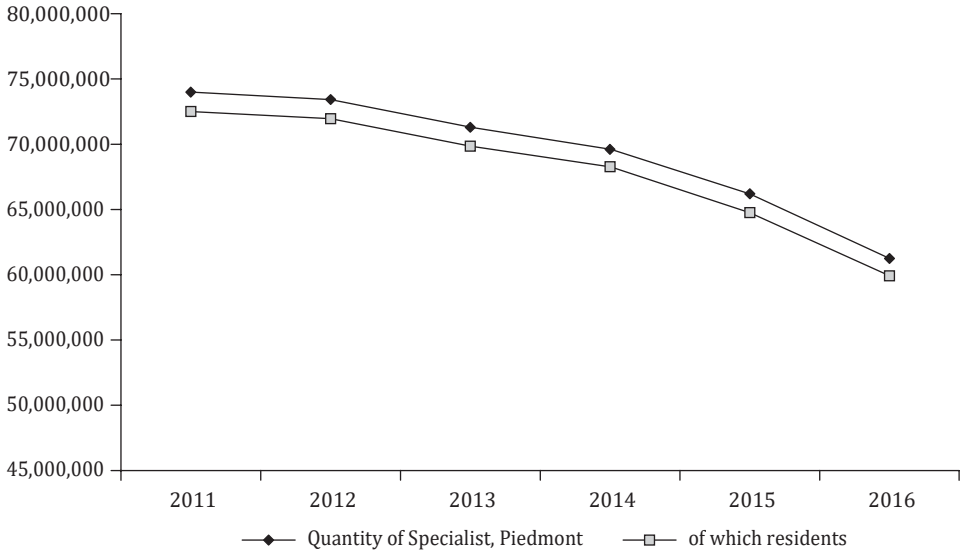

Fig. E.0_Piedmont. Trend in the volume of accesses to outpatient specialist services in Piedmont by the resident and non-resident population - Years 2011-2016.

Source: Calculations based on CSI Piemonte data (C flow).

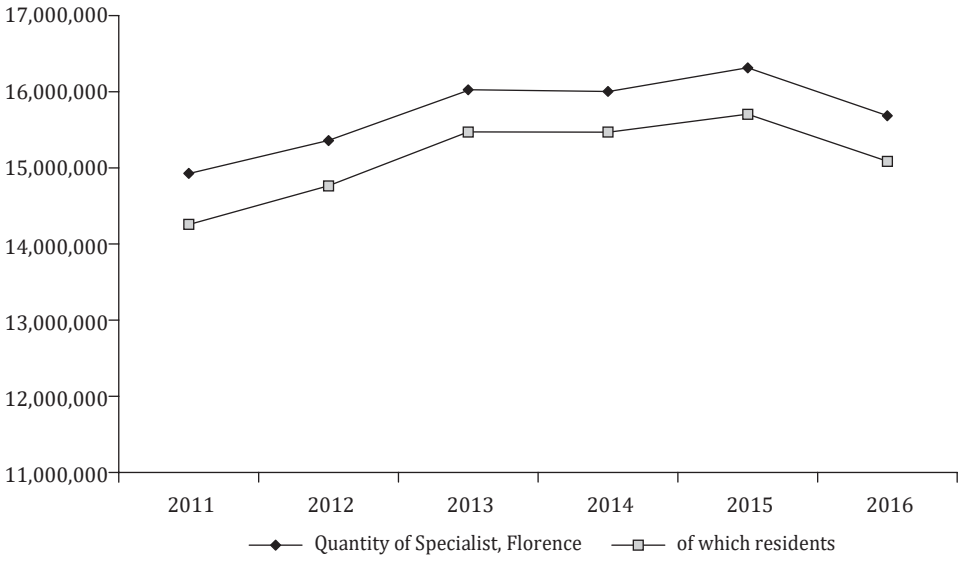

Fig. E.0_Florence. Trend in the volume of accesses to outpatient specialist services in Florence by the resident and non-resident population - Years 2011-2016.

Source: Calculations based on ARS Toscana data (SPA flow).

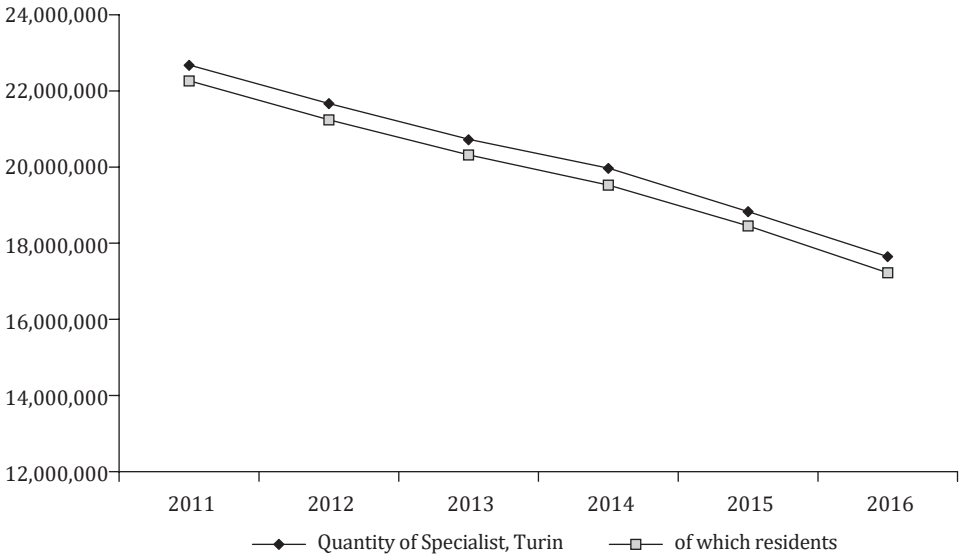

Fig. E.0_Turin. Trend in the volume of accesses to outpatient specialist services in Turin by the resident and non-resident population - Years 2011-2016.

Source: Calculations based on CSI Piemonte data (C flow).

E.1. *Clinical (first visits)*

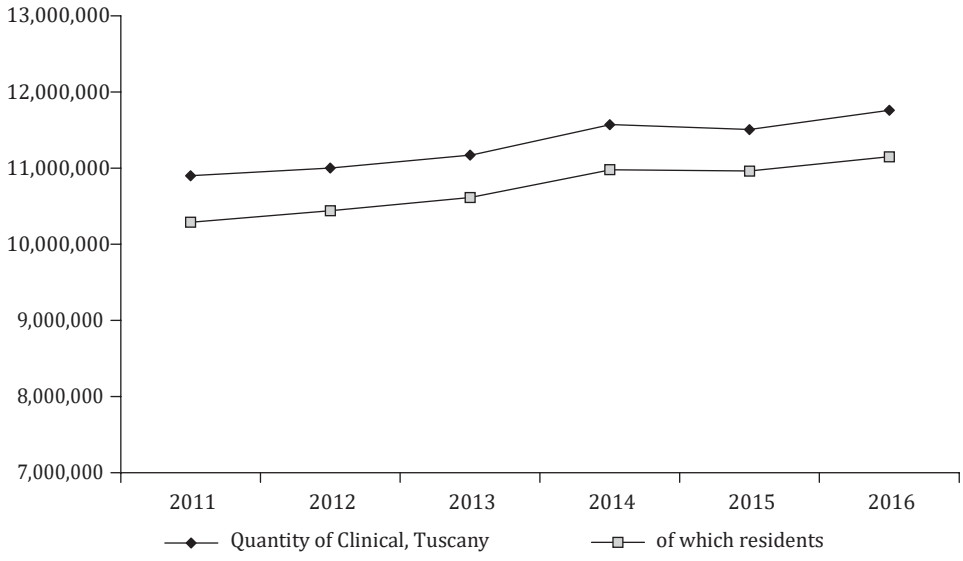

Fig. E.1_Tuscany. Trend in the volume of accesses to first specialist visits in Tuscany by the resident and non-resident population - Years 2011-2016.

Source: Calculations based on ARS Toscana data (SPA flow).

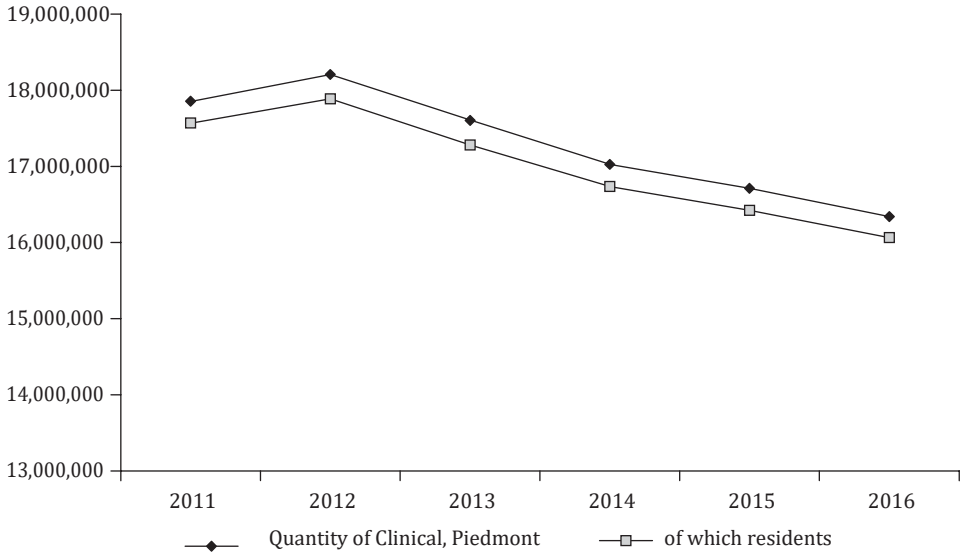

Fig. E.1_Piedmont. Trend in the volume of accesses to first specialist visits in Piedmont by the resident and non-resident population - Years 2011-2016.

Source: Calculations based on CSI Piemonte data (C flow).

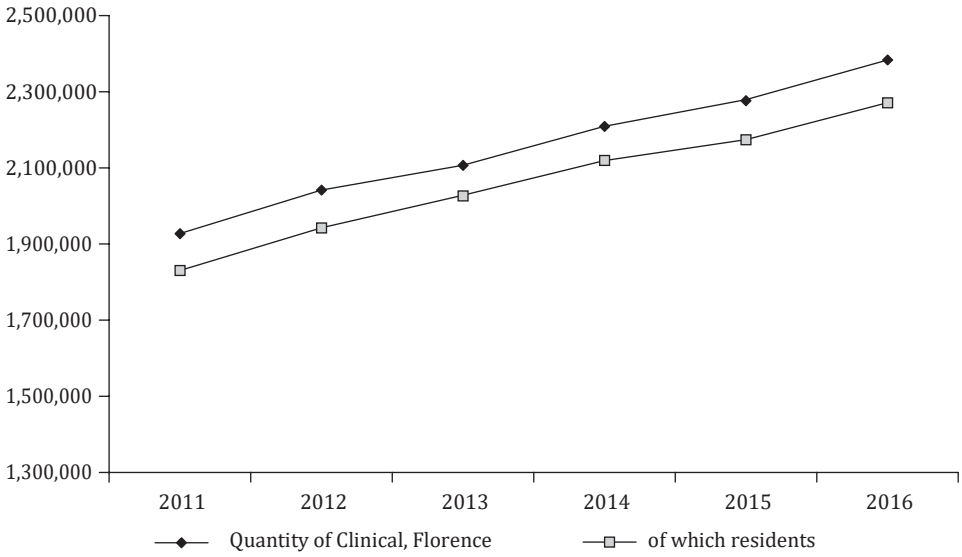

Fig. E.1_Florence. Trend in the volume of accesses to first specialist visits in Florence by the resident and non-resident population - Years 2011-2016.

Source: Calculations based on ARS Toscana data (SPA flow).

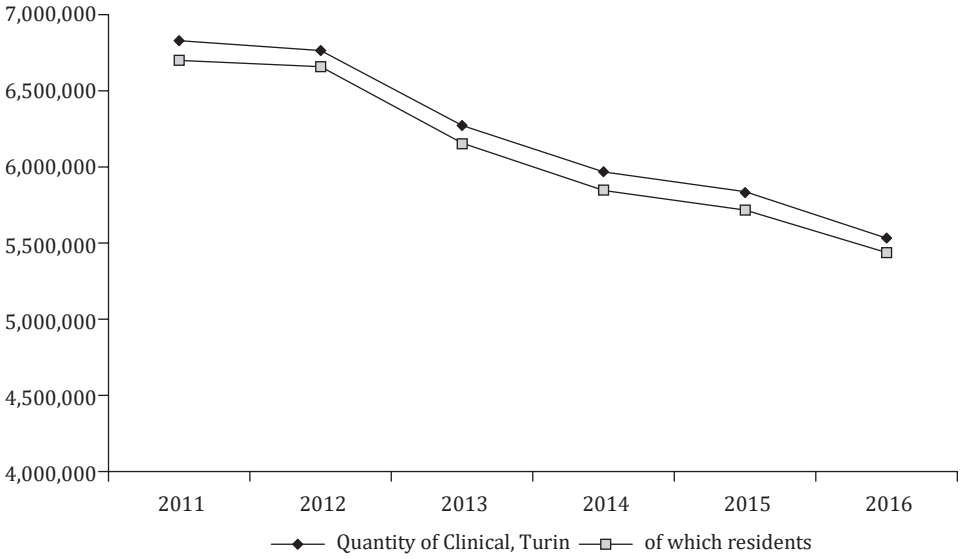

Fig. E.1_Turin. Trend in the volume of accesses to first specialist visits in Turin by the resident and non-resident population - Years 2011-2016.

Source: Calculations based on CSI Piemonte data (C flow).

