LABORATORIO DEI DIRITTI FONDAMENTALI

Informed Consent in the Medical Field: an anthropological and juridical study

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The Laboratorio dei Diritti Fondamentali (LDF) began operating in Torino in 2011. The Laboratorio carries out research into fundamental rights, with particular attention to the practical nature of safeguards in place during the various moments, places and occasions in the life of the population. The Laboratorio, in accordance with the teachings of the European Court of Human Rights, deals with "concrete and effective rights, not theoretical and illusory ones". Through its research, the Laboratorio intends to offer suitable and feasible solutions on the basis of experience or suggested by interdisciplinary studies of human rights.

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This work is the fruit of shared work and constant interdisciplinary discussion. The introduction and the conclusions are a collective product.

- The first chapter was written by Camilla Fin.
- The second chapter was written by Chiara Quagliariello.
- The third chapter was written by Chiara Quagliariello.
- The fourth chapter was written by Chiara Quagliariello.
- The fifth chapter was written by Chiara Quagliariello.
- The sixth chapter was written by Camilla Fin.
- The seventh chapter was written by Camilla Fin.
- All the tables and the graphs were prepared by Chiara Quagliariello.

Contents

This research project, promoted by the Laboratorio dei Diritti Fondamentali, continues the group's previous work in exploring a number of aspects of the right to health, which is guaranteed by the Italian Constitution and by the numerous declarations and international and European conventions to which Italy adheres. As with the previous projects, alongside the examination of the pertinent legal aspects, it deals with the more practical questions. It is the specific intention of the Laboratorio dei Diritti Fondamentali to investigate the materiality of human rights, comparing it with legal declarations and clarifying the reasons for the differences that exist between these two planes. According to a felicitous formula adopted by the European Court of Human Rights and repeated by the Laboratorio, it is necessary to protect "concrete and effective rights, not theoretical and illusory ones". The theoretical and illusory rights are those guaranteed by the normative texts, which never become concrete and effective in the lives of the people.

Consequently, the research into "informed consent to medical treatment" was entrusted to two researchers with very different specialisations. Chiara Quagliariello is an anthropologist with extensive experience in the field of healthcare in Italy, France and Senegal, while Camilla Fin is a civil jurist with a strong link to the German juridical culture. The interest in working together shown by the two researchers has avoided their writings becoming mere juxtapositions that do not substantially interact.

The purpose of the research, or rather the reason that led the Laboratorio to promote it, apart from the evident interest of the subject, was that of verifying how the doctor-patient dialogue was effectively developed, the understanding and aware acceptance by the patient of the treatment proposed, the establishment of the therapeutic alliance. The inquiry into the separation sometimes found between the effective situation and the indications of the normative texts and the jurisprudence was very useful when it identified the reasons; reasons that are increasingly numerous and concurrent, and all the more interesting the less they were linked to the individual inattention that can characterise the work of this or that doctor on specific occasions. In fact, it is worth identifying and emphasising above all the structural reasons of hospital organisation, the often highly technological content of the diagnosis and treatment, the collective (but also fragmented) nature of the medical services offered in hospitals, the personality of the patient with their state of health, their culture, emotions and age, without neglecting the importance – at times decisive – of the role played by the family who accompanies them. All these elements explain the (insuperable?) gap between the rules – by definition general and abstract – and the reality experienced by the individual patients in the extreme variety of practical cases. The research therefore dealt with the question in very different hospital departments: from the urgencies of general medicine to organ

harvesting to transplants, from gynaecology and obstetrics to paediatrics, from intensive care to psychiatry, obviously discovering the profound differences in the situations that the doctors must deal with.

The jurist reacted to the information discovered by the anthropologist, expounding the law, also comparative law, relating to informed consent. The set of contributions supplied by the two authors offers fertile ground for those who want to examine the reasons that make full implementation of the law that should guide informed consent possible. The lack of importance that patients assign to the moment in which the doctor supplies information and their consent to treatment is extremely important, as is the fact that protests about the quality of the information supplied prior to the granting of consent are almost non-existent; although we cannot therefore draw the conclusion that what we read in the law books is perfectly enacted in real life. There is a generally different effectiveness, motivated by reasons other than personal will or the attitude of the individual doctor in the concrete case: an effectiveness that is a right because it seems to be supported by genuine sharing and awareness. In fact, when a controversy arises, the external legal intervention based on the law is seen as an incomprehensible interference. With regard to this aspect we can report the emergence in the practice of medical deontological rules potentially contrasting with legislative rights. These are linked to the history of the medical profession and the deontological code, which should rightly succumb to the law. Nonetheless, in this respect these rules show greater efficacy in the doctor-patient relationship. The ancient set of duties of the doctor, the medical deontology (being inferior to the law in the traditional hierarchy of the sources, should purely and simply bow down to it) define the nature of the profession, which is reluctant to be caged by the fixed forms of the law, by insurance contracts and legal arguments. Profiles relating to the humanisation of the therapeutic relationship seem at times to contrast with the patients' need for information and yet there is a demand for genuine informed consent, which is in turn a condition of self-determination and respect for individual dignity.

The jurist who recognises and appreciates the plurality of legislations, seeing the wealth of values that they express, perceives an interesting area of study. Often the difference between the law and the reality cannot therefore be dealt with in terms of legality/illegality, since we are not dealing with a negative act by someone operating illicitly, but rather the prevailing of another order of needs, values and history of the society in which the vicissitudes of the patient and the doctor are included.

How can we classify in terms of legislative rights the history, registered by the anthropologist author, of the elderly patient, who depends on the family after an operation and asks that the decisions be taken by the relatives who will have to bear the burden of care and guarantee them assistance? This shows the reality of the everyday organisation of the family groups, of the

dependency, but also of the trust that the older generation places in the younger members of the family, who take care of their needs and are often better prepared in understanding the information provided by the doctor.

The research – above all in the field work, carried out on the hospital wards of the Città della Salute e della Scienza di Torino – was made possible by the support offered by the hospital and university authorities of this institution. The Laboratorio dei Diritti Fondamentali would like to thank them. However, the research could never have investigated the reality of the experience studied in such depth if it had not been for the continual, open and cordial willingness of the doctors and the nursing staff, who welcomed the inquiring eye of the anthropologist, foreign to the situation, but so easily accepted and assisted in her work. The willingness to be 'investigated' and at times the request to be so, shows not only a great civic sense of the public service, but also how seriously and importantly the duty (and the problem) examined by the study is seen to be.

VLADIMIRO ZAGREBELSKY

This volume is the result of research into informed consent in the medical field and differs from other studies on the topic inasmuch as it was carried out from two distinct – but constantly coordinated – perspectives: the anthropological and the juridical. In fact, the work intends to highlight the discrepancies between the concept of the doctor-patient relationship as presented by jurisprudence and by doctrine, the effective declination in daily healthcare practices and the occasional inadequacies of the system in the process of acquisition of informed consent of the patient.

This research project was possible thanks to the close correlation between the work of Chiara Quagliariello, who after observing the procedures for acquisition of informed consent on the wards of the hospital *Città della Salute e della Scienza* in Torino for more than one year, carried out an anthropological examination of the material gathered. Her work included observations in the clinics and on the wards, recording interviews, carrying out anonymous studies of medical records, analysing statistical data relating to complaints by patients, semi-structured interviews (192 in all) with health care workers (doctors, nurses, midwives, psychologists, social workers and cultural mediators), the patients and their relatives and that of Camilla Fin, who carried out the juridical inquiry examining the doctrine and the jurisprudence (both Italian and foreign) on the question of consent to medical treatment, which are seen as a complication in hospital practice.

Initially, the volume highlights the way the emergence of the conviction that the patient must give informed consent to medical treatment has overcome a paternalistic attitude in favour of a therapeutic alliance between the subjects involved. After illustrating the reasons that have determined this evolution in the doctor-patient relationship – that is the scientific and technological progress which has connoted medicine in recent decades and the greater awareness of the users of the medical services, thanks to the spread of communication tools – the authors consider the normative basis of the principle of informed consent in national law and in supranational jurisprudence.

In particular, since Italian law lacks regulations of a general nature on informed consent, this normative basis was reconstructed through a systematic analysis of the legislation that, at various levels, refers to this principle. The volume examines constitutional regulations on matters of personal freedom and the right to health (Articles 13 and 32 of the Italian Constitution), the jurisprudence of the Italian Constitutional Court, which is based on these articles, certain fundamental Italian laws (for example Law 194/1978; Law 180/1978; Law 40/2004) and finally, the medical deontological code.

With regard to supranational law, the analysis maintains conceptually distinct the tools that refer to the informed consent of the patient identifiable as *soft law* – concentrating above all on the

principles contained in the Nuremberg Code of 1974 and the Declaration of Helsinki (DoH) of the World Medical Association in 1964 – from those tools that are legally binding. Amongst the latter, particular attention was paid to the European Convention on Human Rights and Fundamental Freedoms of 1950 (now ECHR), together with the jurisprudence drawn up by the European Court of Human Rights, the Oviedo Convention on Human Rights and Biomedicine of 1997 and the Nice Charter of 1997.

Subsequently, starting from the results of the anthropological research the authors reviewed the difficulties encountered by the medical personnel in responding to their new duty to inform the patients of the proposed treatments, the risks and the possible alternatives before proceeding with any diagnostic tests or therapies. The questions examined in Chapter III refer to the transverse or *systemic* problems, not linked to specific clinical situations. The recurrence of the elements described permitted the authors to consider them structural or physiological limits, *independent* of the will of the individual health worker. These were summarised in two macro categories: 1) factors linked to the characteristics of the hospital procedures (the speed of the hospital procedures, lack of time to talk to the patients, lack of suitable places to talk to the patients, the increasing numbers of sick people to be treated every day, limits set by the patients' urgent need for treatment; 2) factors linked to the way in which informed consent should be gathered (the complex vocabulary used in the informed consent forms, lack of standardisation in the forms of oral consent, fragmentation of the informative process offered to the patients, the complexity of gathering of 'multiple consents', the absence of cultural and linguistic mediation in order to overcome language barriers in the case of foreign patients). In the light of the many obstacles encountered by the medical personnel in informing the patients, the question that recurred continually was how far the consent demanded of the patients *could possibly be* informed.

In continuity with the previous chapter, the analysis proposed in chapter IV highlights the difficulties encountered during the process of informing patients for other reasons. A primary problem is the question of *how far* it is possible or right to inform the patients. A second problematic question is represented by the choice of *who* to inform, together with, or instead of, the patient. Through the restitution of various stories from patients, the analyses proposed in this chapter attempt to show the frequent discrepancies between the principles promoted by informed consent, such as the principle of *autonomy* and that of the patient's *self-determination* with regard to decisions, and the effective interactions between the medical staff and the patients. To what extent can knowledge of the illness be shared with the patient? Do the doctors always have complete and thorough information regarding the risks of the therapies proposed? To what extent does the informative process involve only the doctor and the patient? By reviewing the problems presented, together with the *content* of the information to be transmitted to the patients and their relatives (the

passage from active treatment to palliative care in oncology, information regarding end-of-life treatments, communication of the death of a patient, the request for consent to the removal of organs, tissues or cells, information on risks that cannot always be foreseen during birth, to give just a few examples) and the possible *degree of involvement* of the patients in the therapeutic decisions (the analyses proposed concern, in particular, incapable or disabled patients, psychiatric patients, paediatric patients, adolescents, elderly patients who depend on their relatives, women accompanied by their partner during meetings with the gynaecologists) the chapter gives an answer to these questions.

Unlike chapters III and IV, chapter V examines the informative process for the gathering of consent in the light of *dependent* factors or those linked to the profile of the healthcare workers. The analysis proposed in the first part of the chapter emphasises that the investment in informing patients is a phenomenon that does not involve all the healthcare workers in the same manner. The time taken for interviews and the gathering of informed consent varies according to the position held within the hospital hierarchy. Usually, the more important the position held by the professionals, the less time they dedicate to informing the patients. The tendency observed within the hospital space is, in other words, that of a *downwards delegation* of the activity of informing the patients. Thus, in many cases, the person who informs the patient is a nurse who will neither carry out the treatment, nor sign the consent. Nevertheless, the need to avoid falling into a rigid *care* vs *cure* conflict is emphasised in all those cases in which the relationship of *care* offered by the nurses and the clinical assistance (*cure*) usually guaranteed by the doctors is inverted. Apart from the position occupied in the hospital hierarchy, much depends also on the *professional philosophy* of the individual health worker. This aspect means that in many cases, informing the patients is a terrain of opposition between the professionals involved in defending public medicine that is *humanitarian* or *humanist*, that is to say, based on the needs of the person as a whole, and those who see the informative activity as a secondary aspect with regard to the operative dimension of hospital care; or the commitments linked to the private practice in which they are involved outside their hours at the hospital.

The second part of the chapter emphasises the way the *quantity* and the *quality* of the information transmitted by the health workers are often linked to the biographical, social and cultural characteristics of the patients. Through a study of the factors that lead to the selection of the patients with whom it is considered worth spending time on an in-depth discussion – such as the degree of instruction, social class, the network of personal acquaintance or the nationality of the patients – the authors emphasise the extent to which the characteristics of the doctor-patient dialogue are closely linked to the phenomenon of social inequality within the hospital; from which derives the need to critically consider the forms assumed today by the so-called *health democracy.*

The last part of chapter V concentrates on the opinions of the patients as expressed during the interviews. When asked to describe the purpose of informed consent, some patients stressed that it is, in their opinion, a mere *administrative formality*. For others, the consent forms have legal value and are used by the doctors to protect themselves against any medical-legal problems. The question of strengthening *defensive medicine* is often flanked by the idea that, apart from safeguarding the doctors, informed consent is a practice that has little use for patients. In some cases, the patients interviewed emphasised that this procedure does not encourage greater dialogue with the doctors, since the time taken for reading the forms is minimal and the language used is often incomprehensible for the patients (see chapter III). In other cases, the patients stressed that the recourse to informed consent only partially guarantees greater freedom of choice, which depends first of all on the clinical situation. In yet other cases, the patients insisted on the fact that their level of information depends only partially on the explanations received during the interviews with the medical personnel before signing the consent forms; much of their knowledge of the illness and the possible treatments comes from other sources (experiences of family members or friends, Internet searches, conversations with other patients in the hospital).

At the same time, although we increasingly hear of *autonomous* patients who are *responsible* for their own choices, many patients seemed to present an attitude of total trust in the medical personnel. In some cases, the choice of not knowing translated into an automatic acceptance of the opinion of the medical staff and the signing of the informed consent "on the basis of trust". In other cases, the reliance on the therapeutic choices of the medical personnel was linked to the recognition of an asymmetry between their own knowledge and that of the medical professionals. The decision to trust the opinion of the doctors and the need to receive their advice on the procedures shows to what extent the principle of self-determination of choices by the patient is effectively exercised. On the other hand, although the patients have the opportunity to negotiate the characteristics of their healthcare and can make use of various tools to refute the suggestions of the medical personnel, these tools are only used by patients in a very few cases. The rate of refusal of the therapies proposed by the doctors – corresponding to less than 5% during the period in which the research was carried out – is a clear example of this situation. The same is true for the choice to withdraw consent after the therapies have started, or after agreeing to surgery. In none of the cases analysed was it possible to observe this type of choice by the patients. Finally, the sharing of an idea of medicine in which the role of the doctors is above all to take the best possible care of the patients' health was emphasised by the relative importance assigned to the problems that exclusively concern the information for patients. With regard to this aspect, amongst the reports made by patients to the tribunal for patients' rights in Torino and the Public Relations Office (URP) at the *Città della Salute e della Scienza*, those concerning lack of information for patients were 3.3% of complaints in 2013,

4.1% in 2014 and 4.6% in 2015. Comparison with the topics that are more widely reported shows that the questions of most interest for patients are the quality of service (waiting times) and the guarantee of physical safety thanks to the efficacy of the treatment (technical-health aspects and reports of medical errors).