E.2. *Diagnostic imaging*

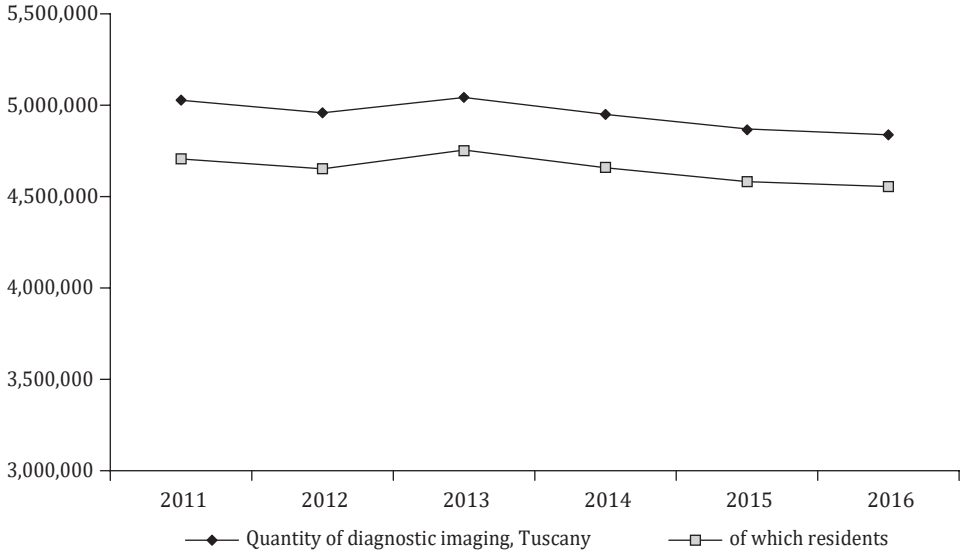

Fig. E.2_Tuscany. Trend in the volume of accesses to diagnostic imaging services in Tuscany by the resident and non-resident population - Years 2011-2016.

Source: Calculations based on ARS Toscana data (SPA flow).

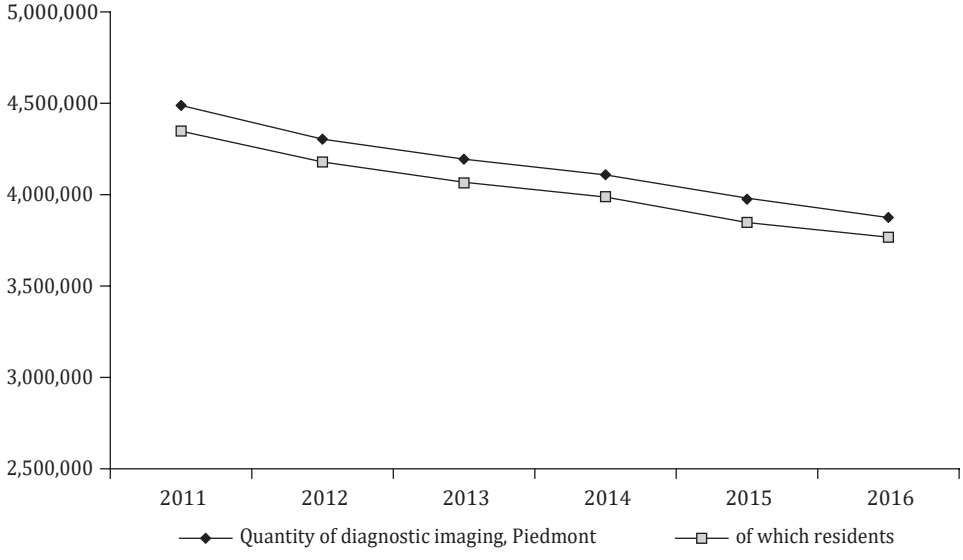

Fig. E.2_Piedmont. Trend in the volume of accesses to diagnostic imaging services in Piedmont by the resident and non-resident population - Years 2011-2016.

Source: Calculations based on CSI Piemonte data (C flow).

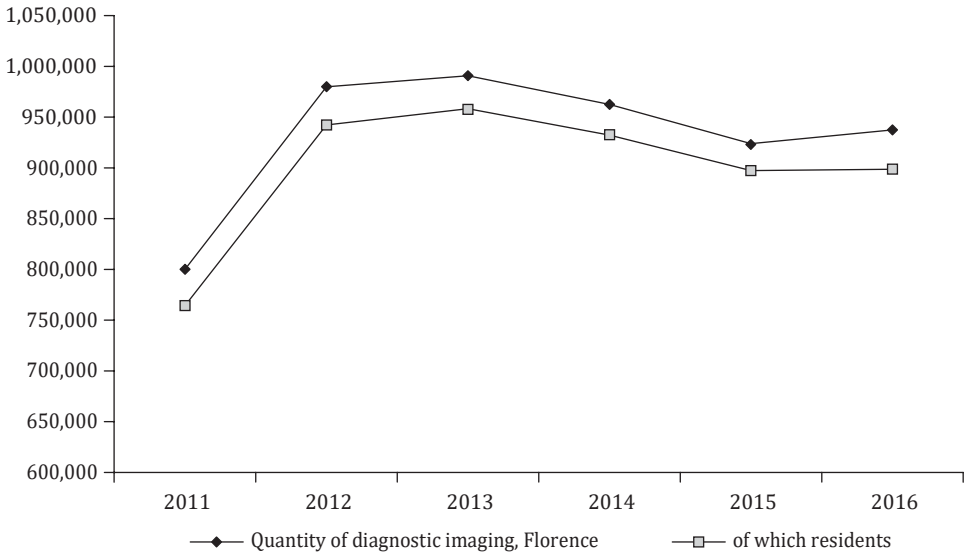

Fig. E.2_Florence. Trend in the volume of accesses to diagnostic imaging services in Florence by the resident and non-resident population - Years 2011-2016.

Source: Calculations based on ARS Toscana data (SPA flow).

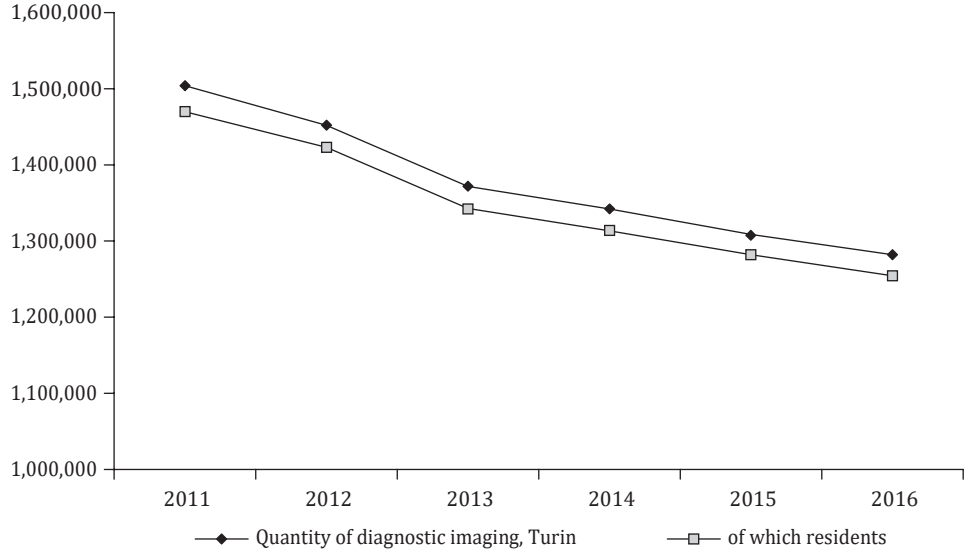

Fig. E.2_Turin. Trend in the volume of accesses to diagnostic imaging services in Turin by the resident and non-resident population - Years 2011-2016.

Source: Calculations based on CSI Piemonte data (C flow).

E.3. *Laboratory diagnostics**

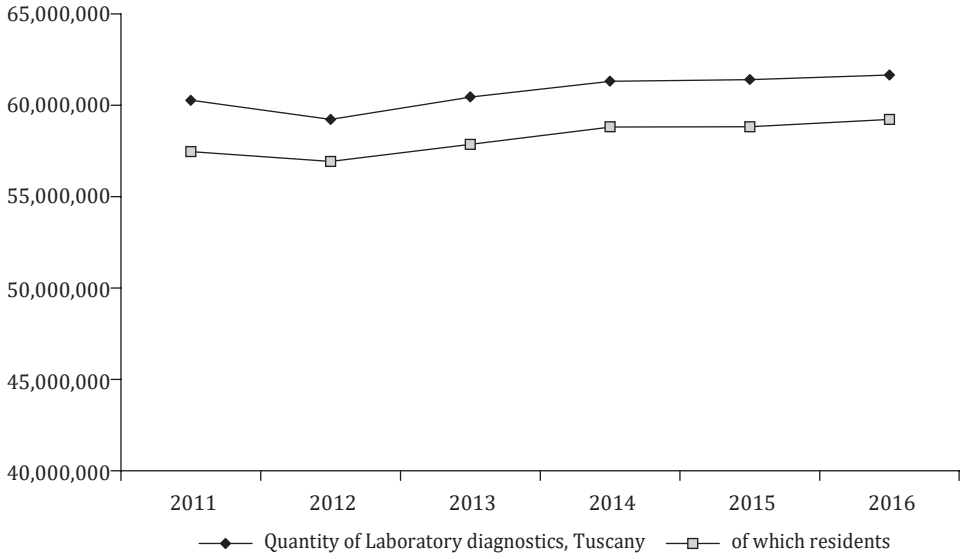

Fig. E.3_Tuscany. Trend in the volume of accesses to laboratory diagnostic services in Tuscany by the resident and non-resident population - Years 2011-2016.

Source: Calculations based on ARS Toscana data (SPA flow).

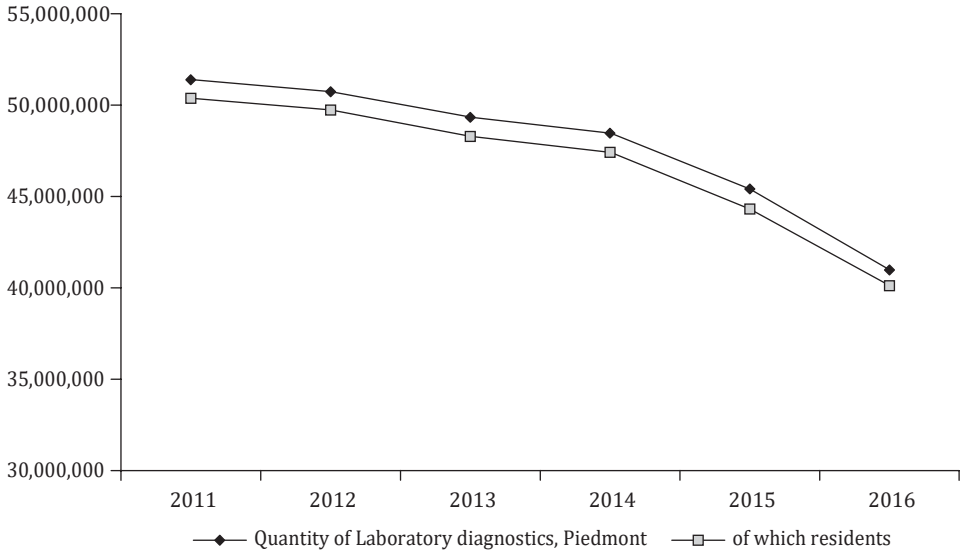

Fig. E.3_Piedmont. Trend in the volume of accesses to laboratory diagnostic services in Piedmont by the resident and non-resident population - Years 2011-2016.

Source: Calculations based on CSI Piemonte data (C flow).

- Data on the remaining types of specialist outpatient services (instrumental diagnostics and the residual category of procedures) are not reported because, due to different registration systems, comparison between the two Regions is not possible.

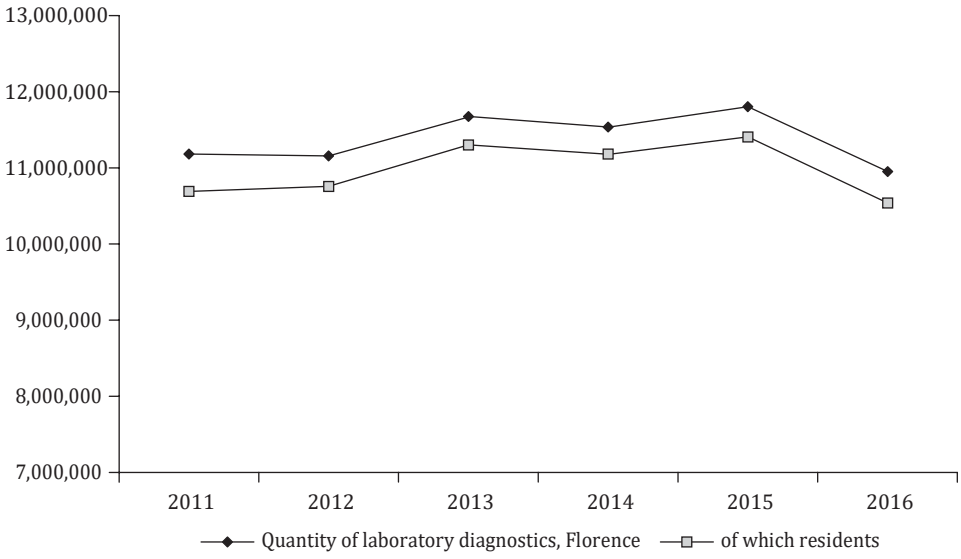

Fig. E.3_Florence. Trend in the volume of accesses to laboratory diagnostic services in Florence by the resident and non-resident population - Years 2011-2016.

Source: Calculations based on ARS Toscana data (SPA flow).

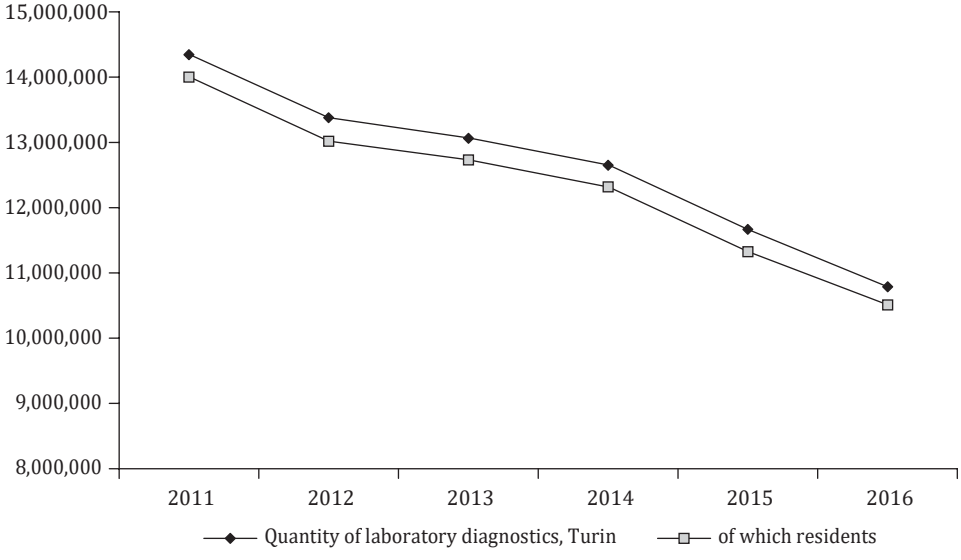

Fig. E.3_Turin. Trend in the volume of accesses to laboratory diagnostics services in Turin by the resident and non-resident population - Years 2011-2016.

Source: Calculations based on CSI Piemonte data (C flow).

F. *Data on single outpatient specialist services at high risk of lack of appropriateness provided in Piedmont and Tuscany in the period 2011-2016 (ultrasound of the upper abdomen, nuclear magnetic resonance of the spine and computed tomography of the spine and vertebral canal)*

Ultrasound of upper abdomen (88.74.1)

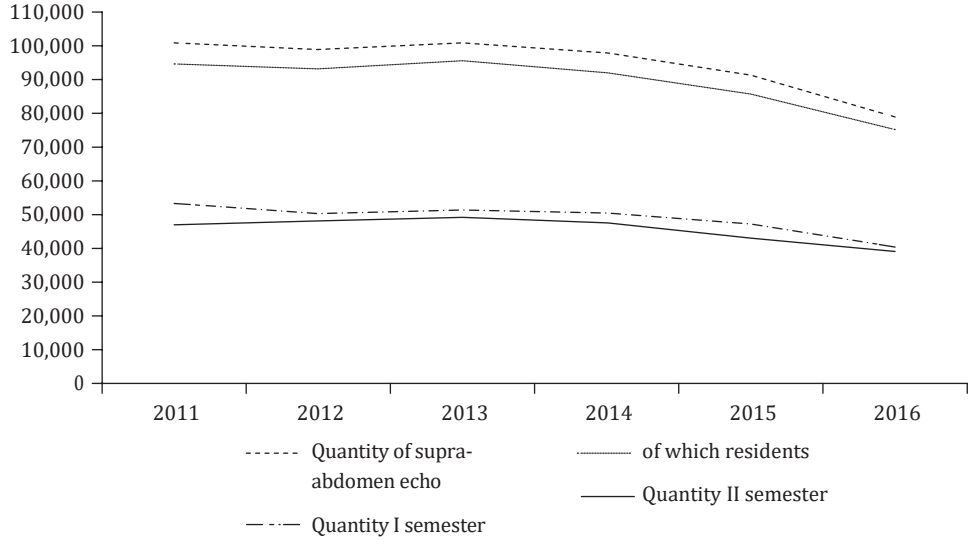

Fig. F.1_Tuscany. Trend in the volume of accesses to service no. 88.74.1 in Tuscany by the resident and non-resident population - Years 2011-2016.

Source: Calculations based on ARS Toscana data (SPA flow).

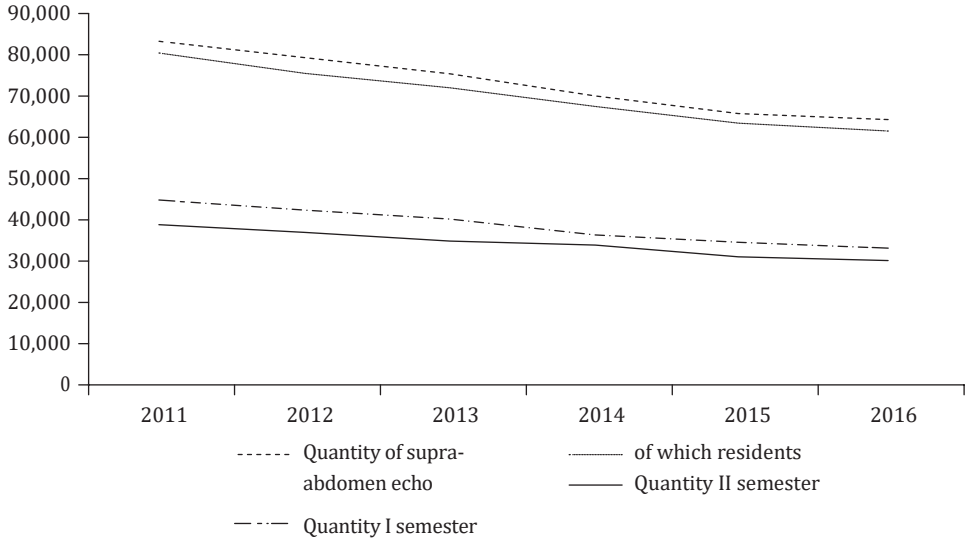

Fig. F.1_Piedmont. Trend in the volume of accesses to service no. 88.74.1 in Piedmont by the resident and non-resident population - Years 2011-2016.

Source: Calculations based on CSI Piemonte data (C flow).

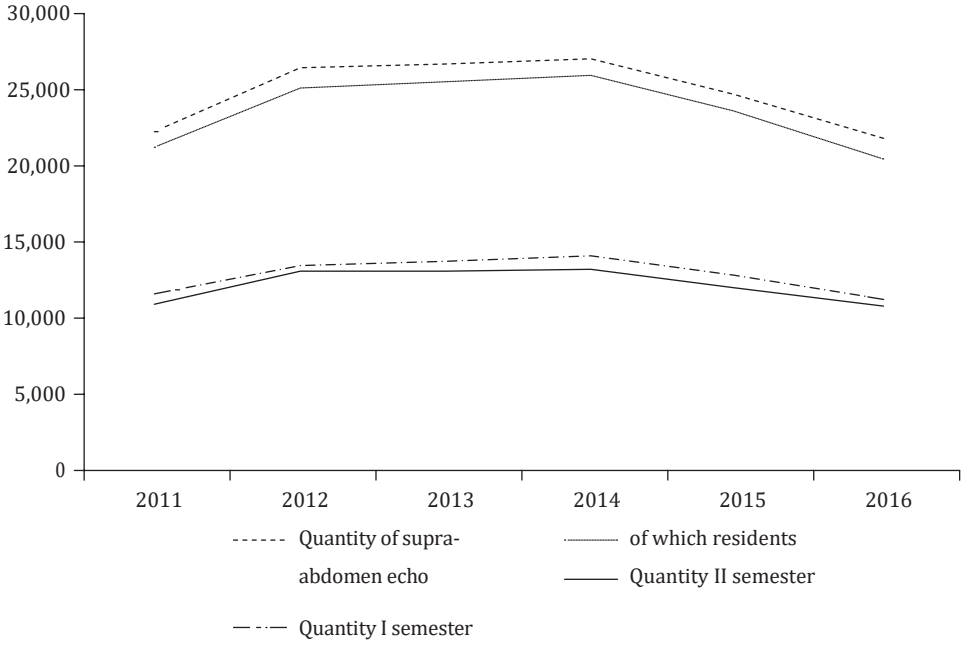

Fig. F.1_Florence. Trend in the volume of accesses to service no. 88.74.1 in Florence by resident and non-resident population - Years 2011-2016.

Source: Calculations based on ARS Toscana data (SPA flow).

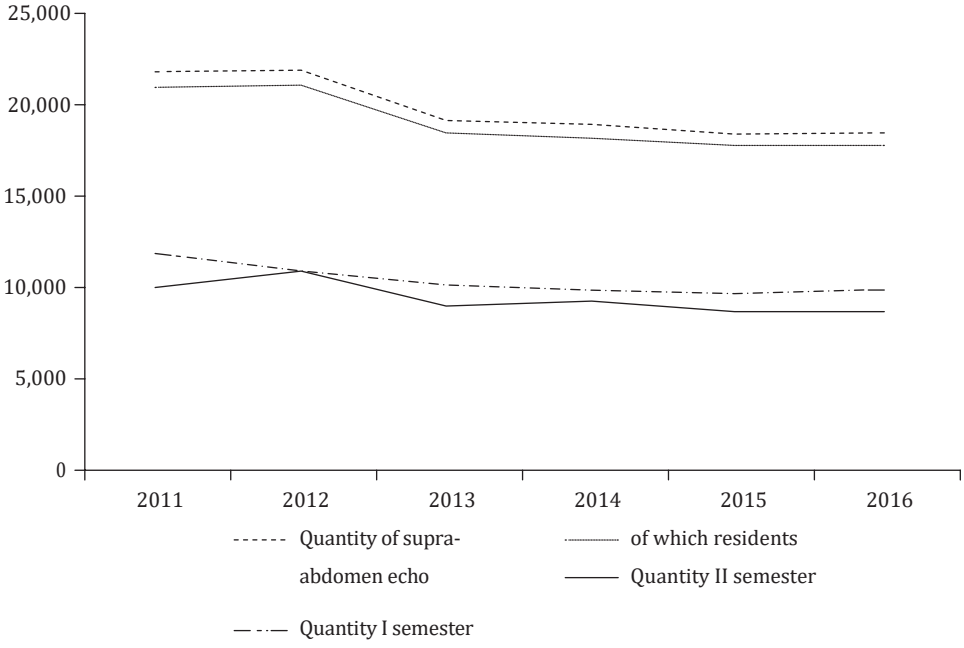

Fig. F.1_Turin. Trend in the volume of accesses to service no. 88.74.1 in Turin by the resident and non-resident population - Years 2011-2016.

Source: Calculations based on CSI Piemonte data (C flow).

F.2. *Nuclear magnetic resonance (NMR) of the spine (88.93)*

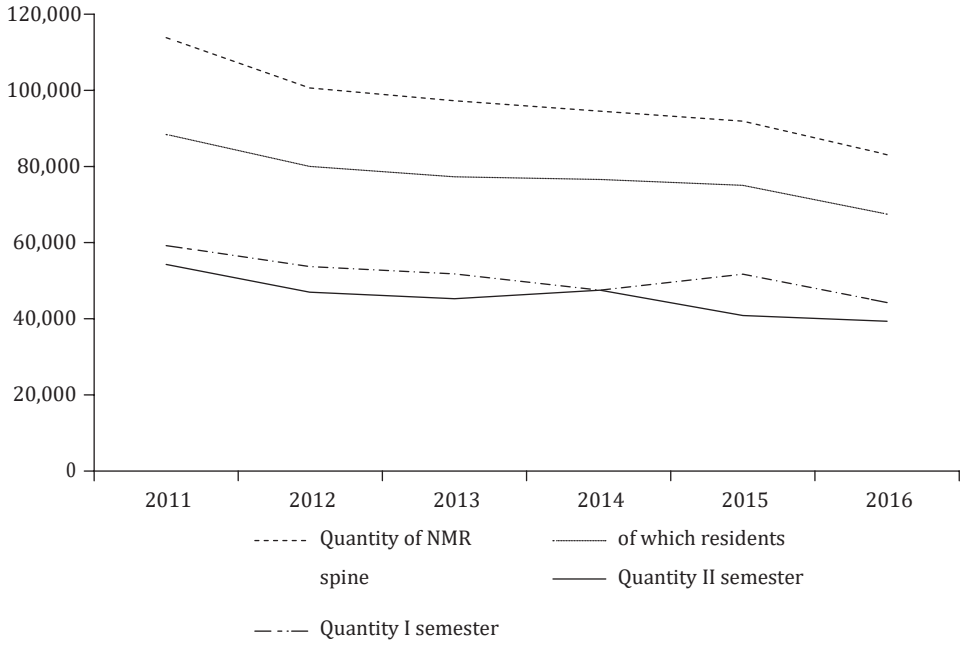

Fig. F.2_Tuscany. Trend in the volume of accesses to service no. 88.93 in Tuscany by the resident and non-resident population - Years 2011-2016.

Source: Calculations based on ARS Toscana data (SPA flow).