After illustrating the principal difficulties seen to characterise the doctor-patient relationship at the time of the acquisition of informed consent, the legal analysis of the requisites that should, in theory, connote this consent to treatment are examined, with the aim of showing the response of the regulations to the practical problems highlighted by the anthropological study.

In effect, the analysis of the principal characteristics that must connote the patient consent allowed the authors to illustrate the jurisprudential and doctrinal guidelines that have arisen with regard to particularly controversial questions.

More precisely, they examined the aspect of *preventive information*, and here illustrate the content of the information that the doctor must give the patient, and how this varies according to the type of procedure to be undertaken, the type of patient and the moment in which the information is transmitted. From this point of view, a comparison was made with German legislation, since the solutions adopted by the new laws on the improvement of patients' rights could offer a clear example for the Italian legislator, inasmuch as the regulations clarify the characteristics that the consent to medical treatment must have and the time needed for its acquisition.

Secondly, the examination of the requisite of the *capacity* to express consent to medical treatment allows the authors the opportunity to discuss the situation of minors and in particular to consider the importance that their manifestation of will has in the process of acquiring consent when the patient is an adolescent (that is a person capable of consciously deciding with regard to their therapeutic choices). A further problematic aspect considered is the identification of the subject authorised to take decisions regarding the health of a minor when there are a number of figures who must guarantee their safety (the parents and the doctors). In particular, the situations in which the manifestations of will must come from either only one of the parents or from both are examined, and cases in which there is a disagreement regarding the treatment to be carried out on a minor between the parents with parental liability, or between the parents and the doctors are discussed.

Subsequently, the volume considers the cases of interdicted patients and patients who have granted power of attorney. In particular, a distinction is made between the possibility that the patient is completely unable to understand the effects of the choices concerning their health, and a situation in which they are at least partially incapacitated.

With reference to the first of these two situations, the authors illustrate the jurisprudential guidelines which, under certain conditions consider it possible for the legal representative of the interdicted person or the holder of the power of attorney, to express consent or to refuse medical care on behalf of the patient, also where this manifestation of will may lead to the death of the person represented.

With regard to the second possibility, that is when the patient is at least partially capable of power of judgement, the question of who should give consent to treatment (the patient or their legal representative) is considered and we become aware – thanks to the systematic reading of a series of rulings scattered throughout Italian legislation – of an independent legitimation of the incapacity to express personal choices regarding our right to health.

Finally, the authors consider – again in relation to the capacity to express consent – the case of the subject who is naturally incapable, that is those who although not legally interdicted, but for transitory reasons are unable to fully decide with regard to their health. In this case, the study shows that – in the absence of any rulings on the subject – it should be possible to attribute a decisive role in the manifestation of consent to the natural protectors, that is the persons closest and dearest to the patient, and (above all) to the doctor who holds a position of guarantee with regard to the patient.

The last of the requisites of the consent to medical treatment taken into consideration is that of the *actuality*. On this point, the authors have especially analysed the paradigmatic case that has involved Italian jurisprudence with regard to the actuality of refusal of treatment, that is, the case of the Jehovah's Witnesses who, while unconscious manifested their refusal of blood transfusions that would save their lives, by means of a card saying "no blood". With reference to the possibility for the healthcare worker to consider this method of refusing treatment efficacious or not, the authors illustrate the two existing guidelines in Italian doctrine and jurisprudence. According to the first, the activity of the doctor who intervenes against the will of the patient to save their life should be considered justified by necessity, while vice versa, the second gives absolute pre-eminence to the refusal expressed by the patient (when this refusal has not been revoked) thus considering the blood transfusion carried out by the doctor against the patient's wishes illegitimate.

In conclusion, chapter VII of the volume looks in depth at the problem of the civil liability of the doctor who carries out treatment in the absence of consent from the patient, or in the presence of their explicit dissent.

Above all, the question of the juridical nature of the liability of hospital doctor is considered, observing how between the theories that qualify this figure as contractual and those that consider it extra-contractual, the latter is to be preferred, not only in view of the regulations contained in the recent Law 189/2012 (*Legge Balduzzi*) and the new bill with the *regulations regarding the professional liability for healthcare workers*, but also in the comparative analysis of the jurisprudence from the French courts, which, after a series of oscillations, seem to have settled on the reconstruction of the liability of the hospital doctor in extra-contractual terms.

After these explanations, the authors examine the various types of harm that could derive from the lack of, or insufficient, information for patients, distinguishing in particular between the violation of the right to health and the violation of the patient's right to self-determination. For both cases, the authors examine in depth the conditions necessary for its configuration, the sharing of the burden of

proof between the parties and the criteria that the jurisprudence follows in their determination. In particular, with reference to the harm due to violation of the right to self-determination, for which part of the doctrine and the jurisprudence denies independent compensation, the authors carried out a comparison with the French and Spanish legislation, in order to show that the tendency to award compensation also in Italian legislation is preferable, providing there is serious prejudice and the violation exceeds a certain level of offensiveness.

Subsequently, the authors examine specific profiles of liability for violation of the rule of informed consent that may involve certain categories of doctor: the gynaecologist and the plastic surgeon.

With reference to the gynaecologist, they examine the case of the doctor who does not note foetal malformation in an ultrasound scan, or who does not inform the pregnant woman, thus depriving her of the right to choose an abortion. In particular, they try to answer the question of whether the birth of a child affected by malformations or disabilities as a consequence of the mother's decision not to abort, can be considered prejudicial to the child itself or to the parents. With reference to the first aspect, the volume illustrates both the jurisprudence inclined to accept the claim for compensation presented by the child against the doctor, and that – recently approved also by the Joint Sections of the Italian Court of Cassation – which, on the contrary, considers non-existent any harm to the foetus directly attributable to the doctor and therefore liable for compensation from the same, further illustrating the reasons (including the particular importance of the comparison with German, French and British legislation) according to which the second solution must be considered preferable. With regard, on the other hand, to the material and non-material harm suffered by the mother due to the birth of a deformed or disabled child, the authors illustrate the conditions under which the most recent jurisprudence considers it possible for the parent to claim compensation from the doctor, looking in particular at the techniques for demonstrating the causal link between the lack of information and the harm.

With regard to the figure of the plastic surgeon (aesthetic surgery), particular attention was paid to the aspects that characterise this branch of medicine with respect to the general system of medical liability: that of the extension of the informative obligation to which the doctor is subject, and that relative to the criteria used by jurisprudence to ascertain the causal link between the violation of the obligation to inform and the harm to the patient's health.

In conclusion, the volume deals with the two exceptions existing in Italian legislation to the doctors' obligation to acquire informed consent from the patient: compulsory and emergency medical treatment. With regard to the former, the authors illustrate the limits that the Constitutional Court has identified in relation to the possibility for the legislator to foresee these treatments and the ways in which they should be ordered. With regard to the state of medical necessity, the various reconstructions proposed by the doctrine and by jurisprudence in relation to the justification for the

medical treatment are examined and the authors also propose some examples of practical application of this discrimination.

Chapter One

From Medical Paternalism to the Principle of Informed Consent

1. *The paternalistic model*

Over recent decades, the doctor-patient relationship has been characterised by a progressive abandonment of the paternalistic conception of medical activities in favour of a therapeutic alliance between the subjects involved in the healthcare relationship.

The traditional model of medical paternalism[1] fully devolved on the medical personnel, considered the exclusive holders of the necessary knowledge for treating the individual, responsible for all decisions regarding the course of the illness and the treatments to be used, and the

1 On the general concept of paternalism See also R. Caterina, *Paternalismo e antipaternalismo nel diritto private,* in Rivista di diritto civile, I, 2005, pages 771 *et seq.*, which referring to the definition given by F. Casentino, *Il paternalismo del legislatore nelle norme di limitazione dell'autonomia dei privati,* in Quadrimestre, 1993, page 120, describes it as "the privation or considerable reduction of the individual's freedom of choice, enacted by the system in order to ensure particular protection of the person, or of an entire category of persons, against acts contrary to their interests".

assumption by the patient of the role of passive subject ready to allow others to manipulate their body[2].

The basis of medical paternalism was both a particular conception of the tasks delegated to the medical class, and a specific ethical model (that of beneficence) in the field in which the function of the healthcare worker was collocated.

With reference to the first of these aspects, the fact that illness is now seen as an event susceptible to analysis and scientific knowledge – and not as a strictly mythical and religious phenomenon, within which the medical practitioner only had the task of *helping* the sick person to get better and assisting them in their sufferings – has meant that the doctor has abandoned the function of mere "advisor" of the sick person and assumed that of "technician" and "expert"[3], invested with the task of deciphering, according to scientific categories known only to him, the nature of the disease and with identifying the most suitable remedy in the interests of the patient.

This progressive evolution of the figure of the doctor into a subject gifted exclusively with the knowledge necessary to heal the patient has (inevitably) aggravated the disparity – above all on the informative plane – that already existed between the positions of the doctor and the patient[4] and thus encouraged the establishment of the paternalistic model in the therapeutic relationship[5]

If we then analyse the bioethical profile, we realise that medical paternalism is normally considered an expression – as we said before – of the model of beneficence)[6]. According to this scheme, the doctor receives from the patient a sort of proxy to decide in their interests and must therefore modulate the information "to convince the patient, and if necessary force them, 'for their own good', even when this means sacrifices that the sick person would prefer not to face[7]. In other

2 We refer to a sort of *corporis possessio*, that is the availability for the therapist of the body of the patient, U. G. Nannini, *Il consenso al trattamento medico, Presupposti teorici e applicazioni giurisprudenziali in Francia, Germania e Italia,* Milano, Giuffré, 1989, page 9.

3 See also Italian jurisprudence, according to which "the doctor has the presumption of capability thanks to his degree" (Court of Cassation, 25th December 1925, in Giurisprudenza Italiana, I, 1, 1926, page 537).

4 D. Giesen, *From Paternalism to Self-Determination to Shared Decision Making in the Field of Medical Law and Ethics*, in L. Westerhäll and C. Phillips (ed.), *Patient's Rights. Informed Consent, Access and Equality*, Stockholm, Nerenius & Santérus, 1994, page 20: "The potential for medical paternalism is increased by the growing informational imbalance that exists between doctor and patient, extending the power of the former and the dependency and vulnerability of the latter".

5 For these considerations See also Nannini, *Il consenso al trattamento medico* op. cit., pages 22 *et seq.*, who emphasises the negative effects of this transformation of the role of the doctor. "As we can easily imagine, the advantages that this new vision of things determines – in relation to the increased chances of recovery – are countered by an impoverishment of the human content of the relationship between the two subjects. In fact, while the sick person could previously "see in the eyes of the doctor a reflection of their own suffering", now there is a risk of finding ourselves before a technician whose attention is exclusively concentrated on deciphering, according to scientific categories, the nature of the illness and who is therefore not inclined to enter the drama in which the patient is often involved."

6 E. Sgreccia, A.G. Spagnolo and M.L. di Pietro (ed.), *Bioetica. Manuale per i diplomi universitari della sanità*, Milano, Vita e Pensiero, 2002, pages 213 *et seq.* For a brief illustration of the various bioethical principles See also E. Calò, *Il consenso informato: dal paternalismo all'autodeterminazione*, in Notariato, 2000, page 184.

7 Comitato Nazionale per la Bioetica, *Informazione e consenso all'atto medico*, 20th June 1992, page 61; E. Sgreccia, A.G. Spagnolo and M.L. di Pietro, *Bioetica. Manuale per i diplomi universitari della sanità*, op. cit., page 213: "The doctor must *for the good of the patient* and in their interests modulate the information in order to encourage the patient to 'make decisions in their best interests'."

words, according to the ethic of beneficence (or morality), the medical act has positive value not because it is the fruit of a free choice of the patient – as in the opposing ethical vision of freedom – but because it is capable of *enforcing the patient's good*[8].

Therefore, the paternalistic model we have just described, where the consent to the medical activity was presumed simply because it was for the good of the patient and the wishes of the latter were relegated to a secondary role, substantially becoming merely the opportunity to choose the doctor in which to place one's trust, should not surprise us.

2. *The affirmation of the principle of informed consent*

It was only when the conviction that the patient should give their informed consent to the medical activity that a relationship previously strongly biased – as we have seen – in favour of the doctor[9], that on the one hand fundamental values such as dignity and the individual's right to self-determination were re-evaluated, and on the other hand, the patient was given an active participative role in the decision-making concerning their own body[10]. The consequence was the emergence of the therapeutic alliance in the treatment relationship[11].

Before we examine the characteristics of informed consent and the juridical consequences relating to its emergence, above all with regard to the limits and the nature of medical responsibility[12], it is however important to enquire what are the *reasons* that have given rise to a similar evolution, and the *tools* through which it is realised.

In the first case, it is necessary to emphasise that the reasons that encouraged the move from the "paternalistic" phase to the "autonomous" phase in the doctor-patient relationship are above all to be found in the scientific-technological progress that has connoted medicine in recent decades;

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8 See also M. Graziadei, *Il consenso informato e i suoi limiti*, in L. Lenti, E. Palermo Fabris and P. Zatti (ed.), *I diritti in medicina*, in *Trattato di biodiritto*, directors S. Rodotà and P. Zatti, Milano, Giuffrè, 2011, page 209: "The doctor, as the custodian of the patient's welfare, became their tutor, and could decide on their behalf […]. The message to patients in this cultural setting was simply that they should trust the doctor."

9 It is opportune to point out that the emergence of the doctrine of informed consent was not unanimously welcomed. In fact, some declared that it was possible to interpret the paternalistic phenomenon not merely as a form of supremacy of the doctor over the patient. For example, it has been said that *a)* at times the patient turns to the doctor for reassurance and, in such cases, the doctor is generally reluctant to deny them comfort, even if this means not revealing the entire truth; *b)* emphasising the positive effects of the therapy and downplaying the negative can make the patient more optimistic, with the consequence that they – as has been scientifically proven – will respond better to the treatment compared with a pessimistic patient. S. Wear, *Informed Consent. Patient Autonomy and Physician Beneficence within Clinical Medicine*, Dordrecht-Boston-London, Springer, 1993, page 26. The author emphasises that "On this view, truth-telling can be counter-therapeutic". Further aspects were shown by G. Hermerén, *Informed Consent from an Ethical Point of View*, in L. Westerhäll and C. Phillips (ed.), *Patient's Rights. Informed Consent, Access and Equality*, op. cit., pages 56 *et seq.* Italian doctrine, although it does not contest the elimination of the paternalistic principle, does not consider the patient capable of knowledgably taking decisions due to the informative imbalance between the parties (P. Stanzione, *Attività sanitaria e responsabilità civile*, in «Danno e responsabilità», 2003, page 696).

10 R. Pucella, *Autodeterminazione e responsabilità nella relazione di cura*, Milano, Giuffrè, 2010, pages 12 *et seq.*

11 The therapeutic alliance is a relationship in which the doctor and the patient agree to engage with each other in order to effect beneficial change for the patient in the light of their life experiences and individual wishes, balancing the possible benefits and the cost in suffering. (See also C.D. Leotta, article *Consenso informato*, in *Digesto delle discipline privatistiche*, Aggiornamento, Torino, Utet, 2010, vol. V, page 102).