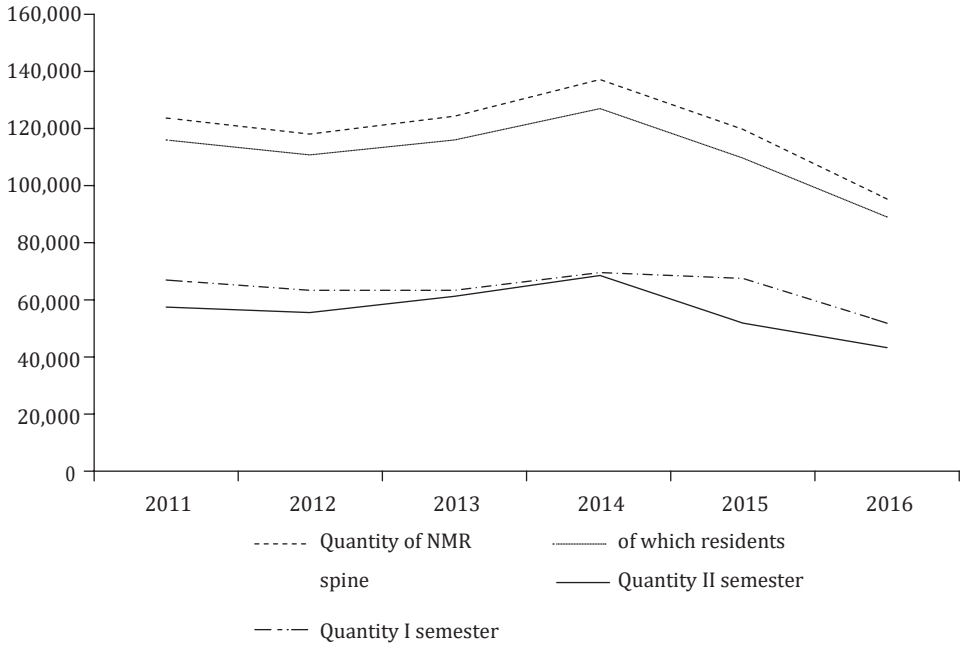

Fig. F.2_Piedmont. Trend in the volume of accesses to service no. 88.93 in Piedmont by resident and non-resident population - Years 2011-2016.

Source: Calculations based on CSI Piemonte data (C flow).

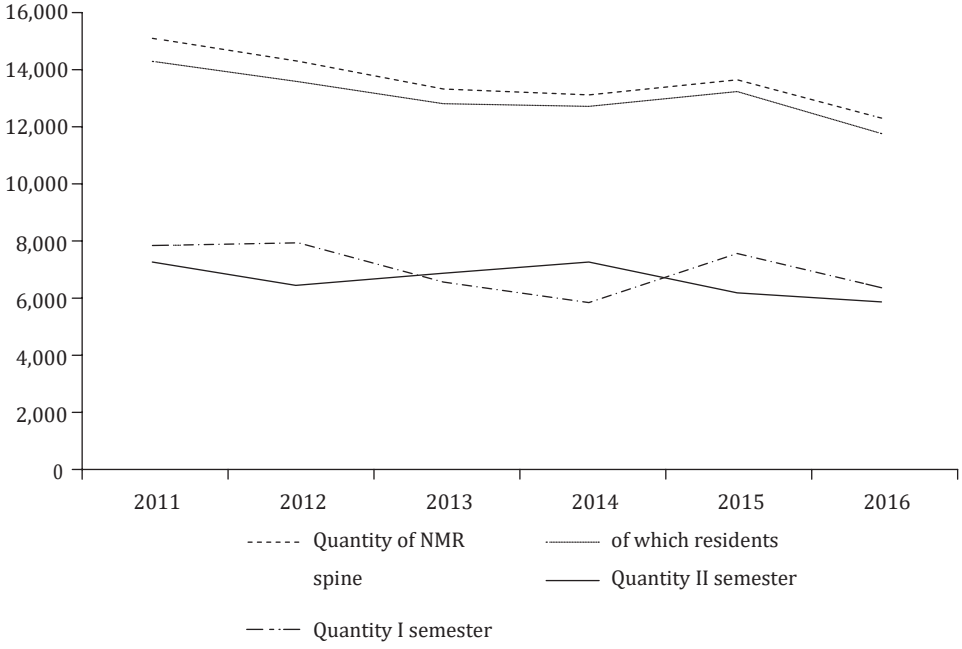

Fig. F.2_Florence. Trend in the volume of accesses to service no. 88.93 in Florence by the resident and non-resident population - Years 2011-2016.

Source: Calculations based on ARS Toscana data (SPA flow).

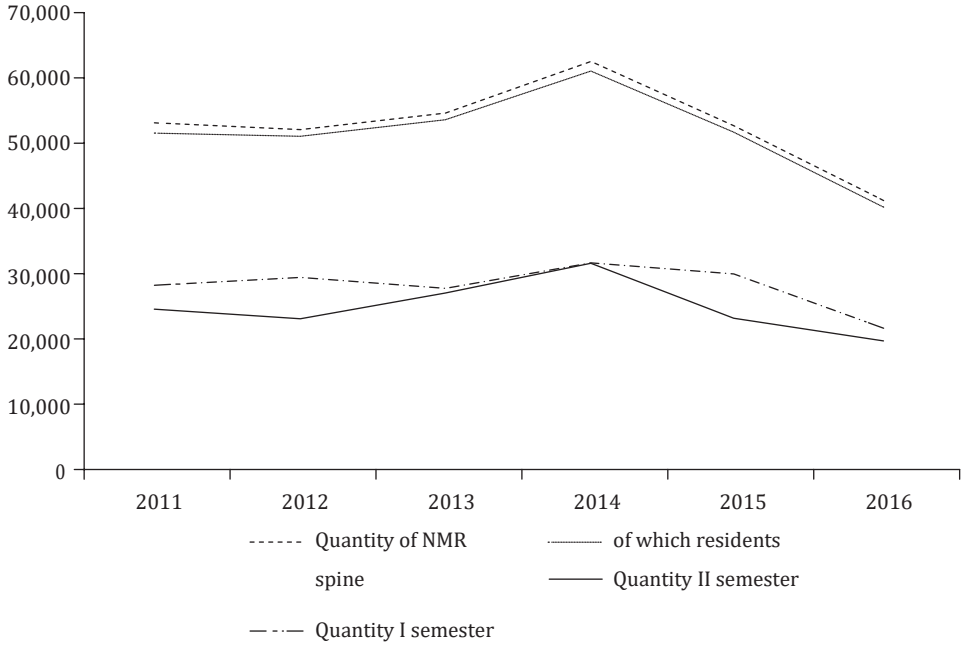

Fig. F.2_Turin. Trend in the volume of accesses to service no. 88.93 in Turin by the resident and non-resident population - Years 2011-2016.

Source: Calculations based on CSI Piemonte data (C flow).

F.3. *Computed tomography (CT) of the spine and vertebral canal (88.38.1)*

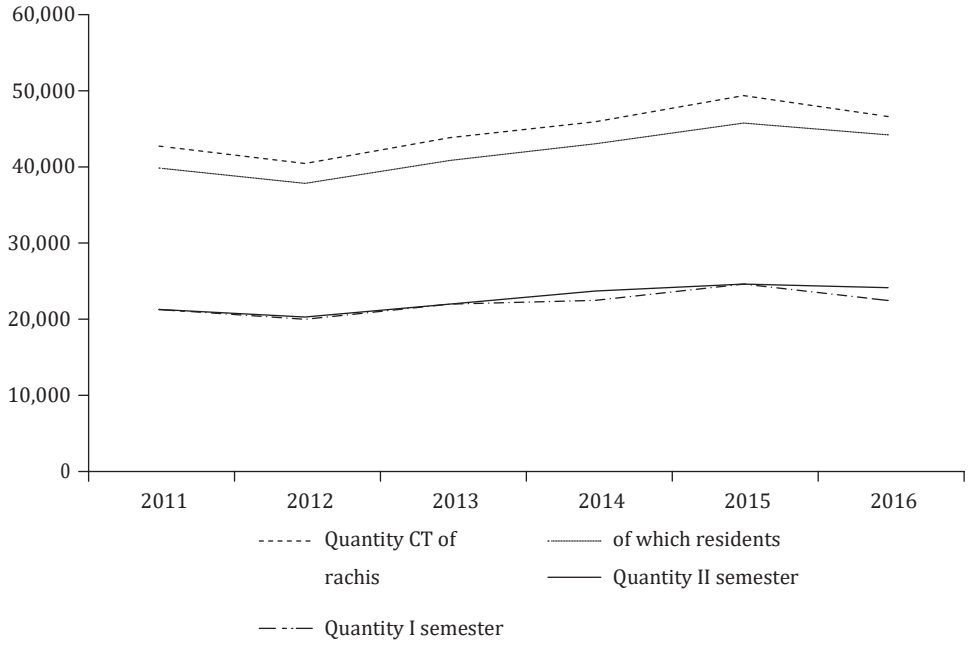

Fig. F.3_Tuscany. Trend in the volume of accesses to service no. 88.38.1 in Tuscany by the resident and non-resident population - Years 2011-2016.

Source: Calculations based on ARS Toscana data (SPA flow).

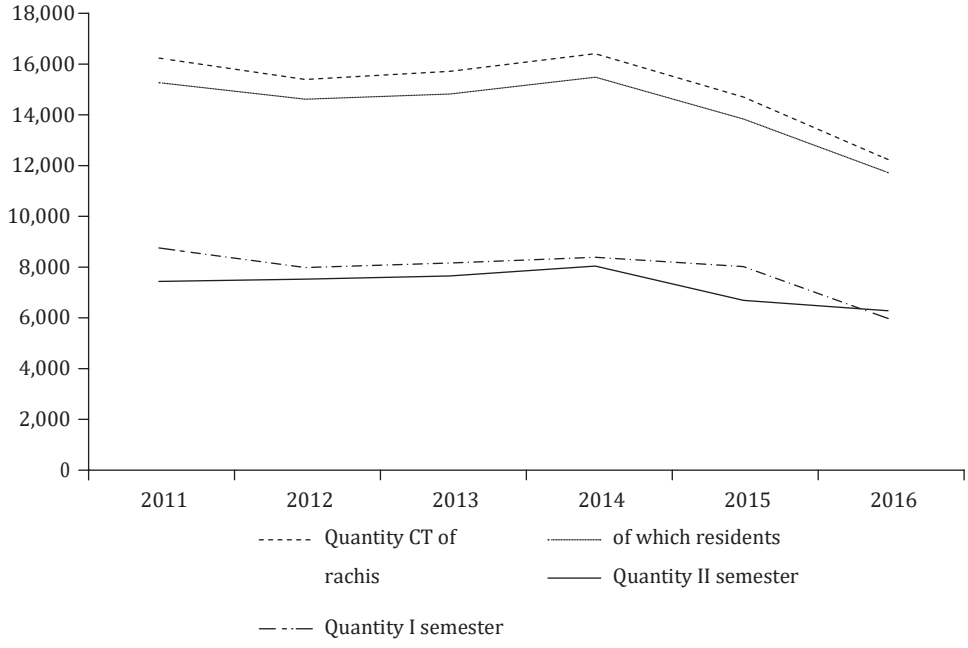

Fig. F.3_Piedmont. Trend in the volume of accesses to service no. 88.38.1 in Piedmont by the resident and non-resident population - Years 2011-2016.

Source: Calculations based on CSI Piemonte data (C flow).

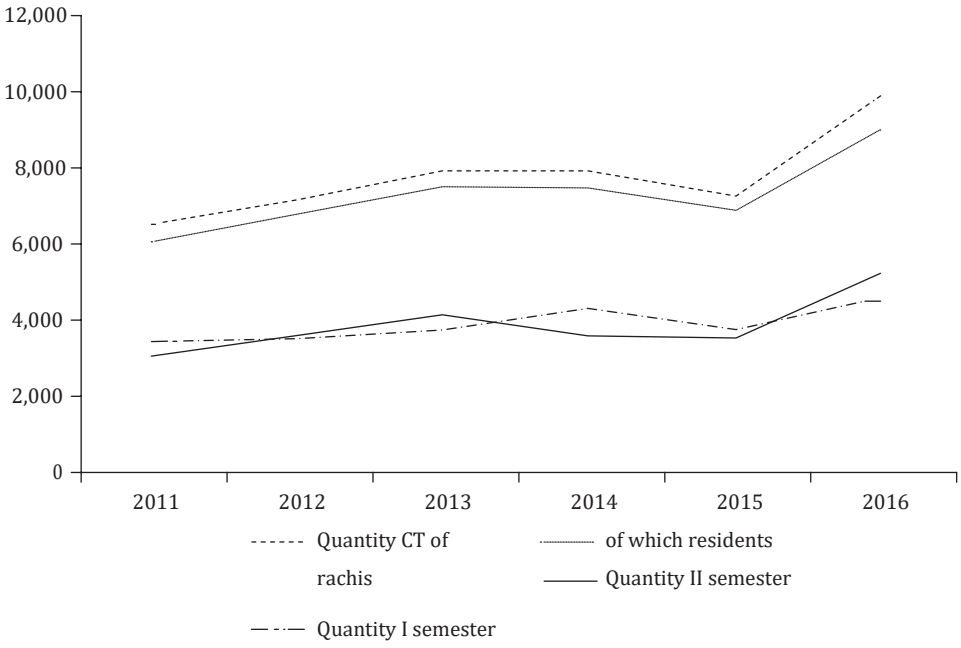

Fig. F.3_Florence. Trend in the volume of accesses to service no. 88.38.1 in Florence by resident and non-resident population - Years 2011-2016.

Source: Calculations based on ARS Toscana data (SPA flow).