12 See also *infra*, chapters seven and eight.

together with greater general awareness acquired by the receivers of medical treatment thanks to the spread of communicative tools[13].

In fact, in the era in which human existence was marked by the rhythms of nature and in which the (limited) efforts of the doctors were almost exclusively directed at saving the patient's life, the need to inform the patient about their illness or to involve them in determining the treatment was less urgently felt [14].

It was only when, thanks to the scientific and technological evolution, medicine stopped pursuing the pure and simple recovery of the patient, becoming capable of ensuring, more widely, their physical and mental well-being, thanks to increasingly efficacious interventions, that self-determination began to play a decisive role in the medical relationship[15].

From one point of view, the patient has in effect, acquired awareness of the fact that medical science can bring to bear a vast range of curative tools capable of extending, and at times improving, their lifespan. On the other hand, greater attention paid to individual freedoms and social equality has strengthened the idea that the choice (necessarily discretional) regarding the use of these tools cannot be delegated exclusively to the doctor, but should be the fruit of a decision-making process that involves the patient first and foremost[16].

A further explanation, for the passage from medical paternalism to the principle of consent, with respect to the historical one we mentioned, can be seen in the development of a strictly *moral* nature of the choice that the patient has to make. In particular, it has been shown by part of the doctrine[17] that while it is true that the information on which the patient's choice is based is characterised by its strongly technical nature (such as the percentage of success, the alternatives to an operation, contraindications, side effects, etc.), it is however equally true that the patient's final decision is effectively based on a judgement of the compatibility of the choice itself with their own moral structure and with the image they have of themselves and that they wish to transmit to others.

13 See also D. Giesen, *From Paternalism to Self-Determination to Shared Decision Making in the Field of Medical Law and Ethics*, op. cit., page 25: "Increasing public awareness and the growth of consumerist attitudes to the provision of medical services have rendered this medical paternalism and its judicial endorsement outmoded and inappropriate."

14 G. Montanari Vergallo, *Il rapporto medico-paziente. Consenso e informazione tra libertà e responsabilità*, Milano, Giuffrè, 2008, page 15.

15 The doctrine shows how this changed the attitude of the patients, who now turn to the doctor with the attitude not of someone who puts their trust in his ability to heal, but rather that of a client who demands that the professional offer the best service possible. M. Franzoni, *Fatti illeciti*, in A. Scialoja and G. Branca (ed.), *Commentario del codice civile*, Bologna-Roma, Zanichelli/Il Foro Italiano, 2004, pages 105 *et seq.*; G. Montanari Vergallo, *Il rapporto medico-paziente. Consenso e informazione tra libertà e responsabilità*, op. cit., pages 15 *et seq.*

16 See also C. Casonato, *Il consenso informato. Profili di diritto comparato*, in «www.cortecostituzionale.it»; S. Rossi, article *Consenso informato*, in *Digesto delle discipline privatistiche*, Aggiornamento, Torino, Utet, 2012, vol. VII, page 183: "The emergence of the principle of consent in the doctor-patient relationship can be traced back to that of the 'therapeutic revolution', which in the second half of the twentieth century, expanded the traditional limits of intervention of medical science, making increasingly refined procedures, which were decisive for vital processes possible. The possibilities offered by science thus allowed the individual the right to make decisions that previously were taken by others, accordingly linking the consequence of these choices to a human act and therefore to a personal responsibility."

17 C. Casonato, *Il consenso informato. Profili di diritto comparato*, op. cit.

It is therefore understandable – it has been said – that the "will on which the (moral) choice regarding a given treatment depends must be that of the subject (moral agent) who will be treated."[18]

Therefore, in this renewed cultural context, the first explicit recognition of the principle of patient consent to the medical treatment appeared, as is known, in American jurisprudence at the start of the twentieth century[19].

Of particular importance in this field is the sentence in the well-known *Schloendorff* case heard before the Appeals Court in New York[20] in which it was stated that:

Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault for which he is liable in damages. This is true except in cases of emergency where the patient is unconscious and where it is necessary to operate before consent can be obtained […]

and therefore a first enunciation was made of the principle of self-determination underlying the management of the doctor-patient relationship, although without attributing – as we can see from the passage cited – specific importance to the requisite of informing the patient[21] .

Nevertheless, it was above all following the notorious events of human experimentation that occurred during the Second World War that there was a process of awareness of American public opinion (and not only) with regard to the problem of *free* and *informed* patient consent. This process resulted in the ruling of the Nuremberg Court – proclaimed in the sentence of the American military tribunal *United States v Karl Brandt et al.* that, on 19th August 1947 condemned twenty-three Nazi doctors for the experiments carried out in the concentration camps – on the principle that:

"The voluntary consent of the human subject is absolutely essential"[22].

18 *Ibidem.*

19 Although some of the enunciations date from a much earlier period, such as *Slater v. Baker and Stapleton*, 95 Eng. Rep. 860 – K.B. 1767, in which the patient complained about the behaviour of the doctors who, after removing the bandages from a fractured leg, realised that the fracture had only partly healed and re-fractured the leg without the patient's consent, binding it with an experimental sling. The Court sentenced the defendants both for having acted with negligence, and for having acted without the consent of the patient.

20 *Schloendorff v. Society of New York Hospital*, 211 N.Y. 125, 105 N.E. 92 (1914).

21 It must be emphasised that it is necessary to refer to the next "Salgo case" (*Salgo v Leland Stanford Bd. Trustees*, 154, Cal. App. 2d 560 [1957]) for the further development of the doctrine of informed consent, finding here the first use of the adjective *informed* (See also A. Santosuosso, *Il consenso informato: questioni di principio e regole specifiche*, in Id. (ed.), *Il consenso informato, tra giustificazione per il medico e diritto per il paziente*, Milano, Raffaello Cortina, 1996, page 6; M. Graziadei, *Il consenso informato e i suoi limiti*, op. cit., page 211, N. 51).

22 On the history and the content of the Nuremberg Code See also G. Mazur, *Informed Consent, Proxy Consent, and Catholic Bioethics. For the Good of the Subject*, Dordrecht, Springer, 2012, pages 13 *et seq.*

Following this first formulation of the principle in question and the intervention of some sentences that, during the fifties, expressly referred to the doctors' duty to inform[23] – also following the adoption by numerous American states of specific laws on informed consent, in order to limit the controversies over medical liability and the relative costs for the health services (malpractice crisis) – became one of the most widely discussed topics in the legal and health sectors in the United States[24].

That said, if we then evaluate the emergence of the same principle within the Italian legal system, we see that the idea according to which the patient's consent to the medical activity can affect the legitimacy of the latter was taken up by our Courts at quite an early date. In fact, the ruling that, according to some[25], introduced the jurisprudential evolution in the area of informed consent is dated only two decades after the American sentence previously mentioned.

In fact, it is the sentence of the Appeals Court of Milano dated 21st March 1939[26], handed down in a case dealing with a claim for damages, brought by the spouse of a patient who died after an operation. The doctor was accused of negligence during the operation and the lack of specific authorisation from the patient to the operation was introduced as evidence.

In this case, the Court, although they have the merit of establishing for the first time the principle that the patient has the right to express their informed consent to medical treatment, nonetheless limited the application of this principle only to operations with a high level of risk and, in any case, excluded the duty of doctors to inform the patient of *all* the dangers that could arise during the operation[27].

However, with reference to what will be said later about the presuppositions required by jurisprudence in order to make a claim for damages against a doctor for the lack of, or incorrect, acquisition of informed consent, it is now opportune to consider the second aspect mentioned and to examine the normative tools through which the principle of informed consent[28] has been gradually recognised, both nationally and internationally.

2.1 The normative basis of the principle of informed consent in national legislation: a) constitutional rules

23 See also in particular the "Salgo case", mentioned in note 21, to which *informed consent* is traditionally traced.
24 For a brief historical review of the emergence of informed consent in the United States See also O. Guillod, *Le consentement éclairé du patient. Autodétermination ou paternalisme?*, Neuchâtel, Ides et Calendes, 1986, pages 31 *et seq.*
25 U.G. Nannini, *Il consenso al trattamento medico*, op. cit., pages 358 *et seq.*
26 Appeals Court Milano, 21st March 1939 "Monitore dei tribunali", 1939, pages 587 *et seq.*
27 The Appeals Court stated that "the principle that consent is required prior to a dangerous operation is undeniable because […] everyone is free to trust the inscrutable forces of nature in the face of the risk of immediate death."
28 See also *infra*, chapter eight.

In Italian legislation, there are no general laws on informed consent[29]. The subject must therefore be reconstructed in an interpretive manner through systematic analysis of the rules that, more or less explicitly, refer to this principle.

Starting with a review of the constitutional profiles on which the question of informed consent is based, we can see that one reconstruction identifies the source of legitimation of the patient's right to express their consent to medical treatment exclusively in Article 32 of the Italian Constitution. Another interpretive indication, which constitutional jurisprudence has accepted, reconstructs the principle of informed consent through a joint interpretation of Articles 2, 13 paragraph 1, and 32 of the Constitution.

The first of these theories begins with the directives set out in paragraph 1 of Article 32 of the Constitution, according to which, "The Republic safeguards health as a fundamental right of the individual and as a collective interest, and guarantees free medical care to the indigent" and in paragraph 2 of the same article, "No one may be obliged to undergo any health treatment except under the provisions of the law", in order to state that, within our constitutional regulations, the *rule* is the voluntary nature of medical treatment, while the *exception* is represented by the obligatory nature of the same, possibly ordered by the legislator to safeguard the community's need for health[30]. On the basis of this premise and of the valorisation of the right to health not only as a

29 With the aim of introducing a general discipline on the question of informed consent, a bill was presented entitled *Disposizioni in materia di alleanza terapeutica, consenso informato, dichiarazioni anticipate di trattamento* (regulations concerning therapeutic alliance, informed consent, advance declarations of treatment). The law was approved first by the Senate on 26th March 2009 and later, with numerous amendments, by the Parliament on 12th July 2011. The second reading by the Senate was never concluded. With reference to the profile of informed consent, Article 2 of the text foresaw that: "1. Except in cases foreseen by law, all medical treatment is enacted following explicit and immediate informed consent by the patient, given in a free and conscious manner. 2. The expression of informed consent is preceded by correct information given by the doctor to the patient, in a comprehensible manner, regarding the diagnosis, prognosis, purpose and nature of the treatment proposed, the benefits and the possible risks, any side effects and the possible alternatives and the consequences of refusing the treatment. 3. The therapeutic alliance formed within the relationship between the doctor and the patient pursuant to paragraph 2 is set out in a document of informed consent, signed by the patient and will become part of the medical records. 4. The patient has the right to refuse wholly or in part the information due to him. The refusal can be expressed at any time and must be expressed in a document signed by the interested party. 5. Informed consent to medical treatment can be revoked at any time, also partially. 6. In the case of interdicted persons, the informed consent is expressed by the legal guardian, who signs the document. In the case of a disabled person or an emancipated minor, the informed consent is given jointly by the interested party and the legal guardian. If no legal guardian has been nominated and the decree of nomination foresees assistance or representation in medical situations, the informed consent is given also or only by the legal guardian. The decision of these subjects regarding matters set out in Article 3 is adopted for the exclusive purpose of safeguarding the health of the person with diminished responsibility. 7. The informed consent to medical treatment of a minor is expressed or refused by those exercising parental authority or guardianship after carefully listening to the wishes and the requests of the minor. The decision of these subjects with regard to Article 3 is adopted exclusively to safeguard the psychophysical health of the minor. 8. Should the subject be a minor or legally interdicted, or of diminished responsibility and the urgency of the situation does not allow time for obtaining informed consent as indicated in the previous paragraphs, the doctor shall act honourably and conscientiously, according to the principles of medical deontology and current legislation. 9. Informed consent to medical treatment is not required when the life of the person with diminished responsibility is in danger due to an acute event." For a critical examination of the project See also D. Carusi, *Sulle spiccate singolarità del disegno parlamentare in tema di «alleanza terapeutica, consenso informato e dichiarazioni anticipate di trattamento»*, in D. Carusi, S. Castignone e G. Ferrando (ed.), *Rifiuto di cure e direttive anticipate. Diritto vigente e prospettive di regolamentazione*, Atti del Convegno di Genova, 23rd May 2011, Torino, Giappichelli, 2012, pages 165 *et seq.*

30 It has been pointed out that paragraph 2 of Article 32 of the Italian Constitution can desume that good health, apart from being a fundamental right of the individual, is also in the interest of the community, and therefore it is sometimes necessary for the interests

social right (that is the expectation of the individual to receive certain treatment) but also as the right of freedom (in particular freedom of treatment)[31], this indication draws the consequence that, *consensuality* being a necessary corollary of the rule of voluntariness, the consent of the patient must be asked for in order to subject them to medical treatment in all the situations not foreseen by the legislator as compulsory pursuant to paragraph 2 of Article 32 of the Constitution. This said, it must also be stated that the consent itself, in order to be 'informed', presumes that – as far as is possible – the informative asymmetry that characterises the doctor-patient relationship has been overcome, and that the patient has been able to access the information necessary for serenely pondering the risks and the benefits of a given treatment, so that the right to be informed, being propaedeutic with respect to the freedom of healthcare, is clearly also fundamental to Article 32 of the Constitution[32].

According to the theories presented so far, in effect, the expression "informed consent" could represent rights that differ, but that can all be traced to Article 32 of the Italian Constitution:

"[…] on the one hand, the right to health, like the right to freedom, or more precisely the freedom of treatment seen as the freedom to consent to treatment (or to refuse it) and therefore [being] a rule of the voluntary nature of healthcare; on the other hand, the right to health as the right to information on the treatments, that is the right to be informed about the treatments (but more generally with regard to all the treatments, also when they are not specifically curative) and therefore to receive the information necessary for the formation of consent (or refusal) within the therapeutic alliance with the doctor"[33].

This first elaboration, which refers to the constitutional foundation of the informed consent in the ruling that safeguards the right to health, we can oppose another – prevalent nowadays – which tends to reconstruct informed consent through the systematic interpretation of Article 2 of the

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of the individual to be balanced by the interests of the community, as for example, in the case of a situation that demands compulsory treatment (Cfr also G. Gliatta, *La dignità e la salute del paziente e il trattamento in assenza di consenso*, in «Responsabilità civile», 2010, page 785).

31 It is debatable whether this right can be considered *fundamental.* In favour of the fundamental nature of the right to health is the literal meaning of Article 32 of the Constitution and the ruling N. 277 of the Constitutional Court of 17th June 1987, in "Giurisprudenza Costituzionale", I, 1987, pages 1710 *et seq.* On the concept in general of "fundamental right" See also A. Baldassarre*, I diritti fondamentali nello Stato costituzionale*, in *Scritti in onore di Alberto Predieri*, Milano, Giuffrè, 1996, vol. I, pages 63 *et seq.* "In all the pluralistic democracies of the western world – including Italy – the constitutional rights of the individual and, in particular, the freedom of man and of the citizen are "fundamental rights".