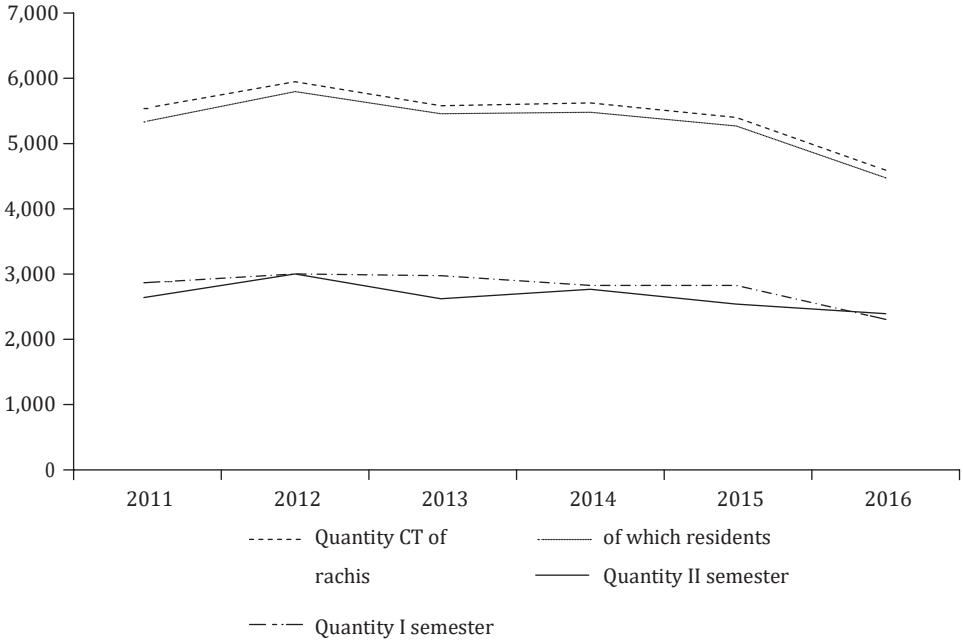

Fig. F.3_Turin. Trend in the volume of accesses to service no. 88.38.1 in Turin by the resident and non-resident population - Years 2011-2016.

Source: Calculations based on CSI Piemonte data (C flow).

G. Data on single outpatient specialist services at medium risk of low appropriateness provided in Piedmont and Tuscany in the period 2011-2016 (computed tomography of the lower and upper abdomen)

G.1. *Computed tomography (CT) of the upper abdomen (with and without contrast) (88.01.2)*

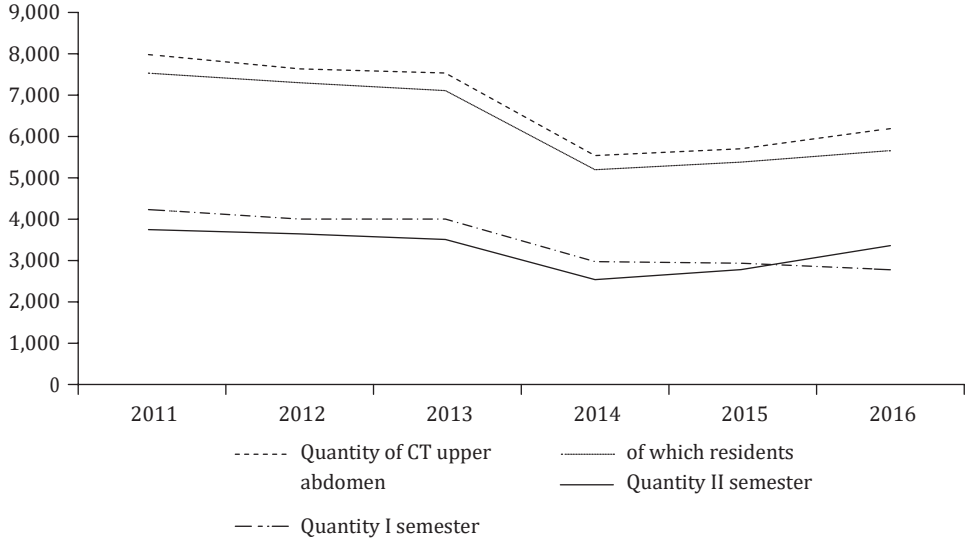

Fig. G.1_Tuscany. Trend in the volume of accesses to service no. 88.01.2 in Tuscany by the resident and non-resident population - Years 2011-2016.

Source: Calculations based on ARS Toscana data (SPA flow).

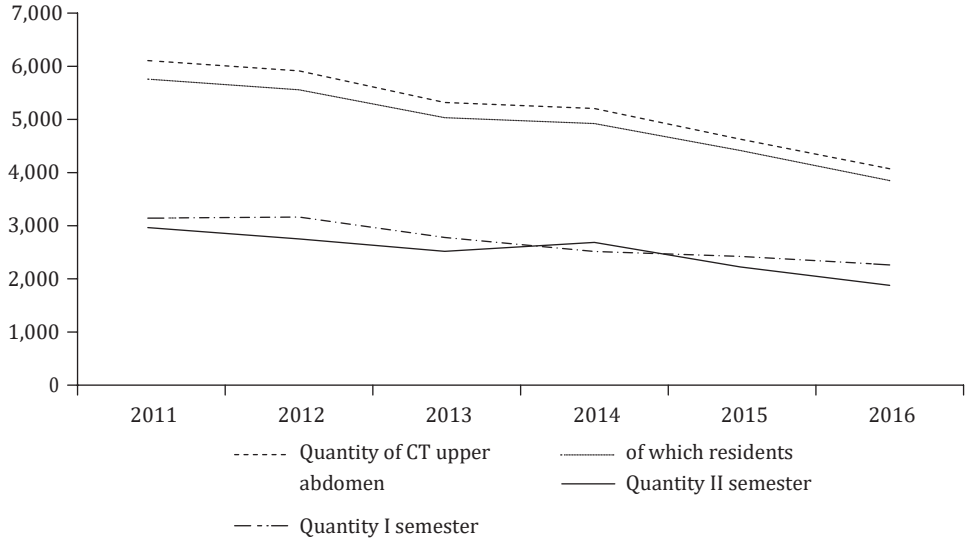

Fig. G-1_Piedmont. Trend in the volume of accesses to service no. 88.01.2 in Piedmont by the resident and non-resident population - Years 2011-2016.

Source: Calculations based on CSI Piemonte data (C flow).

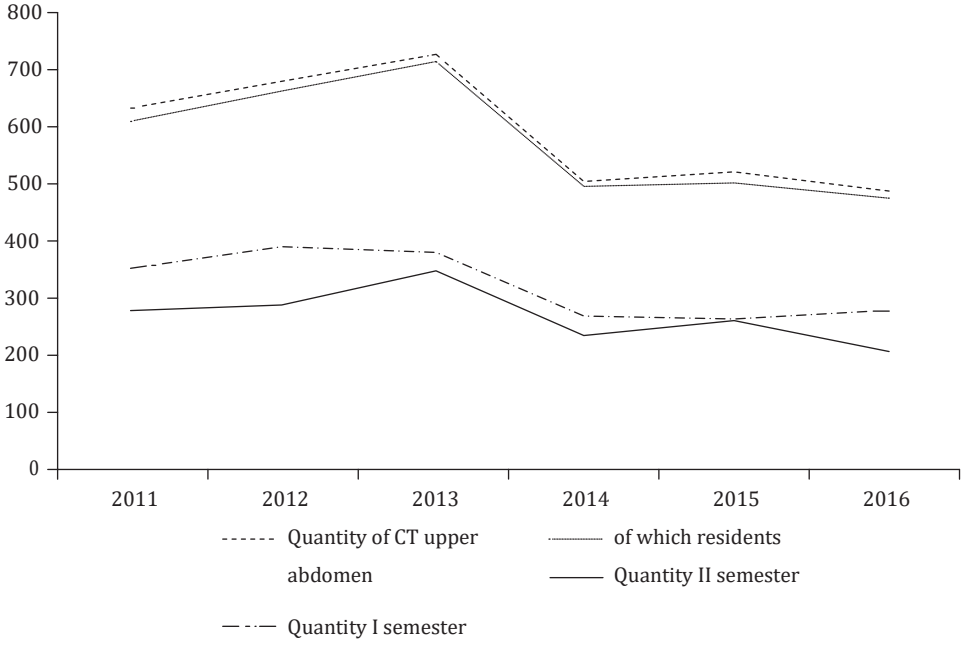

Fig. G.1_Florence. Trend in the volume of accesses to service no. 88.01.2 in Florence by the resident and non-resident population - Years 2011-2016.

Source: Calculations based on ARS Toscana data (SPA flow).

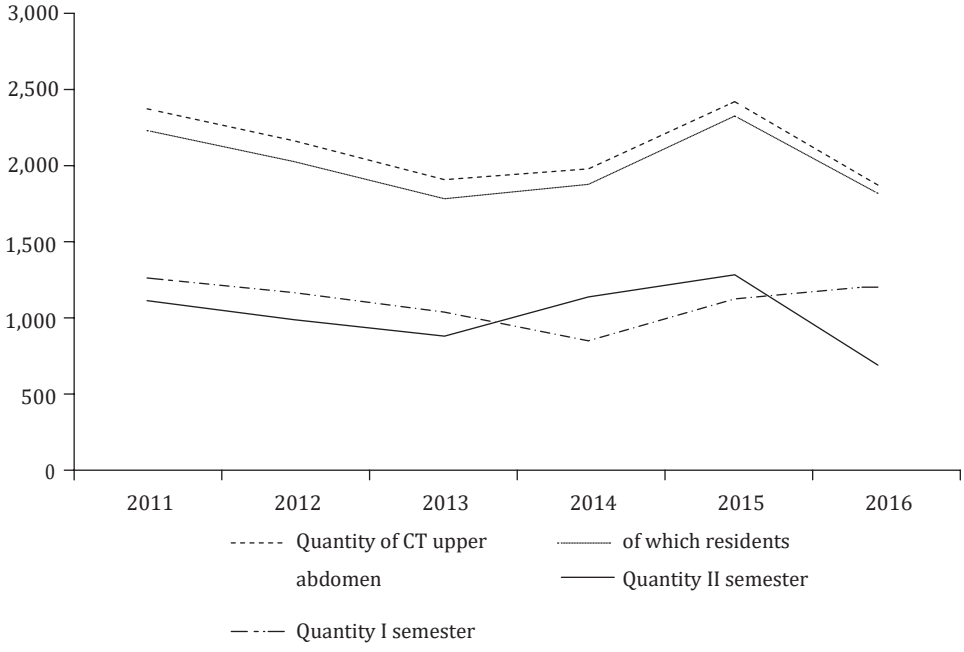

Fig. G.1_Turin. Trend in the volume of accesses to service no. 88.01.2 in Turin by the resident and non-resident population - Years 2011-2016.

Source: Calculations based on CSI Piemonte data (C flow).

G.2. *Computed tomography (CT) of the lower abdomen (with and without contrast) (88.01.4)*

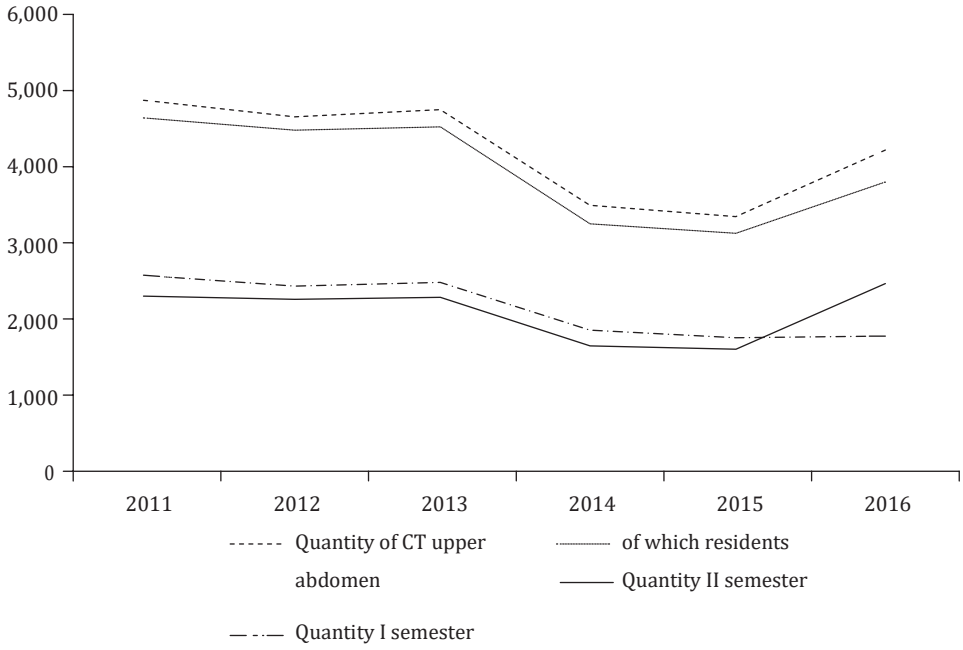

Fig. G.2_Tuscany. Trend in the volume of accesses to service no. 88.01.4 in Tuscany by the resident and non-resident population - Years 2011-2016.

Source: Calculations based on ARS Toscana data (SPA flow).