32 D. Morana, *A proposito del fondamento costituzionale per il «consenso informato» ai trattamenti sanitari: considerazioni a margine della sentenza n. 438 del 2008 della Corte costituzionale*, in «Giurisprudenza costituzionale», 2008, pages 4972 *et seq.* This conclusion was also supported, amongst others, by G.U. Rescigno, *Dal diritto di rifiutare un determinato trattamento sanitario secondo l'art. 32, comma 2, Cost., al principio di autodeterminazione intorno alla propria vita*, in «Diritto pubblico», 2008, page 91, for whom the right of the patient to information is "an implicit right in the right to health and in the right to refuse treatment" emphasising however that "in effect Article 32 says nothing on this matter. But the right to refuse medical treatment presumes a sufficient understanding of the treatment proposed or suggested and, applying the principle of reasonableness, it is correct and not easily questionable according to reason that the interested party also has the instrumental and prejudicial right to know the characteristics of the treatment beforehand, and the doctor has the duty to inform them correctly". For a review of the various perspectives See also S. Rossi,article *Consenso informato*, op. cit., page 187.

33 D. Morana, *A proposito del fondamento costituzionale per il «consenso informato» ai trattamenti sanitari: considerazioni a margine della sentenza n. 438 del 2008 della Corte costituzionale*, op. cit., page 4976.

Constitution, which guarantees the inviolable rights of the person[34], of Article 13 of the Constitution, which formulates the inviolable nature of personal freedom[35] and of Article 32 of the Constitution, mentioned above.

A similar interpretation underlies an evolutionary conception of both health and personal freedom.

With reference to the first aspect, in particular, this theory adopts a concept of health that is not seen as the mere absence of illness, but appears to conform to the wider and more complex sense, developed by the World Health Organization (WHO) which, in the introduction to its Constitution, describes it as "[…] a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity," adding that "The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition,"[36] and by the Committee for Economic, Social and Cultural Rights of the United Nations, which adopted the General Comment N. 14 setting out in detail the various forms of the right to health and indicating the standards that the nations should respect in order for the right to health to be realised[37].

So, such a varied perception of the concept of the right to health, which includes not only the physical health, but also the psychological and social health of the individual, inevitably determines the adhesion to a conception of health that is no longer "normative" but rather "identitary"[38] and this means that within the therapeutic choices, this right can be concretised through the indication that, for the patient, the treatment corresponds to *their* best health, that is it conforms to their "personal and unquestionable expectations of life".[39]

This reading of the right to health accompanies a much more extensive conception of the right to personal freedom, which is no longer restricted to safeguarding the individual from any form of

34 Article 2 Italian Constitution: The Republic recognises and guarantees the inviolable rights of the person, both as an individual and in the social groups where human personality is expressed. The Republic expects that the fundamental duties of political, economic and social solidarity be fulfilled."

35 Article 13, paragraph 1, Constitution: "Personal liberty is inviolable."

36 Introduction to the WHO Constitution, approved on 22nd July 1946 and ratified on 7th April 1948, transposed with D.L.C.P.S. N. 1068 4th March 1947 *Approvazione del Protocollo concernente la costituzione dell'organizzazione mondiale della sanità stipulato a New York il 22 luglio 1946.*

37 Committee for Economic, Social and Cultural Rights, *General Comment 14 – The Right to the Highest Attainable Standard of Health*, Un Doc. E/C.12/2000/4 11th August 2000. For a review of the principle rulings of the General Comment See also I. Biglino and A. Olmo, *La salute come diritto fondamentale: una ricerca sui migranti a Torino*, Bologna, Il Mulino, 2014, pages 36 *et seq.*

38 See also P. Zatti, *Rapporto medico-paziente e «integrità» della persona*, in «Nuova giurisprudenza civile commentata», II, 2008, pages 404 *et seq.,* which emphasises that following the definition of 'health' by the WHO, health itself was exposed to contact with the individuality of the person, becoming the only welfare of each individual. Each person could therefore have their own health, which they could pursue and claim in the therapeutic relationship. The "normative" health, that is health linked to the standard of the pathologies and a scientific configuration of well-being, although it could represent the criteria followed by the doctor, would no longer be the dominant indicator of the therapeutic relationship. Cfr also R. Pucella, *Autodeterminazione e responsabilità nella relazione di cura,* op. cit. pages 69 *et seq.*

39 P. Zatti, *Il diritto a scegliere la propria salute (in margine al caso S. Raffaele)*, in «Nuova giurisprudenza civile commentata», II, 2000, pages 1 *et seq.*

physical coercion, but is amplified to guarantee the free and full development of the individual[40]. Thus intended, Article 13 of the Constitution is destined to operate in every sector in which the person is expressed, so that also decisions regarding healthcare must necessarily be considered not only a determination functionally linked to the safeguarding of the right to health, but more widely, as an expression of the general right to the freedom of the individual, protected by Article 13 of the Constitution.[41]

A similar perspective, which it must be said, outlines the right to informed consent as a summary of the right to health and the right to self-determination[42], has found confirmation at the Constitutional Court, which through a gradual process, begun in the early twentieth century, has identified the constitutional basis of informed consent not only in Article 32 of the Constitution, but also in Article 13.

And in fact, it was with the ruling N. 471/1990[43] that the Constitutional Court began to interpret the possibility of having control over one's own body as a "freedom" and not as a "power" and for the first time the Court found the basis for this right in Article 13 of the Constitution, rather than in Article 32[44]; however it was necessary to await the well-known ruling N. 438/2008[45] for informed consent to be expressly raised to a synthesis of the rights expressed in the two rulings in question. In this latter ruling, in effect, the Court, after defining informed consent as "an expression of the informed agreement to the medical treatment proposed by the doctor", clarifies that it "is a genuine right of the person and is based on the principles expressed in Article 2 of the Constitution, which safeguards and promotes these fundamental rights, and in Articles 13 and 32 of the Constitution, which respectively that, "personal liberty is inviolable" and that "No one may be obliged to undergo any health treatment except under the provisions of the law", concluding that:

[…] the circumstances that informed consent finds its basis in Articles 2, 13 and 32 of the Constitution highlights its function of synthesis of two fundamental rights of the person: that of self-

40 A. Barbera, *I principi costituzionali della libertà personale*, Milano, Giuffrè, 1967, pages 98 *et seq.*

41 G. Gennari, *Consenso informato: ritorno all'anno zero*, in «Responsabilità civile e previdenza», 2006, page 1415. For an efficacious summary of this view of informed consent Cf., also, S. Rossi, voce *Consenso informato*, op. cit., page 188.

42 See also the clear considerations of S. Rossi in *Consenso informato*, op. cit. page 188 regarding the framework of the problem of informed consent on the constitutional plane. "In conclusion, we can note that, also at constitutional level, at the root of the problem of consent lies the enucleation of a fundamental right that is expressed most clearly and fully by formulating the principle according to which the evaluation of the relationship between the therapeutic proposal, the relative benefits and risks, the possible well-being, appertains exclusively to the interested party as an exercise, that can be neither suppressed nor influenced, of their perception of self and of a freedom that belongs to the configuration of their personal identity and individuality, as autonomous moral subjects." See also also P. Zatti, *Il diritto a scegliere la propria salute (in margine al caso S. Raffaele)*, op. cit., page 8.

43 Constitutional Court, 9th October 1990, N. 471, in www.giurcost.org.

44 E. Rossi, *Profili giuridici del consenso informato: i fondamenti costituzionali e gli ambiti di applicazione*, in "www.rivistaaic.it", 4, 2011, page 5.

45 Constitutional Court 23rd December 2008, N. 438, in «Giurisprudenza italiana», 2009, pages 2382 *et seq.*; in «Giurisprudenza costituzionale», 2008, pages 4945 *et seq.*, with note by R. Balduzzi and D. Paris, *Corte costituzionale e consenso informato tra diritti fondamentali e ripartizione delle competenze legislative*, by D. Morana, *A proposito del fondamento costituzionale per il «consenso informato» ai trattamenti sanitari: considerazioni a margine della sentenza n. 438 del 2008 della Corte costituzionale*, and by C. Coraggio, *Il consenso informato: alla ricerca dei principi fondamentali della legislazione statale*.

determination and that of health, since, while it is true that each individual has the right to be treated, they also have the right to receive opportune information regarding the nature and the possible developments of the therapeutic treatment to which they will be subject, and any alternative therapies; information that must be as comprehensive as possible, precisely for the purpose of guaranteeing the free and conscious choice by the patient, and therefore, their personal liberty, in accordance with Article 32, paragraph 2 of the Constitution[46].

2.2 (continued) b) informed consent in the ordinary normative sources

Having examined the constitutional rulings from which it is possible to deduce the safeguards for the patient's right to give informed consent, it is now necessary to examine more carefully which basic normative tools expressly foresee the need for the consent of the patient to medical treatment.

Proceeding chronologically, also in order to highlight the increasing role that informed consent has come to play in our legislation, it is necessary to stress that a first recognition of the role of consent at normative level was contained in Law N. 458 on the transplant of kidneys between living persons and in Law N. 592 on the gathering, storage and distribution of human blood, which both date from 1967.

In particular, Law N. 458/1967 establishes in Article 2, paragraph 2 that "the donation of a kidney can be authorised, providing the donor has reached the age of majority, is capable of discernment, is aware of the limits of the therapy of the transplant of a kidney between living patients and is also aware of the personal consequences that their sacrifice involves". Paragraph 3 of the same article requires the donor to be "freely and spontaneously determined to donate a kidney", and paragraph 4 adds that "the act is free of charge and cannot be subject to the setting of conditions or other additional intentions; it can be revoked up to the moment of the surgical operation and does not give the donor rights of any sort towards the receiver." [47]

Finally, Article 4 of the same law foresees, that "the transplant of the kidney legitimately harvested and destined for a given patient, cannot take place without the consent of the patient or in absence of a state of necessity."[48]

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46 These conclusions were embraced also by the Constitutional Court, N. 253, 30th July 2009, in www.giurcost.org.

47 On this point cfr G. Giacobbe, article *Trapianti* in *Enciclopedia del diritto*, Milano, Giuffrè, 1992, vol. XLIV, pages 900 *et seq.*, which highlights the fact that Law N. 458, when it identifies a voluntary basis for transplants between living persons, conforms to the constitutional principles on personal safeguards (Articles 2, 13 and 32 Italian Constitution). In fact, the author states, while it is true that the donation of part of one's body may seem obligatory from an ethical standpoint, this is not equally so from the legal standpoint, in relation to which the interests of the giver and the receiver are both worthy of protection, since, on comparison, it is not possible to identify one who should be sacrificed for the other. See also also P. M. Vecchi, article *Trapianti e trasfusioni, I) diritto civile*, in *Enciclopedia giuridica*, Roma, Treccani, 1994, vol. XXXVI, page 10, which excludes the proposal presented at the time by part of the doctrine of compulsory gathering of body parts, and in particular blood, harvesting that would be carried out in an expropriatory manner.

48 For a comparative overview, see also L. Mezzanotte, article *Trapianti e trasfusioni, III) diritto comparato e straniero*, in *Enciclopedia giuridica*, Roma, Treccani, 1994, vol. XXXVI, pages 1 *et seq.*

Article 9 of the law on the harvesting, preservation and distribution of human blood in the first two paragraphs ordered that "the collection of human blood for use in transfusions can only be carried out by a doctor on persons who give their consent and following tests to guarantee that no harm can result from the effects of the donation. It is not possible to take blood for transfusions from persons under eighteen years of age. For persons aged under twenty-one, it is necessary to have the consent of the parents or the guardian."

The first of the two disciplines mentioned, in particular, is characterised by the fact that in addition to asking for the interested party to express their positive agreement to the operation, it also enucleates some of the fundamental requisites that the later jurisprudence and doctrine have always considered essential (in particular those of revocability and freedom) and attributes express recognition to one of the situations in which even today – as we will see – the consent of the patient is not considered necessary: that is the state of necessity.[49]

So, while these rulings have an undoubted importance within the process that has led to the affirmation of the principle of informed consent within our legislation, an even more systematic importance lies in Law N. 194/1978 (*Norme per la tutela sociale della maternità e sull'interruzione volontaria della gravidanza* – regulations on social safeguards for maternity and abortion).[50] In this law, the legislator conceived a procedural scheme for authorisation of abortions, promoted by the request of the pregnant woman and in which the role of the doctor, or in the case of the legally interdicted the role of the guardian, was important. In this specific case, it is necessary to consider Article 5, which prescribes for the doctor actions that will allow the woman to take an informed and pondered decision[51] and article 12, which sets out the norms relating to the manifestation of the will by the pregnant woman and which disciplines, together with Article 13, the possibility of an abortion chosen by a minor or by a legally interdicted woman[52].

In this normative context, moreover, the principle of informed consent appears to have an even greater value with respect to that which a first reading of the rulings in it would seem to offer. On this question it has, in fact, been stated by part of the doctrine that, on the one hand, the problem

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49 See also E. Rossi, *Profili giuridici del consenso informato: i fondamenti costituzionali e gli ambiti di applicazione*, op. cit., page 1. On the legal relevance of the state of necessity regarding matters of informed consent See also *infra*, chapter seven, paragraph 7.

50 On the genesis see also C. Casini and F. Cieri, *La nuova disciplina dell'aborto (Commento alla legge 22 maggio 1978, n. 194)*, Padova, Cedam, 1978, pages 3 *et seq.*

51 Paragraph 2 of Article 5 is particularly significant, it states that: "When the woman turns to her doctor he must carry out the necessary health checks, respecting the dignity and the freedom of the woman; he must discuss with the woman herself and with the father of the foetus, where the woman agrees, also on the basis of the results of the tests previously mentioned, the circumstances that have led them to ask for the termination of the pregnancy; he informs her of her rights and of the assistance of a social nature available to her, of the clinics and the health and welfare structures."

52 See also L. Buffoni, *Le fonti nazionali del biodiritto: alcuni appunti per una teoria della «sovranità» dell'individuo nella produzione giuridica*, in «Diritto e società», 3, 2010, page 53, for whom the law on abortion "attributes to the woman the 'personal' presentation of the request for reasons of safeguarding her physical or psychological health, guarantees the understanding of the consent and devises agile artifices to allow the expression of their will by minors or the mentally ill."

of informed consent is not complete in the initial moment in which the pregnant woman asks for an abortion,[53] but it is also re-proposed (although outside the procedure conceived by the legislator) at the time of the operation and, on the other hand, it is not in any case sufficient for the doctor, for the purpose of becoming exempt from liability, to trust in the material willingness of the woman on the basis of the mere observance of the aforementioned procedural obligations.[54] Similar observations would in fact find confirmation, besides the criminal relevance ascribed to the behaviour of those who interrupt a pregnancy without the consent of the pregnant woman (Article 18), also in Article 14, which, in addition to ordering the doctor to observe the most comprehensive duties of information, further foresees that he must make the woman "aware of the abortive procedures."[55] More precisely, the necessity that the pregnant woman be effectively made *participative* in the abortion procedures means that the observance of the procedures governed by the law do not exonerate the doctor from verifying the ongoing, free and aware decision of the woman to the abortion right up to the moment of the operation, at least when there is any aspect, perceptible to the doctor, that indicates repentance or a change of heart by the expectant mother.