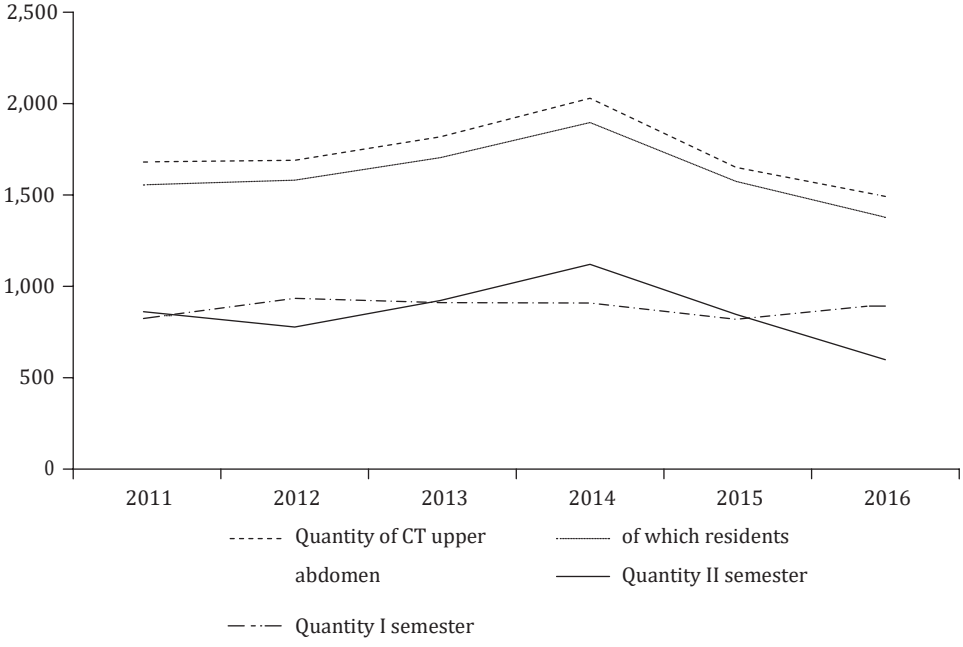

Fig. G.2_Piedmont. Trend in the volume of accesses to service no. 88.01.4 in Piedmont by the resident and non-resident population - Years 2011-2016.

Source: Calculations based on CSI Piemonte data (C flow).

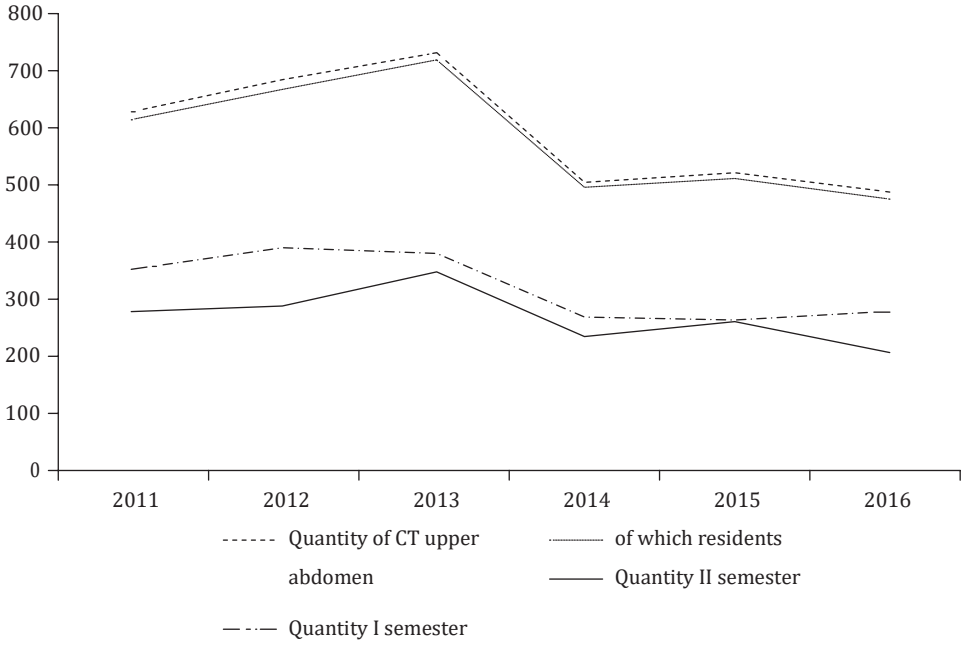

Fig. G.2_Florence. Trend in the volume of accesses to service no. 88.01.4 in Florence by the resident and non-resident population - Years 2011-2016.

Source: Calculations based on ARS Toscana data (SPA flow).

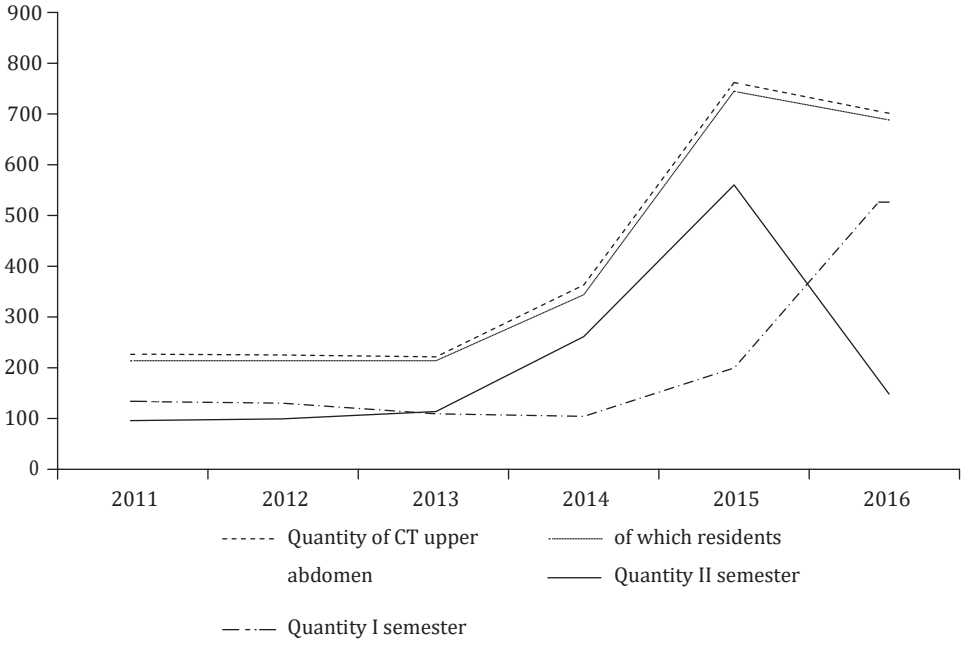

Fig. G.2_Turin. Trend in the volume of accesses to service no. 88.01.4 in Turin by the resident and non-resident population - Years 2011-2016.

Source: Calculations based on CSI Piemonte data (C flow).

H. *Data on single specialist outpatient services with low risk of inappropriateness provided in Piedmont and Tuscany in the period 2011-2016 (neurological examination, simple electromyography, psychiatric interview and psychiatric check-up)*

H.1. *Neurological examination (89.13)*

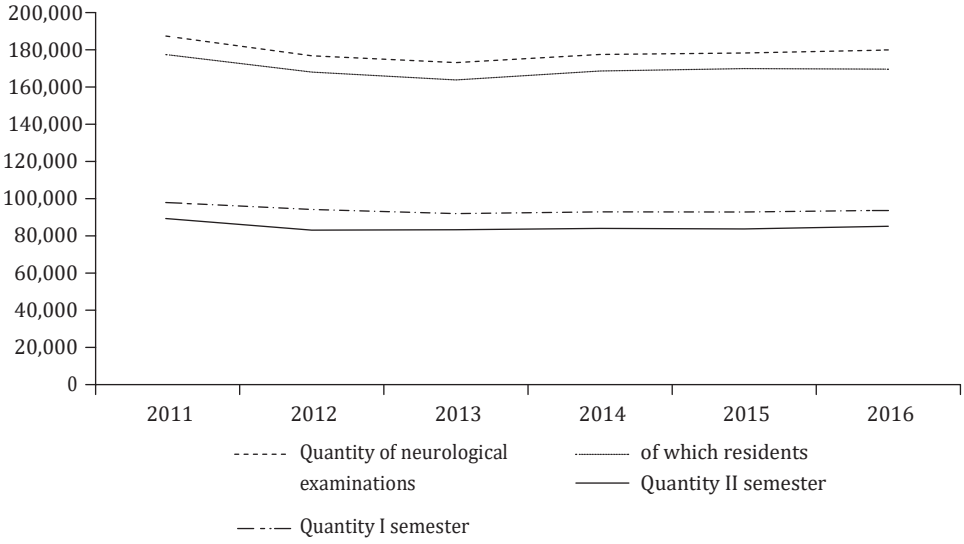

Fig. H.1_Tuscany. Trend in the volume of accesses to service no. 89.13 in Tuscany by the resident and non-resident population - Years 2011-2016.

Source: Calculations based on ARS Toscana data (SPA flow).

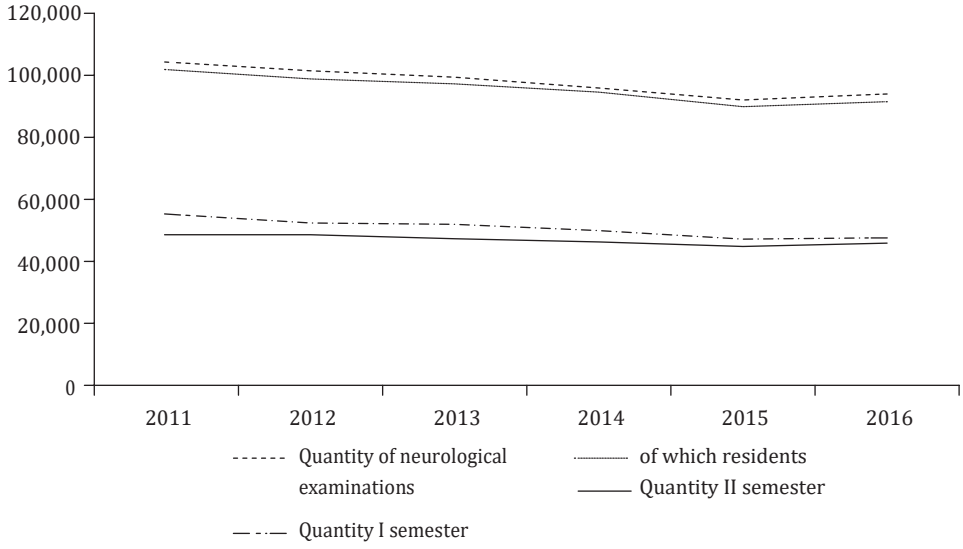

Fig. H.1_Piedmont. Trend in the volume of accesses to service no. 89.13 in Piedmont by the resident and non-resident population - Years 2011-2016.

Source: Calculations based on CSI Piemonte data (C flow).

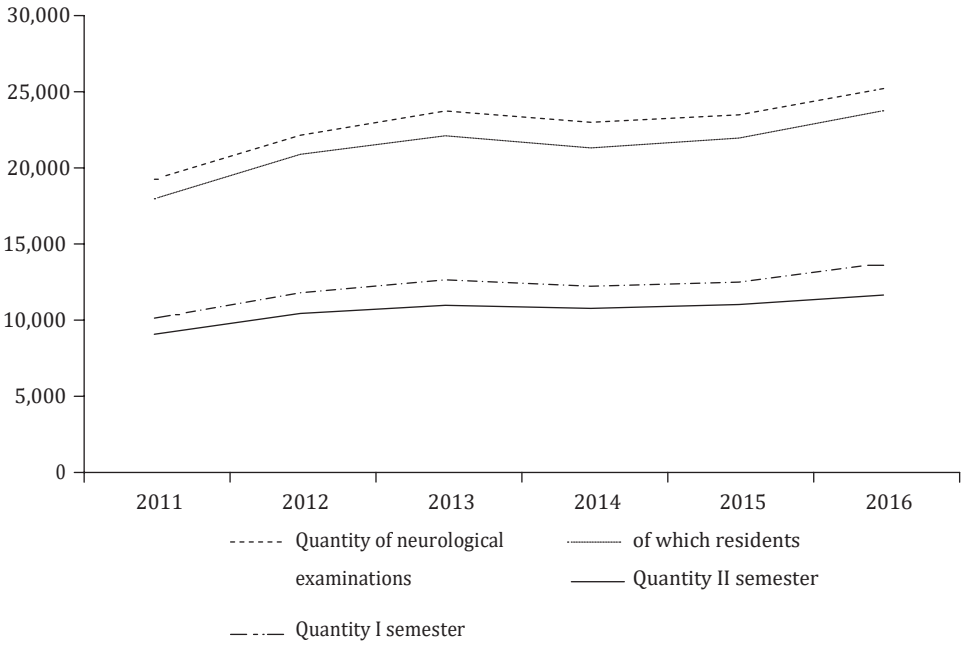

Fig. H.1_Florence. Trend in the volume of accesses to service no. 89.13 in Florence by the resident and non-resident population - Years 2011-2016.

Source: Calculations based on ARS Toscana data (SPA flow).

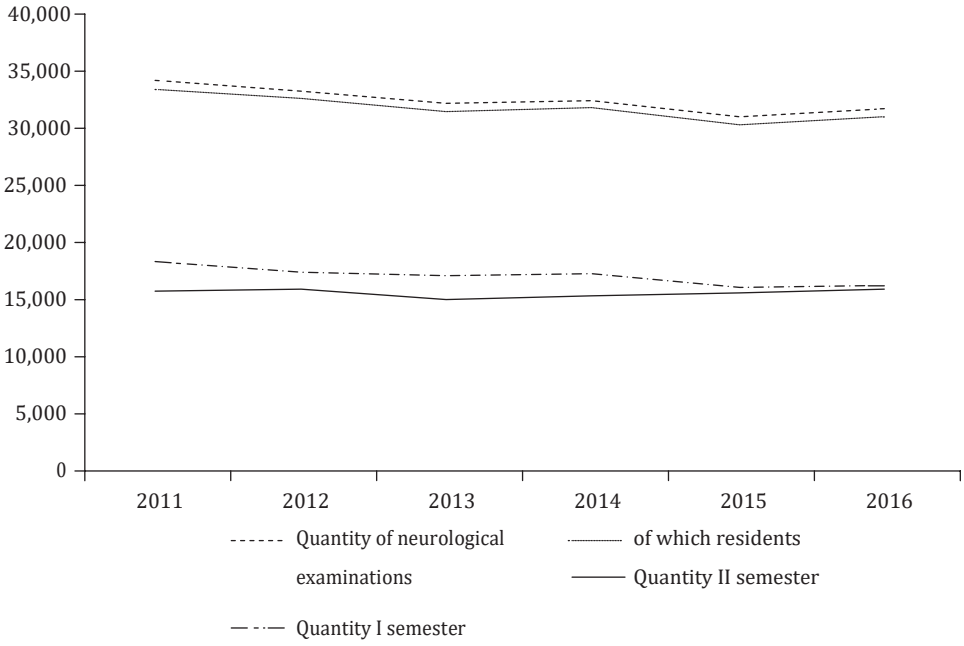

Fig. H.1_Turin. Trend in the volume of accesses to service no. 89.13 in Turin by the resident and non-resident population - Years 2011-2016.

Source: Calculations based on CSI Piemonte data (C flow).

H.2. *Simple electromyography (93.08.1)*

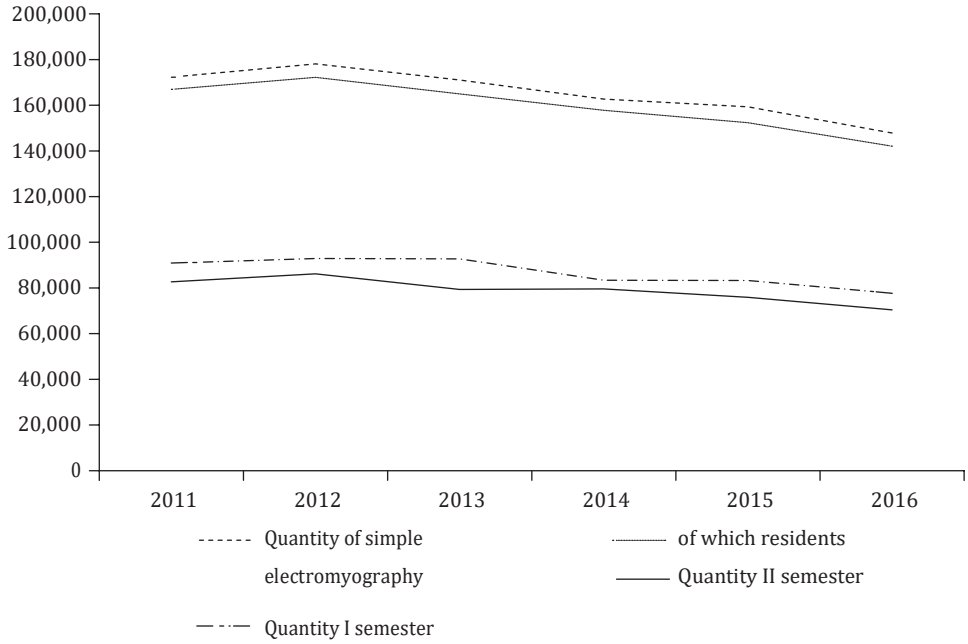

Fig. H.2_Tuscany. Trend in the volume of accesses to service no. 93.08.1 in Tuscany by the resident and non-resident population - Years 2011-2016.

Source: Calculations based on ARS Toscana data (SPA flow).

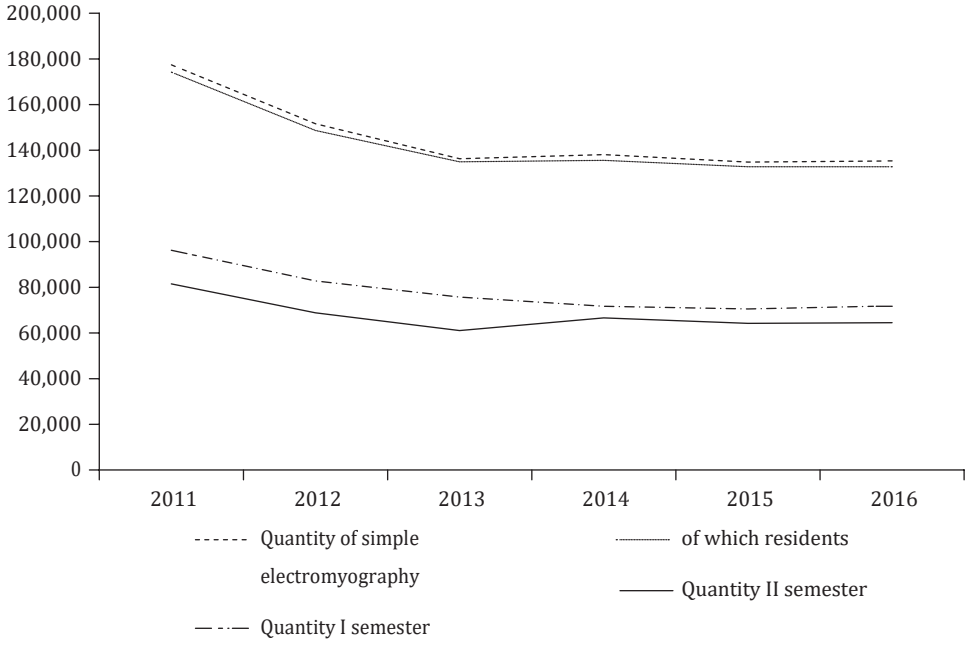

Fig. H.2_Piedmont. Trend in the volume of accesses to service no. 93.08.1 in Piedmont by the resident and non-resident population - Years 2011-2016.

Source: Calculations based on CSI Piemonte data (C flow).

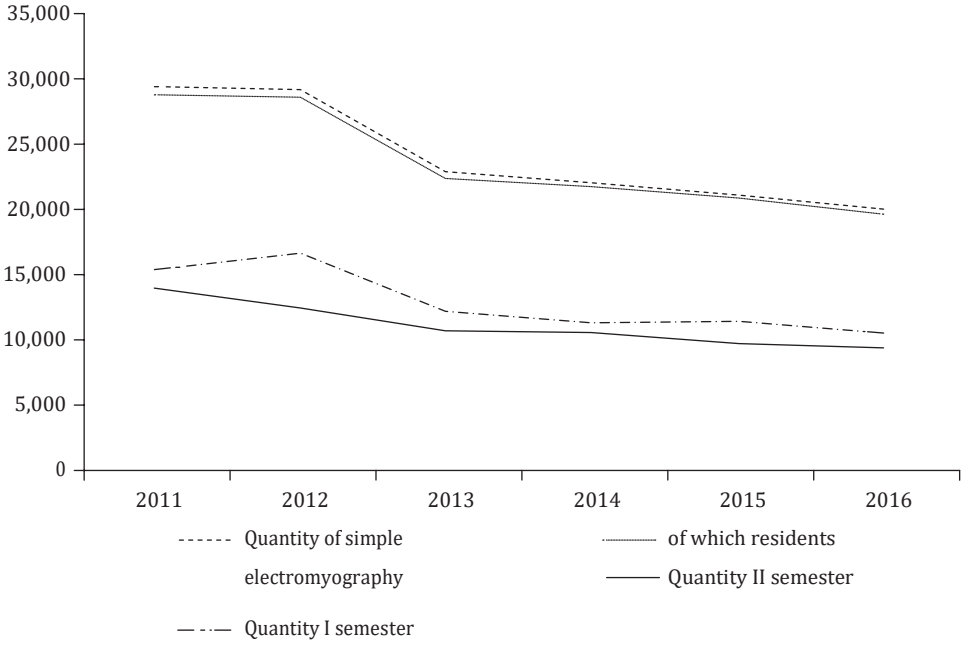

Fig. H.2_Florence. Trend in the volume of accesses to service no. 93.08.1 in Florence by resident and non-resident population - Years 2011-2016.

Source: Calculations based on ARS Toscana data (SPA flow).

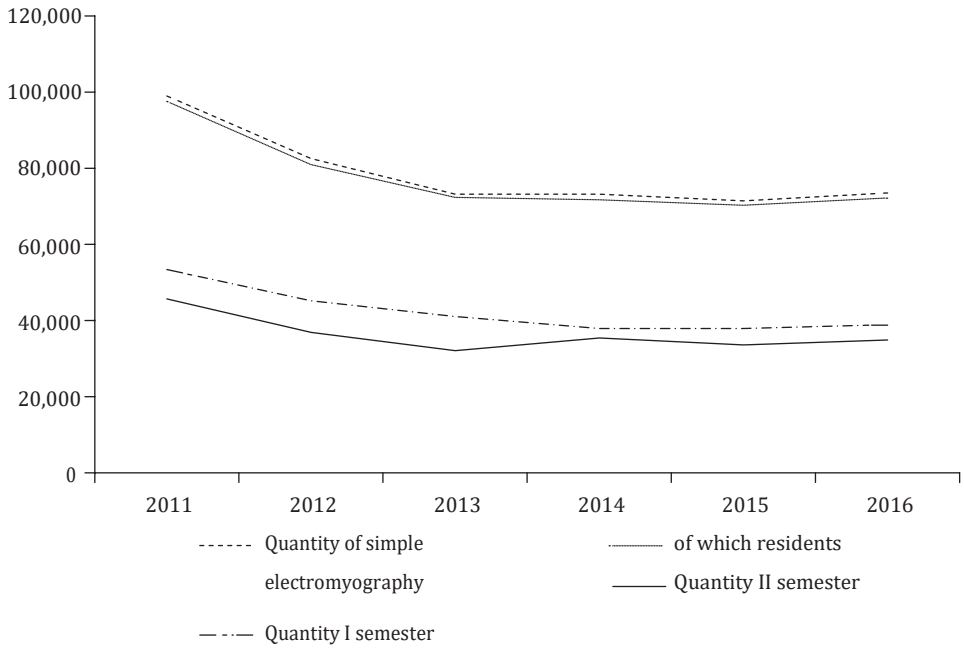

Fig. H.2_Turin. Trend in the volume of accesses to service no. 93.08.1 in Turin by the resident and non-resident population - Years 2011-2016.

Source: Calculations based on CSI Piemonte data (C flow).

H.3. *Psychiatric check-up (94.12.1)*

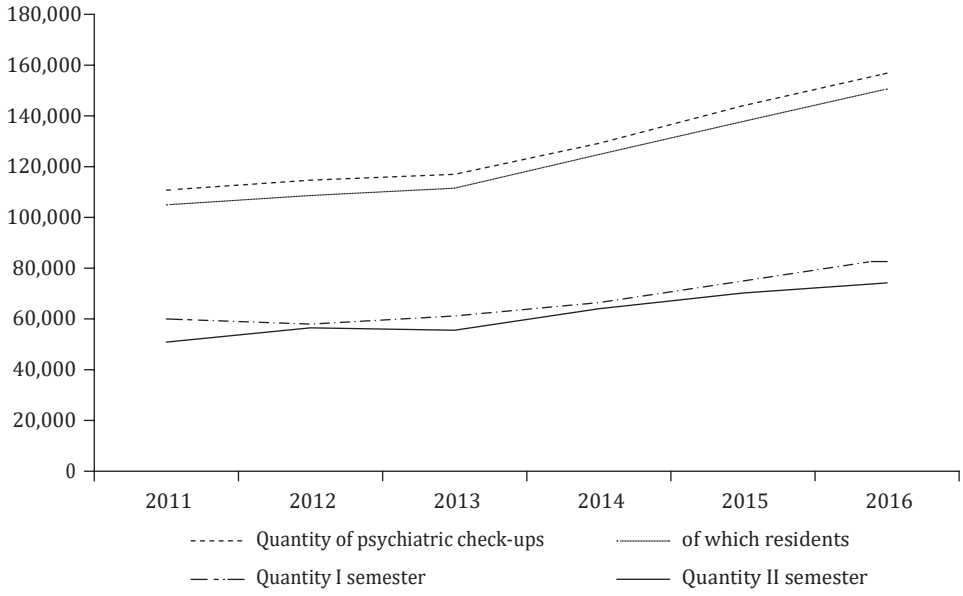

Fig. H.3_Tuscany. Trend in the volume of accesses to service no. 94.12.1 in Tuscany by the resident and non-resident population - Years 2011-2016.

Source: Calculations based on ARS Toscana data (SPA flow).

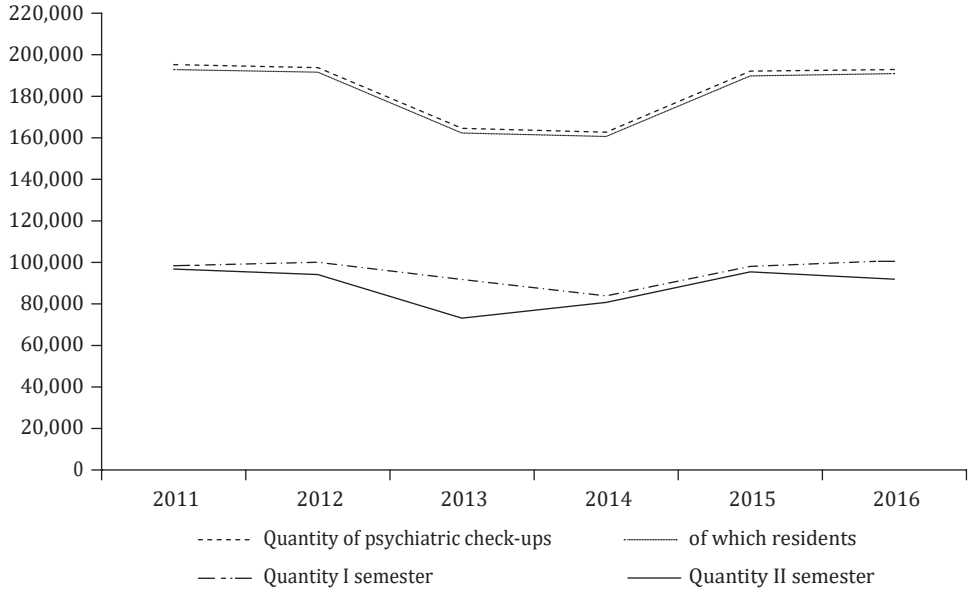

Fig. H.3_Piedmont. Trend in the volume of accesses to service no. 94.12.1 in Piedmont by the resident and non-resident population - Years 2011-2016.