Moving further in the examination of the normative rulings in national law that expressly refer to the informed consent of the patient and limiting the analysis to those which have had a greater incidence in the affirmation of this principle,[56] it is necessary to mention, inasmuch as they

53 In relation to which there have been so far the greatest number of jurisprudential rulings. The problem is, in fact, that of the lesion of the woman's right to conscious and voluntary procreation due to lack of information, from the doctor, regarding malformations of the foetus which, if known, would have led the mother to opt for an abortion. On this matter, which has concerned above all the profile of the causal link between the lack of information and the harm caused to the mother, the method for ascertaining the damages and the possibility of configuring an autonomous claim by the subject born with a malformation, has in recent years focussed the attention of the interpreters: Cf., *ex multiis*, Cass., 22nd March 2013, n. 7269, in «Nuova giurisprudenza civile commentata», I, 2013, pages 1082 *et seq.*; Cass., October 2nd 2012, N. 16754, in «Contratti», 2013, pages 563 *et seq.*., with note by N. Muccioli, *Diagnosi prenatale inesatta e responsabilità del medico*; Cass., 30th November 2011, N. 25559, in «Responsabilità civile», 2011, pages 865 *et seq.*., with note by A. Galati, *Considerazioni su errore diagnostico, danno da nascita indesiderata e danni risarcibili*; Cass., 10th November2010, N. 22837, in «Nuova giurisprudenza civile commentata», I, 2011, pages 464 *et seq.*., with note by E. Palmerini, *Il «sottosistema» della responsabilità da nascita indesiderata e le asimmetrie con il regime della responsabilità medica in generale*; Cass., 14th July 2006, N. 16123, in «Corriere giuridico», 2006, pages 1691 *et seq.*, with comment by A. Liserre *Ancora in tema di mancata interruzione della gravidanza e danno da procreazione*.

54 P. Zatti and U.G. Nannini, article *Gravidanza (interruzione della)*, in *Digesto delle discipline privatistiche*, Torino, Utet, 1993, vol. IX, page 269.

55 In fact, Article 14, paragraph 1 orders that, "The doctor who carries out the abortion is required to give the woman information and indications on birth control, and to involve her in the abortive procedures, which must in any case be carried out in a way that respects the personal dignity of the woman."

56 In addition to those mentioned below, it is possible to recall for example, Law N.135/1990 (*Piano degli interventi urgenti in materia di prevenzione e lotta all'Aids* – urgent measures regard the prevention and treatment of AIDS). Article 5 states that "No one can be subjected, without their consent, to analyses intended to ascertain HIV infection, except for reasons of clinical necessity in their interests." D. Lgs N. 230/1995, Article 108 states: "The exposure of persons for the purpose of clinical scientific research can only be carried out with the written consent of the persons themselves, following information on the risks connected with exposure to ionised radiation and only as part of the programmes approved by the Ministry of Health, which can establish, in relation to the programmes themselves, specific procedures and limits to the doses for the persons exposed." Legislative decree D. Lgs. N. 211/2003 on the application of good clinical practice in clinical experimentation of medicines for clinical use, Article 2, letter *l* gives the following definition of informed consent. "The decision of a candidate to be included in a clinical trial, written, dated and signed, given spontaneously, following comprehensive information regarding the nature, the meaning, the consequences and the risks of the trial and after having received the appropriate relative documentation. The decision is expressed by a subject capable of giving their consent, that is, when the person is not capable of doing so, by their legal representative, or an authority, person or organism, respecting the current normative rulings on the matter. If the subject is not able to write, they may exceptionally give oral consent in the presence of at least one witness, in accordance with current legislation.

are normally interpreted as norms with a general validity in this area,[57] Law N. 180/1978 (*Accertamenti e trattamenti sanitari volontari e obbligatori* – voluntary and compulsory medical tests and treatments), which in Article 1, paragraph 1 clearly states that "medical tests and treatments are voluntary" and in paragraph 4 of the same Article, referring to compulsory medical treatments, that these "must be accompanied by initiatives destined to guarantee the consent and the participation of those who are obliged to submit to them", and Law N. 833/1978 (*Istituzione del servizio sanitario nazionale* – institution of the national health service), which similarly states in Article 33 that "medical tests and treatments are normally voluntary" and that compulsory medical tests and treatments "must be accompanied by initiatives destined to guarantee the consent and the participation of those who are obliged to submit to them." These rulings, in effect, are considered by the doctrine the direct expression of the general principles affirmed at constitutional level and illustrated in the previous paragraph, and as such, suitable for making a clear break with respect to the previous model of healthcare, marked by medical paternalism, and setting out a new "constitutionally oriented" course[58].

To conclude, it is necessary to mention a further prevision of ordinary law that contemplates the principle of informed consent and which, being formulated in a more recent period than the ones so far discussed, is characterised by having assimilated at least in part the jurisprudential evolution, which has formed since it came into force. In particular, Law N. 40/2004 (*Norme in materia di procreazione medicalmente assistita* – rules for medically assisted procreation) an area in which informed consent, apart from being mentioned in Article 4, paragraph 2 as a fundamental principle to be followed together with that of the graduality of the techniques, is the subject of detailed discipline in Article 6:

> 1. For the purposes indicated in paragraph 3, prior to the recourse to and during every stage of the application of the techniques of medically assisted procreation, the doctor must inform in a detailed manner the subjects mentioned in Article 5 regarding the methods, the bioethical problems and the possible health and psychological side effects that may result from the techniques themselves, the probability of success and the risks deriving from them, and the relative legal consequences for the woman, for the man and for the child to be born. The couple must understand that they have the possibility of recourse to adoption or fostering procedures pursuant to Law N. 184 of 4th May 1983 and subsequent amendments, as an alternative to medically assisted procreation. The information in this paragraph and that concerning the degree of invasiveness of the techniques for the woman and for the man

57 M. Graziadei, *Il consenso informato e i suoi limiti*, op. cit., page 197.
58 In these terms speaks S. Rossi, article, *Consenso informato,* op. cit. pages 192 *et seq.*

must be suppled for each of the techniques applied and in a manner that guarantees full understanding and informed consent.

2. The couple must be made fully aware of the economic cost of the entire procedure if they intend to use authorised private structures.

3. The desire of both parties to make use of the techniques of medically assisted procreation must be expressed jointly, in writing, to the doctor heading the structure, according to the methods set out in the decree of the Ministry of Justice and the Ministry of Health, adopted in accordance with Article 17, paragraph 3, of Law N. 400 dated 23rd August 1988, within three months from the date on which this Law comes into force. Between the expression of will and the application for the technique a period of not less than seven days must pass. The expression of will can be revoked by either of the subject indicated in this paragraph up to the moment in which the egg is fertilised.

4. Without prejudice to the requisites foreseen by this law, the doctor responsible for the structure can decide not to proceed with medically assisted procreation, exclusively for medical-health reasons. In this case, the doctor must give the couple a written explanation for this decision.

5. The applicants, when beginning medically assisted procreation procedures, must explicitly and clearly underwrite the legal consequences set out in Articles 8 and 9 of this Law.

This law on informed consent was defined, both by the critics of Law N. 40/2004 and, especially, by its supporters, "the strong point" of the law itself,[59] since it realises, in our legislation, the most evident actuation of the jurisprudential indications that have formed over time on the question of informed consent, with reference above all to the nature of the consent and the information that must be given to the patient.

In fact, a first premise of consent demanded by the law on medically assisted procreation and which seems to be a manifestation of the indications expressed by the doctrine and by the jurisprudence, is that consent must be given in writing, in order to guarantee the gravitas of the application and give certainty in the relationships of paternity and maternity.[60] It is, in fact, shared opinion that the expression in writing of the consent must unfailingly accompany the particularly

59 F. Buzzi and G. Tassi, *La procreazione medicalmente assistita. Normativa, giurisprudenza e aspetti medico legali*, Milano, Giuffrè, 2011, page 123.

60 C. Casini, M. Casini and M.L. di Pietro, *La legge February 19th 2004, N. 40 «Norme in materia di procreazione medicalmente assistita» – Commentario*, Torino, Giappichelli, 2004, *Sub* art. 6, page 119.

invasive or delicate treatments involved and the psychological effects, as was at the time already partly highlighted by the National Committee for Bioethics, which stated:

The written consent is to be considered at present the moral duty of the doctor in all those cases in which the diagnostic and/or therapeutic treatments due to their nature (the risk involved, the duration of the treatment, the personal and family implications, the possibility of alternative options including the possibility of choosing another doctor or another health structure) are such that a unequivocal and documented expression of the patient's wishes is opportune.[61]

Moreover, today it is also foreseen by Article 35 of the code of medical deontology.

The other aspect of the discipline in question, which is in line with the results reached in an interpretive manner, concerns the extension of the obligation to inform for the doctor, which – as we can deduce from the wording of Article 6 – must involve not only the medical-health aspects, but also the ethical and juridical aspects and those relating to the cost of the operation.[62]

We can also see that the discipline examined here places particular emphasis on the informative moment also through two further complementary rules. On the one hand, by specifically defining the timeframe of the informative moment. The guidelines for procedures and techniques of medically assisted procreation, state that apart from preceding the treatment, it must continue "during every stage of the application of the techniques of medically assisted procreation" and until the treatment itself has been carried out. In fact, it is possible to deduce from the prevision that the activity of consultancy and support for the couple must continue also after the treatment has been completed[63]. On the other hand, by specifying – also in the aforementioned guidelines – the purpose of the informative activity, which must, "guarantee the formation of informed and knowledgeably expressed will." This clarification is an expression of the legislators' intention to guarantee the child a birth in a context in which the subjects involved are fully aware of their parental role.[64]

However, while those mentioned are the aspects concerning informed consent in the law on medically assisted procreation that have deserved the approval of the academics who deal with the question, it is necessary to briefly examine also the profile against which, vice versa, the most serious criticisms were made. These pertain to the prevision set out in Article 6, paragraph 3, in the

61 Comitato Nazionale per la Bioetica, *Informazione e consenso all'atto medico*, op. cit., pages 13 *et seq.*

62 The legislator is defined as 'laudable' when setting out in such a generalised manner the content of the information that the doctor must supply to the couple by A. Vicini, *Procreazione medicalmente assistita in Italia*, in P. Giustiniani (ed.), *Sulla procreazione assistita*, Napoli, Esi, 2005, page 154. At the same time he highlights the extent of the areas on which the information touches, demanding of the doctor bioethical and psychological competencies that he/she may realistically lack.

63 Decree of the Italian Ministry of Health, 11th April 2008, *Linee guida in materia di procreazione medicalmente assistita*, *Consenso informato*.

64 F. Buzzi and G. Tassi, *La procreazione medicalmente assistita. Normativa, giurisprudenza e aspetti medico legali*, op. cit., page 124.

part that states that, "the consent can be revoked by either of the subjects indicated in this paragraph up to the moment in which the egg is fertilised", which seems to legitimate *to the contrary* the coactive implant in the woman of the fertilised egg, in breach of the principle of prohibition of compulsory medical treatments found in Article 32, paragraph 2 of the Constitution and of the correlated principle of informed consent, in effect if we consider that one of the characteristics that connote the latter is that it can be freely revoked at any time.[65]

Such perplexities – which arose with regard to the constitutional illegitimacy of the law, because it is in contrast with Articles 2, 13 and 32 of the Constitution[66] – start from the consideration that the purpose of the aforementioned prevision is only to guarantee the right of life to the embryos born in a test tube and to prevent the illicit production of embryos destined for sale. It was, nonetheless, objected that, on the one hand, it is not possible to infer from the law the existence of the doctor's responsibility for implanting the embryos in the woman (particularly in the case of malformations)[67] so that where the latter revokes her consent, the former, far from the duty to carry out a coactive implant, can vice versa abstain on the basis of their clinical evaluation.[68] On the other hand, the right to life of the embryo could also find a suitable guarantee through the similar application of Article 14, paragraph 3, according to which, where it is impossible to transfer the embryo for medical reasons, it is possible to freeze it.[69]

2.3 (continued) c) informed consent in the medical code of deontology

Amongst the instruments of national law that have led to the recognition of the principle of informed consent, there is the code of medical deontology. This normative source – which preferred to deal with separately, in view of the uncertainty existing amongst the interpreters regarding the

65 See in particular, R. Bin, *Sussidiarietà, privacy e libertà della scienza: profili costituzionali della procreazione assistita*, in E. Camassa and C. Casonato (ed.), *La procreazione medicalmente assistita: ombre e luci*, Trento, Università degli Studi, 2005, pages 45 *et seq.*.; F. Buzzi and G. Tassi, *La procreazione medicalmente assistita. Normativa, giurisprudenza e aspetti medico legali*, op. cit., pages 128 *et seq.*

66 See also Court Firenze, ruling, 12th December 2012, in «Nuova giurisprudenza civile commentata», I, 2013, pages 589 *et seq.*, with note by G. di Rosa, *Scienza, tecnica e diritto in recenti applicazioni giudiziali della disciplina in materia di procreazione medicalmente assistita.* More generally, on the aspects of the inconstitutionality of Law N. 4/2004 and the rulings of the Constitutional Court See also M. Abagnale, *La procreazione medicalmente assistita nella metamorfosi della legge 40/2004*, in «www.forumcostituzionale.it».

67 The law does not, in fact, foresee a determined compulsory medical treatment, as is required by Article 32 of the Constitution: M. Sesta, *Dalla libertà ai divieti: quale futuro per la legge sulla procreazione medicalmente assistita?*, in «Corriere giuridico», 2004, page 1408.

68 F. d'Agostino, *Bioetica della riproduzione umana: dibattiti attuali*, in P. Amodio (ed.), *La procreazione medicalmente assistita: attualità bioetica e attualità giuridica*, Napoli, Giannini, 2005, pages 20 e*t seq.*. In agreement with this conclusion are also C. Casini, M. Casini and M.L. di Pietro, *La legge 19 febbraio 2004, n. 40 «Norme in materia di procreazione medicalmente assistita» – Commentario*, op. cit., p. 127 and F. Santosuosso, *La procreazione medicalmente assistita. Commento alla legge 19 febbraio 2004, n. 40*, Milano, Giuffrè, 2004, page 37.

69 C. Casini, *Procreazione assistita. Introduzione alla nuova legge*, Milano, San Paolo, 2005, page 39. Of the same opinion is also C. Parrinello, *Procreazione medicalmente assistita e responsabilità del medico*, in M. Dossetti, M. Lupo and M. Moretti (ed.), *Cinque anni di applicazione della legge sulla procreazione medicalmente assistita: problemi e responsabilità*, Milano, Giuffrè, 2010, pages 247 *et seq.*

juridical value to attribute to it[70] – plays a particularly significant role in this context, since on the one hand it has been considered to contain the only discipline of informed consent that has general validity in Italy[71] and on the other hand, the precepts it includes have represented the faithful reflection of the evolution that has involved the social reality that it regulates, being characterised by a constant and progressive development of the freedom of self-determination of the patient[72].

The most recent version of the code, approved in 2014, confirms and sets out in detail the obligation of the doctor to inform the patient and to operate with their consent. In particular, Article 33 obliges the doctor to inform the patient "regarding prevention, the diagnostic course, the diagnosis, the prognosis, the therapy and any diagnostic-therapeutic alternatives", stating that, in the case of serious or adverse prognosis, the communication must be suited to the patient's capacity to understand, considering their sensitivity and without excluding elements of hope. Article 35 repeats that "the doctor should not undertake or continue any diagnostic procedures and/or therapeutic interventions without first acquiring informed consent or in the presence of informed dissent" and that this consent must be acquired in written form in the cases foreseen by the law and by the deontological code, and in those foreseeably with a high risk of mortality or with results that could considerably affect the psychophysical well-being of the patient.