Source: Calculations based on CSI Piemonte data (C flow).

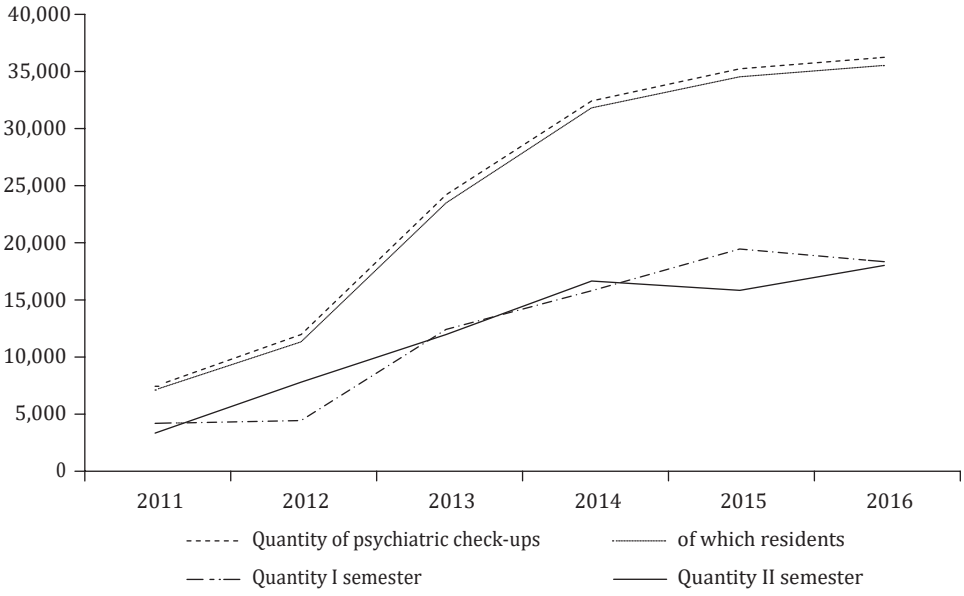

Fig. H.3_Florence. Trend in the volume of accesses to service no. 94.12.1 in Florence by resident and non-resident population - Years 2011-2016.

Source: Calculations based on ARS Toscana data (SPA flow).

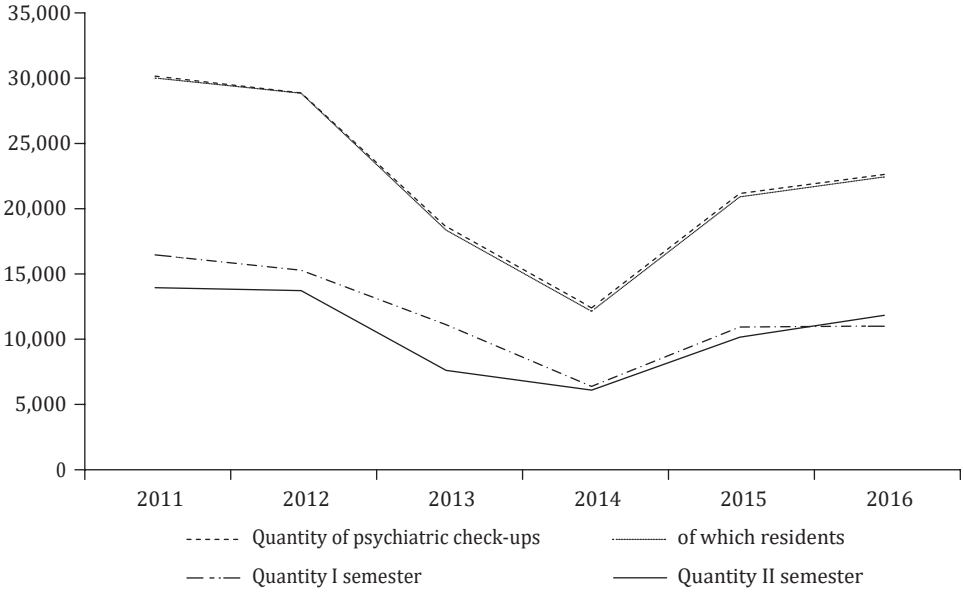

Fig. H.3_Turin. Trend in the volume of accesses to service no. 94.12.1 in Turin by the resident and non-resident population - Years 2011-2016.

Source: Calculations based on CSI Piemonte data (C flow).

H.4. *Psychiatric interview (94.19.1)*

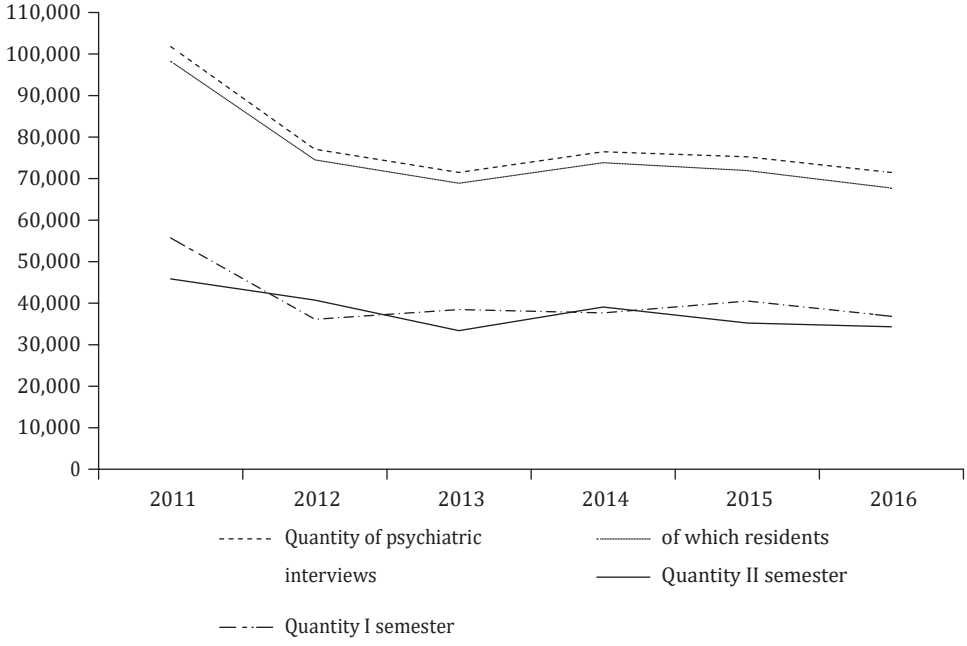

Fig. H.4_Tuscany. Trend in the volume of accesses to service no. 94.19.1 in Tuscany by the resident and non-resident population - Years 2011-2016.

Source: Calculations based on ARS Toscana data (SPA flow).

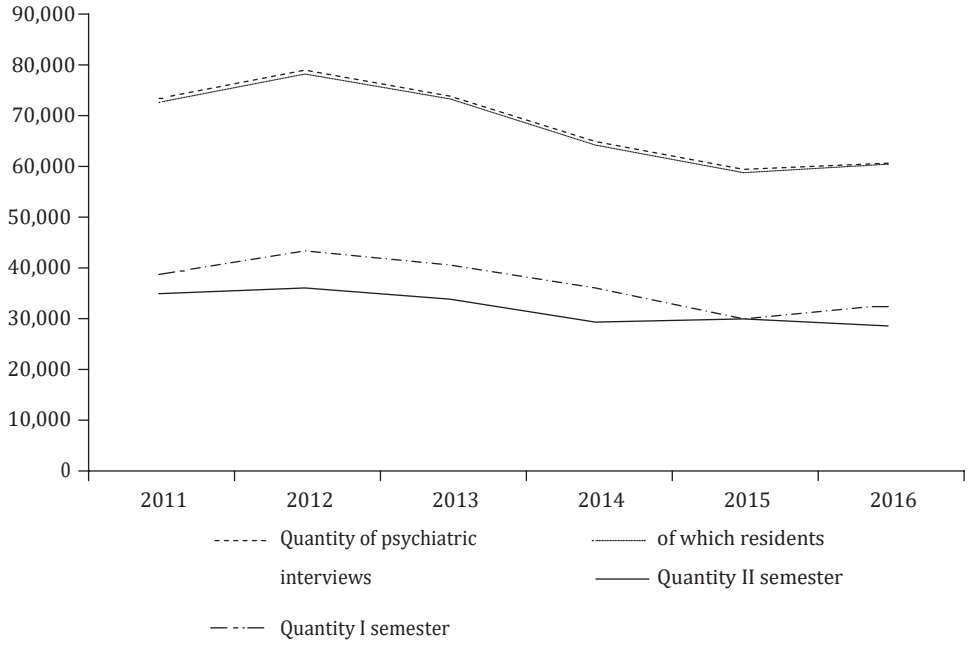

Fig. H.4_Piedmont. Trend in the volume of accesses to service no. 94.19.1 in Piedmont by the resident and non-resident population - Years 2011-2016.

Source: Calculations based on CSI Piemonte data (C flow).

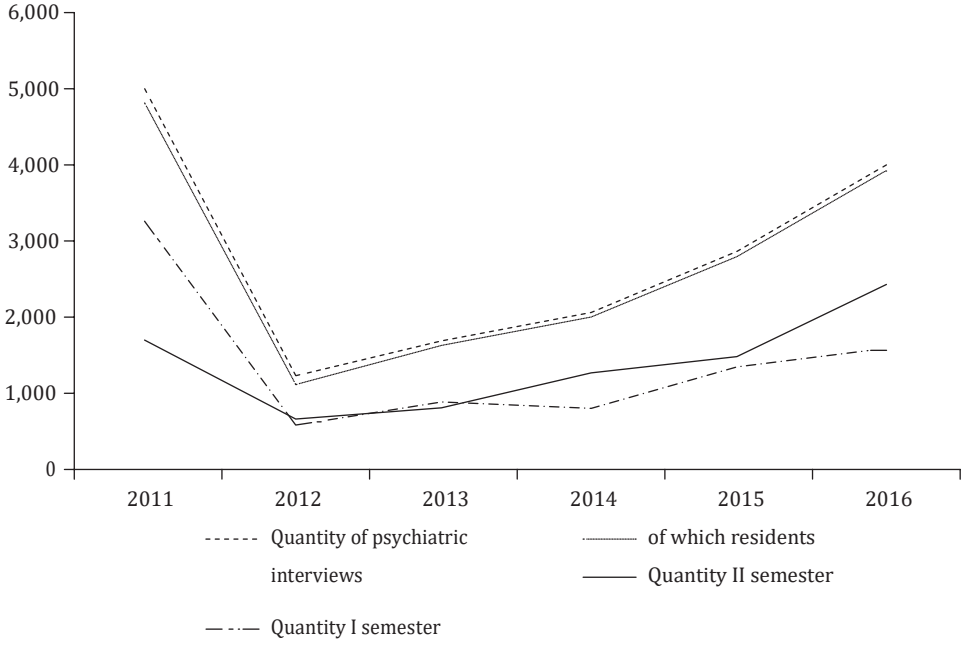

Fig. H.4_Florence. Trend in the volume of accesses to service no. 94.19.1 in Florence by resident and non-resident population - Years 2011-2016.

Source: Calculations based on ARS Toscana data (SPA flow).

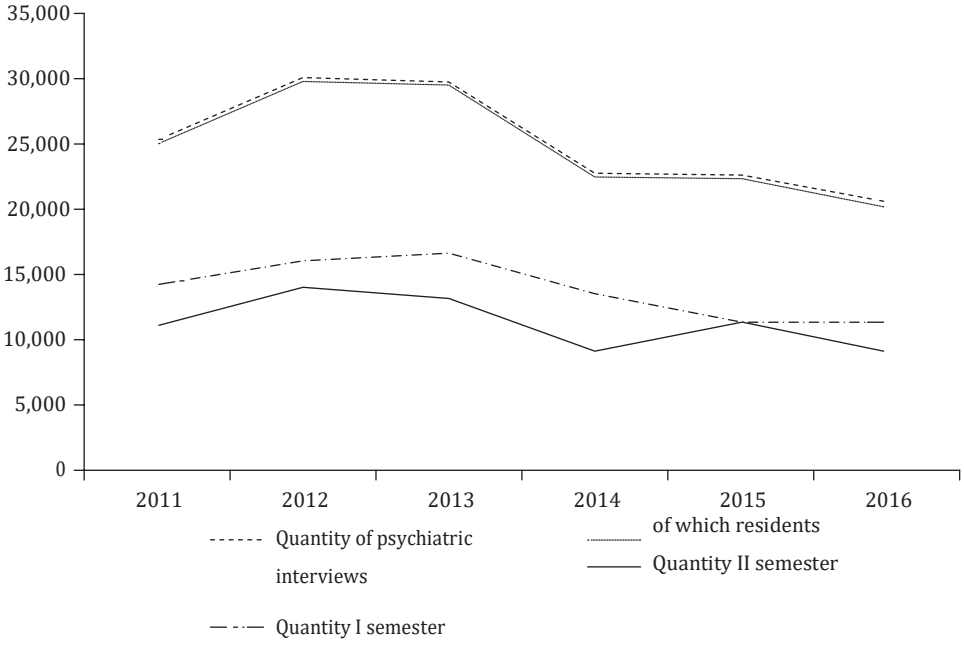

Fig. H.4_Turin. Trend in the volume of accesses to service no. 94.19.1 in Turin by the resident and non-resident population - Years 2011-2016.
Source: Calculations based on CSI Piemonte data (C flow).