With regard to the obligation for informed consent in the field of the deontological code, it has been shown[73] that it improves the doctor-patient relationship, becoming an essential element of the decision-making process, aimed not at creating an impossible uniformity of knowledge, but at laying the foundations for the patient to accept or refuse the treatment proposed. And it has also highlighted the fact that the doctor is not required to "tell all", but to give the elements he considers necessary to allow the patient to decide.[74]

Precisely linked to this last aspect is the very delicate question of how to communicate serious or life-threatening diagnoses. In such cases, the need, emphasised by the code, to follow courses that do not traumatise the patient requires a fundamental indication of method for the

70 On this question See also A. Bellelli, *Codice di deontologia medica e tutela del paziente*, in «Rivista di diritto civile», II, 1995, pages 577 *et seq.* Who feels that the rules of the deontological code can only have general value since it sets out general principles of a juridical nature (such as professional behaviour, diligence, or consent) and this from the moment that, since the orders and the professional boards lack autonomous normative power, they cannot directly introduce rules equivalent to the norms of the general law. On the other hand, we should reject the theory – supported by part of the interpreters – that deontological rules should be considered mere extrajudicial precepts (in this sense, See also for example Cass., 23rd July 1993, N. 8239, in «Repage Foro Italiano», 1993, article *Professioni intellettuali*, N. 135; Cass., 17th January 1991, N. 401, in «Foro italiano», I, 1992, c. 2243). On this point See also also M. Tavani, M. Picozzi and G. Salvati, *Manuale di deontologia medica*, Milano, Giuffrè, 2007, page 48.

71 M. Graziadei, *Il consenso informato e i suoi limiti*, op. cit., page 195.

72 The deontological code, after its first adoption in 1978, has been periodically updated with the versions 1989, 1995, 1998, 2006 and 2014, currently in force.

73 These opinions refer to the 2006 code, which however differs only slightly from the current one, therefore they appear to be still valid.

74 M. Tavani, M. Picozzi and G. Salvati, *Manuale di deontologia medica*, op. cit., page 349.

doctor: he must try to *offer the truth* to the patient "creating the conditions so that it can be revealed, encouraging an opportune time so that the patient can accept it."[75]

While these indications of the new code are in line with the previous versions, it is necessary to emphasise that they also introduce an innovative rule with respect to the past, where it was foreseen that the doctor should also give information about "the behaviour that the patient should observe during the treatment."

With regard to this expectation, it was emphasised by the first commenters of the new discipline that this should be read as the intention to introduce a duty for the patient to abide by the behaviour indicated by the doctor as necessary to improve their state of health, and this could be considered in contrast with the principle of autonomy, that is the freedom of the patient to knowledgeably choose if and when to undergo medical treatment.[76] To justify such an expectation, it has on the other hand been observed, that the behaviour of the patient, who after knowledgeably accepting treatment, acts in a manner contrary to the prescriptions received, could be considered unfair, since he has the duty to behave correctly in his commitment in order to ensure that the efforts of the doctor attain the best results.[77]

3. *The normative basis for informed consent in supranational law*

In classic international law, the discipline of the relationships between the state and the community of individuals residing in its territory was included within the area of *domestic jurisdiction*, that is those sectors in which each state is free to exercise its power, without encountering significant international limitations. It was only after the end of the Second World War that international law, taking into account above all the atrocities committed during this conflict, began to impose limits that increasingly penetrated territorial sovereignty, through, in particular, the use of agreements aimed at pursuing the values of collaboration, solidarity and justice between peoples[78]. Amongst these, of significant importance were the agreements that recognised and guaranteed – not only for the citizens, but for all those subject to the jurisdiction of the state – rights considered fundamental, since they were seen as expressions of human dignity and personality.[79]

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75 *Ibidem,* page 3.

76 G. Montanari Vergallo *et al.*, *La solitudine del medico di fronte al suo «nuovo» codice di deontologia*, in «Responsabilità civile e previdenza», 2014, pages 2096 *et seq.*

77 *Ibidem* the new version of Article 33 is defined as ethically correct.

78 Although it is not binding for the member states of the United Nations, the document that first marked the passage towards a new international order, based on respect for the rights of man, is the 1948 Universal Declaration of Human Rights (See also U. Villani, *Dalla Dichiarazione universale alla Convenzione europea dei diritti dell'uomo*, Bari, Cacucci, 2012, pages 16 *et seq.*)

79 Cf. L. Marini, *Diritto internazionale e comunitario della bioetica,* Torino, Giappichelli, 2012, pages 10 *et seq.*, according to whom we are seeing a conventional movement in favour of the fundamental rights of man, which corresponds to the erosion of the sphere of *domestic jurisdiction* of the nations.

So, the right of the patient to express their informed consent (or dissent) to the medical treatment has found express recognition both in acts with merely political significance, such as the previously mentioned Nuremberg Code of 1947 or the Declaration of Helsinki of the World Medical Association of 1964, and in the field of juridically binding instruments such as the *International Covenant on Civil and Political Rights*, approved by the United Nations in 1966 and, at regional level, the Convention for the Protection of Human Rights and Fundamental Freedoms of 1950 (now, European Convention on Human Rights, ECHR), the Oviedo Convention on Human Rights and Biomedicine of 1997 and the EU Charter of Fundamental Rights, which became legally binding with the Treaty of Lisbon on 1st December 2009.

Finally, to complete this review of the instruments that have led to the establishment of the principle of informed consent, it is therefore opportune to briefly examine the directives that refer to it in the acts previously mentioned.

3.1 The instruments of "soft law"

Amongst the supranational instruments lacking legally binding efficacy that expressly enunciate the principle of informed consent of the patient, we can mention the Nuremberg Code of 1947 and the WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects of 1964.

With reference to the Nuremberg Code[80] – which is generally considered the document that for the first time established the ethical rules for human experimentation based on informed consent – we have already emphasised that its importance is linked to the fact that through this document the rights of the individual in the field of medical practice and scientific experimentation acquired centrality and the foundations for the construction of modern medical ethics were laid. This determined a passage from the paternalistic assistential model, which saw the doctor and his clinical intervention or research activity aimed at scientific progress as the central element of therapeutic activity, to a model that paid more attention to the interests of the patient. This acquisition is most clearly expressed precisely, in the introduction to the Code, already mentioned above, according to which "The voluntary consent of the human subject is absolutely essential."

Although the Code is not legally binding, it is undoubtedly of fundamental importance in the development of the safeguards for human rights and medical ethics. Precisely the principle of informed consent set out therein was, in fact, universally received and has become the basis for a wider expression not only in the area of the Helsinki Declaration on ethical principles for medical

80 For the origins of this Code, See also *supra*, paragraph 2.

research that involves human beings[81], but also in the subsequent international ethical guidelines for biomedical research involving human subjects (including the commitment to guarantee the application of the Helsinki Declaration in developing countries), which were elaborated for the first time by the Council for International Organizations of Medical Sciences (CIOMS) in 1982, of which the third series was published in 2002.[82]

In relation to informed consent, it is important to mention, in particular, the explanatory comment of the guidelines because, in addition to enouncing the purpose of this principle (that is to protect the autonomy and freedom of decision of the individual), it pays particular attention to the process through which consent must be obtained. The comment emphasises that it is not sufficient for the consent to be acquired only during the first contact with the person who will carry out the experiment, but rather, it is necessary for the consent to continue throughout the relationship. It is

81 World Medical Association, *Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects*, 1964, www.wma.net/en/30publications/10policies/b3/. The declaration states, with reference to the principle of informed consent that " 25. Participation by individuals capable of giving informed consent as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no individual capable of giving informed consent may be enrolled in a research study unless he or she freely agrees".
26. In medical research involving human subjects capable of giving informed consent, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, post-study provisions and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participation at any time, without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information. After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's freely-given informed consent, preferably in writing. If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed. All medical research subjects should be given the option of being informed about the general outcome and results of the study.
27. When seeking informed consent for participation in a research study the physician must be particularly cautious if the potential subject is in a dependent relationship with the physician or may consent under duress. In such situations the informed consent must be sought by an appropriately qualified individual who is completely independent of this relationship.
28. For a potential research subject who is incapable of giving informed consent, the physician must seek informed consent from their legally authorised guardian. These individuals must not be included in a research project that has no likelihood of benefit for them, unless it is intended to promote the health of the group represented by the potential subject, or the research cannot instead be performed with persons capable of providing informed consent, and the research entails only minimal risk and minimal burden.
29. When a potential research subject who is deemed incapable of giving informed consent is able to give assent to decisions about participation in research, the physician must seek that assent in addition to the consent of the legally authorised representative. The potential subject's dissent should be respected.
30. Research involving subjects who are physically or mentally incapable of giving consent, for example, unconscious patients, may be done only if the physical or mental condition that prevents giving informed consent is a necessary characteristic of the research group. In such circumstances, the physician must seek informed consent from the legally authorised guardian. If no such representative is available and if the research cannot be delayed, the study may proceed without informed consent, provided that the specific reasons for involving subjects with a condition that renders them unable to give informed consent have been stated in the research protocol and the study has been approved by a research ethics committee. Consent to remain in the research must be obtained as soon as possible from the subject or a legally authorised representative.
31. The physician must fully inform the patient which aspects of their care are related to the research. The refusal of a patient to participate in a study or the patient's decision to withdraw from the study must never adversely affect the patient-physician relationship.
32. For medical research using identifiable human material or data, such as research on material or data contained in biobanks or similar repositories, physicians must seek informed consent for its collection, storage and/or reuse. There may be exceptional situations where consent would be impossible or impracticable to obtain for such research. In such situations, the research may be done only after consideration and approval of a research ethics committee.

82 *International Ethical Guidelines for Biomedical Research Involving Human Subjects*, prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (Who), Genève, 2002. Guideline N. 4 states that "For all biomedical research involving humans the investigator must obtain the voluntary informed consent of the prospective subject or, in case of an individual who is not capable of giving informed consent, the permission of a legally authorized representative in accordance with applicable law. Waiver of informed consent is to be regarded as uncommon and exceptional, and must in all cases be approved by an ethical review committee."

further stated that the existence of this ongoing determination of the patient must be guaranteed, "by informing the prospective subjects, by repetition and explanation, by answering their questions as they arise, and by ensuring that each individual understands each procedure […]. Each individual must be given as much time as is needed to reach a decision, including time for consultation with family members and others."

3.2 The legally binding supranational instruments

Although amongst the legally binding documents that expressly contemplate the principle of informed consent that with the most universal vocation is the *International Covenant on Civil and Political Rights*, approved by the United Nations in 1966[83], it is, however, the CEDU of 1950[84] to which we must turn to identify on the international plane an instrument that guarantees effective protection for human rights in general, and, in particular, for that which most interests us here, the right of the patient to express informed consent to medical treatment. Actually, what makes the CEDU capable of genuinely protecting the fundamental rights is substantially the fact that it does not simply enunciate a catalogue of rights and freedoms that the states agree to guarantee to each person under their jurisdiction, but it also institutes *ad hoc bodies*, charged with overseeing the observance of the rights that they recognise, including, in particular, the European Court's Human Rights.[85]

Furthermore, it is precisely thanks to the jurisprudence that was formed within the European Court for Human Rights that the right to express one's informed consent to medical treatment – otherwise not specifically foreseen by any regulation of the Convention – manages to find adequate recognition and protection. The Court, in fact, identifies the normative foundation in Article 8 CEDU, which, in paragraph 1, states, "Everyone has the right to respect for his private and family life, his home and his correspondence." Including in the concept of "private life" mentioned therein as the right of the individual to physical and psychological integrity. Starting, therefore, from the consideration that physical integrity is a fundamental right of the individual, the Court states that "any interference with the person's physical integrity must be prescribed by law and requires the consent of that person,"[86] and that, consequently, the performance of any medical treatment with or

83 Where it is stated that "No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation." The Covenant was followed in 2000 by the *General Comment 14 – The Right to the Highest Attainable Standard of Health*,, which is considered an instrument of *soft law* (B. Toebes *et al.* (ed.), *The Right to Health. A Multi-Country Study of Law, Policy and Practice*, Den Haag, Springer, 2014, page 343).

84 See also C. Russo and P.M. Quaini, *La Convenzione europea dei diritti dell'uomo e la giurisprudenza della Corte di Strasburgo*, Milano, Giuffrè, 2006, pages 3 *et seq.*

85 See also L. Marini, *Diritto internazionale e comunitario della bioetica*, op. cit., page 13.

86 ECHR, Case of Y. F, v. Turkey, 22nd June 2003.

against the consent of the patient constitutes an illegitimate interference, unless it was justified by the presence of circumstances set out in paragraph 2 of Article 8. This rule notably consents the infringement of the right in question only under certain circumstances when it specifies that, "There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others."[87] It is stated, finally, that the protection of the patient's right – which in any case presupposes that the consent or dissent are comprehensive and informed[88] – cannot be limited even when the respect for the will expressed by the patient will have a fatal outcome.[89]

Alongside the ECHR, another international source that has had a decisive importance in affirming the principle of informed consent is the Oviedo Convention on the protection of human rights and the dignity of the human being regarding the application of biology and medicine dating from 1997.[90] Article 5, in fact, approves the need for prior, free and informed consent of the patient for any medical intervention. It is only possible to ignore this general rule in cases of emergency, providing the intervention is essential and will benefit the health of the person in question (Article 8) and notwithstanding the obligation to consider the wishes expressed by an interdicted person. Article 16, then, includes amongst the conditions under which research carried out on a human being can be considered justified, the necessary information and the written consent, which can be revoked at any time by the patient taking part in the research.

To conclude, amongst the supranational instruments that recognise and guarantee the right to informed consent, we must also mention the EU Charter of Fundamental Rights (Nice Charter), which was proclaimed in 2000 and which, following the enforcement of the Treaty of Lisbon of 1st December 2009, acquired the same legal value as the Treaties, so that the fundamental rights set out in them became binding for all the member states.

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87 ECHR, Roger Acmanne and others v Belgium, 10th December 1984. For an examination of the situations that, pursuant to Article 8, paragraph 2, could legitimate the interference with the right of the individual to private and family life See also L. Tomasi, *sub.* Article 8 in *Commentario breve alla Convenzione europea dei diritti dell'uomo*, directed by S. Bartole, P. de Sena and V. Zagrebelsky, Padova, Cedam, 2012, pages 326 *et seq.*

88 ECHR, V. C, v Slovakia, 16th June 2009.

89 ECHR, *Pretty v United Kingdom*, April 29th 2002.

90 Although the President of the Italian Republic promulgated the Law N.145/2001 which ratified and enforced the Oviedo Convention, Italy is not yet part of this agreement, given the lack of legislative decrees with further rulings necessary for the adaptation of the Italian legal system to the principles and the norms of the Convention (See also Article 3, Law N. 145/2001) and given that the ratification was not filed at the European Council (See also C. Casonato e F. Cembrani, *Il rapporto terapeutico nell'orizzonte del diritto*, in L. Lenti, E. Palermo Fabris and P. Zatti (ed.), *I diritti in medicina*, op. cit., page 56). Despite this, the jurisprudence has established that this international source, although it must give way in the face of contrary national legislation, can and must be used in the exegesis of the latter, in order to guarantee a reading as far as possible in agreement with the Convention itself (Cass., 4th October 2007, N. 21748, in «Corriere giuridico», 2007, pages 1676 *et seq.*, with note by E. Calò, *La Cassazione «vara» il testamento biologico*).

Free and informed consent, in the Nice Charter, finds precise recognition, as an expression of the right to the integrity of the person, in Article 3 paragraph 2, in which it is stated that, "In the fields of medicine and biology, the following must be respected in particular: […] the free and informed consent of the person concerned, according to the procedures laid down by law, […].[91]

With reference to this Charter, the doctrine has emphasised that it is a new ruling in the field of a charter of organic and universal rights, which can be traced, apart from the principles of the previously mentioned Oviedo Convention (to which many countries did not adhere), in the jurisprudence of many countries, and which has led to a widespread recognition of the right to individual self-determination in the medical field and, therefore, to its principal legal instrument, informed consent.[92] Moreover, the emphasis was placed on the systematic collocation of the rule in Chapter 1 of the Charter, which tends to suggest that informed consent is one of the primary rights, which belong to the individual simply because they exist and that therefore they can be safeguarded not only against the State, but also against any other authority: in the specific case, the doctor.[93]

Chapter Two

Anthropology of informed consent. Methodological questions

The anthropological research described in this chapter was carried out between April 2014 and April 2015 at the hospital complex Città della Salute e della Scienza in Torino. Many people were involved in the project: health directors, consultants, doctors, psychologists, radiologists, midwives, nursing staff, obstetricians, social workers, cultural mediators, patients and members of the patients' families.

1. *Protagonists and places of the research project*

1.1. *Institutional support*

The first factor that allowed this research project to take place was the institutional support offered. The prolonged immersion within the hospital spaces would not have been possible without the commitment to the study shown by the chief medical officers of the Città della Salute e della Scienza. The interest shown in the project, considered from the start *a useful opportunity* for

91 The law is to be found in Chapter 1, "Dignity", which includes five articles, dedicated to human dignity (Article 1), the right to life (Article 2), the right to the integrity of the person (Article 3), the prohibition of torture and inhuman or degrading sentences or treatments (Article 4) and the prohibition of slavery and forced work (Article 5).

92 A. Santosuosso, *Integrità della persona, medicina e biologia: art. 3 della Carta di Nizza*, in «Danno e responsabilità», 2002, page 86.

93 S. Andaloro, *Il principio del consenso informato tra Carta di Nizza e ordinamento interno*, in «Famiglia e Diritto», 2011, page 86.

contemplating a topic that is hotly debated inside and outside the hospitals, allowed the researcher to overcome the principle obstacle encountered in many ethnographic research projects: what is known as the *getting-in* or the possibility of access to the field.[94] Together with the possibility that an organisation is not always keen to sit under the anthropologist's analytical magnifying glass, there can be many misunderstandings regarding the research projects carried out in institutional contexts. In this case, the main risk was that the chief medical officers could interpret the research as a "dangerous inquiry" for the medical personnel, observed during an activity already considered problematic at legal level, such as the gathering of informed consent. The preliminary meetings with the chief medical officers allowed the researchers to clarify from the start the intentions of the project. The enthusiasm shown by the doctors has often exceeded our expectations. The willingness to question their attitudes was not, in fact, merely a bureaucratic endorsement. The effort made to allow access to the hospital (*getting-in*) was accompanied by the offer of other operative supports, aimed at guaranteeing the success of the study (*getting-on*). In particular, the support offered by the heads of the Quality and Risk Management Units corresponded to a scientific support for the realisation of the research within a hospital that the management itself has called "a city within a city". The hospital complex Città della Salute e della Scienza, born in 2012, is in fact composed of four different hospitals: the Molinette Hospital for adults, the obstetrical and gynaecological hospital Sant'Anna, the paediatric hospital Regina Margherita and the Centro Traumatologico Ortopedico (CTO)/Maria Adelaide trauma and orthopaedics centre, which are situated just a few blocks from each other, in the urban area of Torino: the so-called "hospital city". The Molinette Hospital, which employs 5,997 people, has 95 wards, 1,270 beds, and treats 50,657 patients and 78,357 cases at the A&E department each year. Sant'Anna employs 1,288 people, with 37 wards, 477 beds, 28,587 patients per year, 25972 cases at the A&E department and 7,667 births per year. Regina Margherita has 1058 employees, 49 wards, 286 beds, 13,521 patients per year, 47,841 cases at the A&E department and the CTO/Maria Adelaide hospital has 1,890 employees, 36 wards, 419 beds, with 15,574 patients and 46,054 cases treated at the A&E department each year.

Help received from the chief medical officers prior to the start of the study included: the issue of an informative circular describing the research project, sent to all the consultants and doctors on the wards; access to all the documents containing the latest regional directives on informed consent; the sharing of a database with all the statistical data on hospitalisation in the various departments of the Città della Salute e della Scienza; evaluation of the best schedule in which to carry out the research work at the clinics and on the wards, in order to have the most complete overview possible of the medical personnel's work. This help was particularly useful in

94 G. Gobo, *Descrivere il mondo. Teoria e pratica del metodo etnografico in sociologia*, Roma, Carocci, 2001; M. Marzano, *Etnografia e ricerca sociale*, Roma-Bari, Laterza, 2006.

formulating more precise research questions and for organising the period of observation in the clinics and on the wards. At the same time, the chief medical officers, who rapidly considered our research project an opportunity to receive an external evaluation from a team composed of a jurist and an anthropologist, asked us to realise a *wide-ranging comparative study* in which we compared the various areas of hospital medicine, in order to allow them to ponder, through a new viewpoint, on the "good" and "bad" practices inherent in informed consent. The request was above all to include in the anthropological field study some areas – such as geriatrics, paediatrics or intensive care, and certain categories of patient – such as the Jehovah's Witnesses – considered particularly problematic from the standpoint of informed consent. The proposal, presented by the chief medical officers and welcomed by our team, was, in other terms, to transform what had been intended as a research project *within and on the hospital situation* also into a study *for the benefit of the hospital situation*. Thus, the choice of the wards on which to carry out the research was made largely together with the chief medical officers of the hospitals that form the Città della Salute e della Scienza. Since it was impossible to observe all the wards, they were chosen on the basis of two criteria: 1) the homogeneity of the treatments and the heterogeneous nature of the patients that is to say, the study of the way the same course of treatment or surgical procedure varies according to the specific categories of patient (newborn babies, adults and children); 2) the heterogeneous nature of the treatments and the homogeneity of the patients, on the other, that is the study of the various courses of treatment according to specific categories of patient, for example the treatments destined for the women in the obstetrical-gynaecological area or the treatments destined for the children on the paediatric wards. In addition to the wards chosen as a representative sample, with the assistance of the chief medical officers, it was necessary to add those that spontaneously offered their participation, showing a considerable interest in the study after receiving the circular. This process of grassroots selection resulted in a study of *more than twenty-five* clinics and wards, in each of which the period of observation lasted on average one month.[95] The places in which the research was carried out were in particular: the clinics and wards of internal medicine, oncology, haematology, cardiac surgery, elective surgery, transplant surgery, gastroenterology, intensive care, reanimation and psychiatrics at the Molinette and Regina Margherita hospitals; the ultrasound scan and prenatal diagnosis centre, the medically assisted procreation centre, the Breast Unit, obstetrics and gynaecology wards at the Sant'Anna Hospital; the A&E department for minor and major trauma, the radiology clinic and ward at CTO/Maria Adelaide. In some cases, the research was carried out in wards belonging to various hospitals, such as the neonatal intensive care ward, which is linked to both Sant'Anna and Regina Margherita hospitals. In other cases, the study involved

95 On this question, we must emphasise that the study of many clinics and wards was carried on contemporaneously. The researcher was present at various times during the day (morning and afternoon) according to the activities of the hospital.

services that are used by various clinics or wards, such as the radiology clinics at the Regina Margherita Hospital or the diagnostic centre at the Molinette Hospital, where the patients on other wards are taken for CAT scans, ultrasound scans, x-rays or other diagnostic tests. The permanence on these wards was a "passing through" presence, justified by the decision to follow the various stages of the hospital treatment of some patients involved in the study (see Table 1 in the appendix).

1.2 *Cooperation from the medical staff*

The second element that contributed to the success of the research was the interest shown by the medical staff encountered at the clinics and the wards. The welcome they gave me[96] allowed me to follow first-hand the daily activities of the hospital world. My attention was concentrated above all on the moments destined for the transmission of information and news, accompanying the health professionals in their numerous interactions with the patients and with the families of the patients. The overcoming of initial concerns and worries, such as the fear of being judged with regard to their attitudes to patients, allowed me access, often very quickly, to places and moments normally reserved for healthcare professionals, such as the daily ward rounds of the doctors, or the ward meetings between doctors and nursing staff. Generally, my access to the consultation rooms – the "heart" of hospital activities – came about on the second or third day after my arrival on the wards. The organisation of preliminary meetings, called each time by the consultants, at which to explain my presence facilitated the introduction of my role to the hospital personnel. Accompanying the healthcare professionals was a research method that allowed me to gather *dense data*, allowing me to construct a *thick description* of the hospital activities and a comparison with the *emic perspective* of the healthcare workers.[97] The explanations given to me by the operators with respect to the treatments proposed in the clinics and on the wards were important resources for understanding concepts and categories specific to the hospital environment. The sharing of the stories of the patients on the wards encouraged my integration within the team, allowing me to follow the discourses between the hospital professionals. Many operators actively supported me during the research, notifying me of interviews with the patients and allowing me anonymous consultation of medical records for the patients on the wards. At the same time, the presence at these meetings allowed me to follow the evolution of the clinical assistance offered to the various patients – what would be proposed and when – helping me to establish the duration of my presence within the services. In this manner, I managed to gather a lot of useful information on the stories of the

96 The use of the first person in this chapter is justified by the wish to involve those who took part in the research in the experience of the anthropologist, the author of this chapter.

97 C. Geertz, *The Interpretation of Cultures*, New York, Basic Books, 1973; Italian translation: *Interpretazione di culture*, Bologna, Il Mulino, 1987.

patients chosen as a representative sample from each of the wards examined. The access to the consultation rooms, on the other hand, multiplied the number of opportunities for observing the interviews with the patients and members of their families, since many professionals chose this place for communicating the information necessary for gathering informed consent. The welcome shown by the medical staff concerned both the persons I met at the clinics and on the wards: from doctors to midwives, from social workers to cultural mediators, and including the ward sisters and the trainee doctors. The cooperation with these figures allowed me to compare their professional experiences and understand their opinions regarding informed consent, the doctor-patient relationship and the relationship between the doctor and the patient's family.

1.3 *The readiness of the patients and members of their families*

The third group of persons that made it possible to carry out this research was composed of the patients and their families, who agreed to take part in the study. The daily contact at the clinics and during the ward rounds with the doctors helped me to understand which patients to try to include in the study. This evaluation was based on various criteria: the heterogeneous nature of the patient profiles, trying to balance as far as possible the number of men, women, young people, adults, elderly patients and children to be included in the study (see Table 1 in the appendix); the diversity of the family frameworks, trying to involve what are known as "isolated patients" (subjects without family, minors fostered by the local authorities) and patients accompanied by their family groups; the clinical situation – terminal patients or at immediate risk of death, and persons in critical situations from a physiological or psychological situation were, for example, excluded from the study; the attitudes of openness or closure shown towards the hospital personnel, trying to involve both those patients who were open to dialogue with the doctors and nurses and those who had an attitude of resistance in interactions with the hospital staff. The extremely heterogeneous nature of their profiles in terms of age (from the youngest patients in paediatrics to the oldest on the geriatric ward) gender identity (men, women, LGBT subjects) socio-cultural origin, Italian and foreign subjects, and pathology allowed me to gather the experiences of many and diverse social groups, representative of the trends and stratifications of our contemporary society (see Tables 6, 7 and 8 in the appendix).

The intention of the study was, in particular, to reflect on the experiences of the "average" hospitalised patient, without considering, above all or exclusively, the problems linked to the minorities. The objective set, together with the jurist, was in fact to examine the *complexity of normality*, in terms of family organisation and socio-cultural identity, and not only the problems

linked to the exceptions. The attainment of this objective was possible thanks to the cooperation of all those who allowed me to know the history of their illness and their opinions on the practice of informed consent. The discussions with the patients and the members of their families always occurred after informing them repeatedly of the objectives of our research. In the majority of cases, the access to the experiences of the patients and their family members was the result of a course of acquaintance that began, often not without ambiguity, with the introduction of my figure by the hospital staff. This process of acquaintance then continued, also during moments not destined for medical treatment. In the case of the minors, the procedure was to systematically inform their parents of the wish to involve their children in the research, trying at the same time to deal with the subjects in question according to their age. Generally speaking, if the parents agreed, the patients aged five and over were directly involved in the study. For the younger patients, I chose to speak exclusively to the parents and other representatives of the family present with them in the clinics and the wards.

2. *Research methodologies*

The research project carried out for thirteen months at the Città della Salute e della Scienza in Torino was mainly a qualitative study. This methodological choice was dictated by the greater pertinence of the tools of qualitative research for gathering the information necessary for understanding the effective functioning of the hospitals. The principle research technique used for this purpose was the "ethnographic method" specific to the anthropological field, full immersion in the hospital space through assiduous attendance at the clinics and presence on the wards included in the study. In the majority of cases, these were analysed one after the other, or simultaneously, according to the therapeutic schedule[98] of patients, which the researcher followed throughout the hospitalisation, from the time of admittance until they were discharged (or died).

2.1 *Participative observation*

The first research tool used at the clinics and on the wards was that of *participative observation*, that is the realisation of observations during the daily activities (ward rounds, department meetings, examination of patients at the clinics, chats in the consultation rooms, meetings with the nurses, meetings with the patients and the families of patients on the wards) of the various components of the hospital personnel (doctors, nursing staff and midwives, but also

98 M. Augé, *L'anthropologie de la maladie*, in «L'Homme», XXVI, 1-2, 1986, pages 81-90.

social workers, psychologists and cultural mediators). This activity of accompanying the hospital personnel during their "daily routine" made it possible to gather information that it would not have been possible to obtain only through the analysis of statistical data. The advantage offered by the participative observation consisted in the opportunity to see *how* the informed consent was gathered, without simply knowing *how many* consents were requested or signed by the patients in the various clinics and wards. At the same time, thanks to this type of activity, it was possible to analyse *changes* in the way the consent was obtained according to the identity of the patient (age, social origin, Italian or foreign nationality) and the position occupied by the professionals involved (doctors, nurses, midwives) within the hospital team. The influence of the social inequalities and the weight of the medical hierarchies were some of the themes that guided the observations, as will be seen in the following chapters. The moments and the places in which the observations were carried out and the way in which the interactions were characterised: 1) between the doctors and the patients, 2) between the doctors and the patients' families, 3) between the patients and their families, 4) between the various patients, or 5) between the doctors and other professionals were the ward rounds, the outpatient clinics, the follow-up clinics, the interviews during the visiting hours for the patients' families, the waiting rooms and the corridors of the clinics and the wards. The average duration of the observation activities was ten hours per day, a period necessary to reach the so-called *perduzione,*[99] or steeping of the researcher in their area of study. The passage from one ward to another required, on the other hand, a continual *adjustment* of the activity of observation of the situations encountered, and a constant *reconfiguration* of the position occupied at the side of the hospital professionals. In this respect, the choice not to concentrate the study on a single hospital sector represented one of the principal difficulties but also an element of originality of the project (see Table 1 in the appendix). Unlike other ethnographic research projects on informed consent, set in just one hospital setting, or centred on only one course of treatment – such as the oncological course,[100] treatment destined for the women in the obstetrical-gynaecological area[101] or the treatments for children in the paediatric area[102] – the dimension at the same time *comparative, qualitative* and *multidisciplinary* (anthropological and juridical) in this study makes it appear to be one of the first of this type, not only in Italy but also abroad.

99 L. Piasere, *L'etnografo imperfetto. Esperienza e cognizione in antropologia*, Roma-Bari, Laterza, 2002.

100 . Marzano, *Problemi etici nella ricerca sociale sui malati terminali: consenso informato, comitati etici e differenze culturali*, in «Sociologia e Ricerca Sociale», 75, 2004, pages 157-174; S. Fainzang, *La relation médecins-malades: information et mensonge*, Paris, Presses Universitaires de France, 2006.

101 M. Dixon-Woods *et al.*, *Why Do Women Consent to Surgery, Even When They Do Not Want to? An Interactionist and Bourdieusian Analysis*, in «Social Science and Medicine», 62, 2006, pages 2742-2753; D. Manaï, C. Burton-Jeangros and B. Elger, *Risques et informations dans le suivi de la grossesse: droit, éthique et pratiques sociales*, Bern-Bruxelles, Stämpfli-Bruylant, 2010; N. Press and C.H. Browner, *Why Women Say Yes to Prenatal Diagnosis?*, in «Social Science and Medicine», 45, 1997, pages 979-989.

102 C. Crocetta, *I diritti e l'autonomia decisionale del minore in ospedale*, Neuchâtel, Faculté de Droit, Université de Helbing Lichten Hahn, 2014.

2.2 *The semi-structured interviews*

Together with the technique of participative observation, the other research tool employed was that of semi-structured interviews. The use of the interviews served to understand what the healthcare professionals, the patients and the families of patients think about informed consent. At the same time, this allowed us to understand the workings of the interactions doctor-patient, doctor-family members, doctor-other healthcare professionals. In some cases, the interviews also served to have confirmation or clarification of the situations observed at the clinics or on the wards. Generally speaking, in fact, the interviews occurred after an initial period of observation – generally two weeks – at the clinics and on the wards.

Overall, 192 interviews were carried out, a considerable number and representative of a qualitative study of approximately one year. Of these, 98 were with representatives of the hospital personnel (half with the medical staff and the remainder with the midwives, nurses, social workers and cultural mediators) and 94 with patients and members of their families (see Tables 2, 3, 4 and 5 in the appendix). In the case of the hospital personnel, the places in which the interviews were carried out were the offices of the healthcare workers, the consultation rooms on the wards, the clinics and the cafeterias of the hospitals. The interviews took place mainly during moments "freed up" for this purpose by the medical personnel, despite the incessant rhythms of their hospital work. Amongst these moments were lunch breaks, coffee breaks, and shift changes at the clinics, the evening shifts on the wards, weekends and days when they were on call. In the case of the patients and their family members, amongst the places where the interviews were carried out we find the patient's bed, the waiting rooms of the clinics and wards, the corridors of the wards, the cafeterias of the hospitals. The duration of the interviews was at least one hour for both the medical personnel and for the patients and their families. The interviews were recorded only after receiving consent from the interviewees. If consent was not given, the researcher proceeded with field notes[103] written immediately afterwards in order to avoid losing the salient details gathered at the time and the sensations raised. The same occurred for the doctor-patient and doctor-family member interviews. The transcription (and the analysis) of the ethnographic notes and the audio recordings of the interviews was always and exclusively in an anonymous form.

2.3 *The statistical data*

103 G. Gobo, *Descrivere il mondo. Teoria e pratica del metodo etnografico in sociologia*, op. cit.

Together with the techniques mentioned so far, the study was also based on the gathering and the analysis of the quantitative data made available by the chief medical officers and the heads of the various clinics and wards. The analysis of the statistics relating to the admittances made it possible to gather more information on the population received by the clinics and the wards, facilitating the process of selection of the patients to be included in the research. Another source used in the study was represented by the data made available for the period between 2013 and 2015 by the Public Relations Office (URP). The analysis of the figures relating to reports by the patients and members of their families regarding the treatment received in the hospital environment was concentrated above all on the complaints regarding the way in which the medical personnel communicated medical information. The reconstruction of the doctor-patient conflicts was accompanied by the study of the courses that determined the resolution within or outside the hospital (tribunal sentences). This analysis was augmented by the data made available by the heads of the Tribunale per i Diritti del Malato (Tribunal for Patients' Rights) and the members of the association Cittadinanzattiva (active citizenship), included in the research as bodies present within the hospitals analysed. Also in this case, the study of the figures relating to complaints lodged by patients and their family members for the period 2013-2015 was accompanied by the reconstruction of the cases, with particular attention for the complaints concerning the information for patients and the gathering of informed consent. In order to look more closely at the statistical data and the anonymous reading of the patients' reports to the Public Relations Office and the Tribunal, I later carried out interviews (four altogether) with the representatives of these bodies involved in safeguarding the patients' rights.

The study of the problematics relating to informed consent was based equally on the analysis of the forms and of the informative brochures distributed by the medical personnel to the patients. The attempt was to understand how the forms were planned and which players were involved at local and national level (Regional authorities, Ministry of Health, Istituto Superiore di Sanità, scientific companies, pharmaceutical companies). Finally, the reference to secondary sources, such as the results of similar research carried out in other areas of Italy and in other national contexts (United States, Canada, France, Britain, Switzerland, Germany amongst others) allowed the author to extend the considerations beyond the context chosen for the research: one of the oldest and most important hospital complexes in the city of Torino. The comparison between what was observed at the Città della Salute e della Scienza and what is described in the Italian, American, German, Anglophone and French literature was particularly useful for highlighting the representative nature of our case study at national and international level. As will be seen during the

following chapters, the complexity and the limits of informed consent examined for the Torino-based reality are valid also elsewhere, in Italy and abroad.

3. *Ethical aspects of the research*

The story of Maria[104] presented here is representative of the challenges posed by the intensity and the dramatic nature of the experiences of the subjects encountered in the field by the researcher who chooses to study illness and the experiences linked to the life and the death of their subjects.

Maria was first admitted to hospital on the morning on which the field research began. When we met, Maria (54 years of age, unmarried and with no children) already knew that she was ill. During our first meeting on the internal medicine ward, her niece Tania and her sister Anna were already present. Maria had been admitted as an emergency, following a worsening of an illness of which she had been informed only a few weeks earlier. The pancreatic tumour diagnosed by her GP required treatment. She was discharged from the internal medicine ward a few days later, following an interview with the oncologist and a number of tests (CAT scan, PEG, EGD[105]) at the diagnostic centre of the hospital complex. From that moment onwards, the patient would return regularly to the clinic of the hospital's oncological centre for various cycles of chemotherapy aimed at containing the illness. However, after a few months of treatment, Maria was again admitted to the internal medicine ward. This time the medical personnel proposed to operate. Following a meeting with the oncologist, the psychologist, the anaesthetist and the surgeon, at which her sister Anna was present, Maria was transferred to the surgical ward. The operation was a success and Maria spent a few days on the intensive care ward and then on the surgical ward. A few weeks after she was discharged, the incision made during the operation became infected and the patient was accompanied by her sister and brother-in-law to the A&E department of the hospital. From here, she was again admitted to the internal medicine ward. At this time, she learned from the doctors on the ward that the tumour had spread to her liver. She did not want to undergo another cycle of chemotherapy. After speaking to the oncologist, the psychologist and the surgeon, the decision was made to carry out a second operation. However, the operation was more complex than foreseen, due to complications, which were described to Maria's sister by the surgeon, while she was still under anaesthetic on the intensive care ward. When she awoke, Maria was informed by the medical personnel and her sister of what occurred in the operating theatre. As the oncologist explained, at this point the only

104 In order to protect the identity of the persons who generously contributed to the research, all the names used in this book have been changed.

105 Percutaneous endoscopic gastrostomy (PEG), esophagogastroduodenoscopy (EDG).

alternative was chemotherapy. Despite Maria's uncertainty, the third meeting between the patient and the psychologist led to the decision to attend the oncological clinic of the hospital once again. However, the oncological treatment lasted only a few weeks. In view of the evident inefficacy of the therapy, the oncologist decided to activate palliative care at home. The difficulties that Maria's sister encountered in dealing with the increasingly intense pain over the weeks that followed the suspension of the chemotherapy led to a new admittance to the internal medicine ward. Maria was in the same room where we had met five months earlier. The news that Maria had died was communicated to me by her niece Tania two days after she had been admitted to hospital from her sister Anna's home.

As shown by the anthropologist Leonardo Piasere,[106] the impossibility of separating the scientific objectives of the anthropological research from the underlying human dimension of the interpersonal relationships constructed and experienced, often on a daily basis, with the interlocutors represents both one of the main limits and one of the greatest resources of the production of knowledge in the field of social sciences. The difficulties that the anthropologists often encounter in maintaining the correct "distance" from their interlocutors, who are both *subjects* and *objects* of the field research, is particularly evident when the topics concern health and illness. In this case, in fact, the human challenges that characterise anthropological research are accompanied by other challenges, often experienced directly by the researcher.

3.1 *The adaptation of the researcher to the hospital space*

The first challenge concerned a phenomenon often experienced by medical students during their first bedside encounters with the patients,[107] that is, the tendency to identify with the patient and allow themselves to be carried away by their suffering. The second concerns the feeling of empathy that researchers feel with regard to the suffering of their interlocutors. In both cases, the difficulty in remaining "neutral" goes hand in hand with the need to pass through a process of socialisation of the *modus facendi* of the medical personnel. What represents normality for the medical personnel becomes, or rather must be transformed into daily experience for the researcher. The lack of familiarity with the daily contact and the close relationship with illness and death can, nonetheless, represent an obstacle for this transformative process. The result, in many cases, is a tension between the emotional involvement felt by the researcher and the attempt to enact a course of *distancing* from that which they have chosen to examine within the hospital environment. As shown during the research, the difficulty in *objectivising* the subjects involved in the study – like

106 L. Piasere, *L'etnografo imperfetto. Esperienza e cognizione in antropologia*, op. cit.
107 G. Pizza, *Antropologia medica. Saperi, pratiche e politiche del corpo*, Roma, Carocci, 2005.

the difficulty in transforming the stories and the experiences of the patients into simple research data – accompanies a tendency towards self-reflexivity by the researcher[108]. The elements that led me repeatedly to examine the legitimacy of my presence during certain key moments of the lives of the patients were mainly, on the one hand, the physical adaptation demanded by the hospital environment, and on the other, the continual need to play my role within the medical environment.

The complete immersion of the researcher within the world of the hospital demands an adaptation not only of the individual personality, but also of the body, to that which is observed every day in the clinics and on the wards. The importance of the physical dimension in my fieldwork emerged from the first days of the research, when I was asked to undergo certain blood tests in order to gain access to the clinics and the wards. This procedure, which was presented to me as a routine test to which all the professionals are subject before they come into contact with the patients, authorised access to my body, even to my person, within the medical environment. As shown in an explicit manner by this procedure, the presence in the field linked to anthropological work corresponds to the introduction of an *external body* in environments that are kept as closed and aseptic as possible for the well-being of the patients. The penetration into spaces in which one does not have free access but into which it is necessary to be officially admitted therefore requires a verification of suitability, or the ascertainment that the researcher is a subject with a healthy, or "non-contaminating" body for the patients and the medical personnel. The physical examination of the anthropologist prior to the access to the more "intimate" areas of the hospital environment was not, however, the only element that underlined the importance of the somatic dimension of ethnographic work in a medical context. Once the admissibility of the researcher was established, the enrolment in the hospital world required an important effort of control of self and of the body. To become accustomed to the often intense smells of the hospital environment, to overcome the physical reactions to the frequent exposure to the sight of blood and other biological matter, to become accustomed to the bearing the patients' expression of pain, to overcome the fear of contagion and the transmission of illnesses are all passages necessary for the success of work in the field or the medical anthropologist. The close contact with sick people, like the degree of unusual proximity with the bodies of hospital patients, shows just how far the organisation of ethnographic research in the hospital environment represents a *test* that demands a course of physical and psychological adaptation by the anthropologist.

3.2 *The relationship with the medical personnel*

108 G. Althabe and V.A. Hernandez, *Implication et réflexivité en anthropologie*, in «Journal des Anthropologues», 98-99, 2004, pages 15-36.

The adaptation to the challenges posed by the hospital routine do not, nonetheless, eliminate the condition of extraneousness that the anthropologist often feels within an environment that does not belong to them. The attempt to adjust one's behaviour to life on the wards in many cases clashes with the role of "spectator" played within them. At the same time, the effort to try to make one's presence as "invisible"[109] as possible is frequently invalidated by the expectations of the protagonists in the interactions that he or she wishes simply to observe. As emphasised by the work of other medical anthropologists,[110] the ambivalence inherent to participative observation is largely linked to the fact of wearing the same uniform as the medical personnel. Another of the limits placed on the permanence within the services is in fact the request to wear a white coat during the ethnographic observations.[111] The symbol *par excellence* of the medical profession, the use of the white coat distances the anthropologist from the image of an external observer bringing them closer *in effect* to the image of a player on the hospital team. As emerged during the research, the doctor's garb that I wore during the hours I spent in the hospitals, and not only during the doctor-patient interviews, facilitated my camouflage in the medical situation – the fact that I was wearing a white coat, for example, allowed me to follow the patients from one ward to another inconspicuously and without being queried by the hospital personnel.[112] At the same time, looking like a doctor attributes greater authority to the work carried out by the researcher and may help in the construction of a dialogue with the medical personnel. Thanks to the white coat, in fact, the anthropologist becomes, in the eyes of the medical personnel, a sort of colleague, a figure who, although not a doctor, has expertise in the medical field, an interlocutor authorised to express themselves on topics regarding medicine, a subject with whom it is possible to discuss questions relating to one's professional sphere. The assiduous presence and the apparent similarity with any other hospital professional frequently helped to disguise the fact that mine was a temporary presence. In various cases, after a while, the barriers initially raised against my figure were replaced by attitudes of complicity and alliance by the medical personnel.

The influence of the researcher's presence on the performance of the subjects studied is a phenomenon well known to anthropologists.[113] The organisation of long-term research, like that carried out in Torino, helps nevertheless to identify any attitudes enacted by the researcher's

109 C. Geertz, *Local Knowledge. Further Essays in Interpretive Anthropology*, New York, Basic Books, 1983.
110 S. Fainzang, *La relation médecins-malades: information et mensonge*, cit.; D. Fassin, *Pouvoir et maladie en Afrique. Anthropologie sociale dans la banlieue de Dakar*, Paris, Presses Universitaires de France, 1992.
111 In some services, such as reanimation, intensive care, haematology and post-transplant surgical wards, together with my white coat my hospital garb also included green scrubs – with overshoes, mask and sterile cape, as foreseen by the protocol of the wards. In the majority of cases, paradoxically, the more my "medical garb", the more my feeling of extraneousness – and not of integration – within the hospital spaces.
112 E. Goffman, *Asylums: Essays on the Social Situation of Mental Patients and Other Inmates*, New York, Anchor Books, 1961; Italian translation: *Asylums. Le istituzioni totali: i meccanismi dell'esclusione e della violenza*, Torino, Einaudi, 2003.
113 J.-P. Olivier de Sardan, *La rigueur du qualitatif. Les contraintes empiriques de l'interprétation socio-anthropologique*, Louvain-La-Neuve, Academia/Bruylant, 2008.

interlocutors in order to respond to their expectations, above all during the first stages of the research. One example is the progressive reduction in the time destined for compiling the informed consent forms, generally completed with great care during the first days of my presence on the wards, but gradually decreased as time passed. On this matter, while on the one hand the perception of a lack of judgement in many cases encouraged the abandonment of the "filters" initially used in the interactions with the patients, which progressively became more spontaneous despite my presence, on the other hand the relationship of trust constructed with the medical personnel was translated into the progressive tendency to ask my opinion on the situation observed. Thus, in a short time, the possibility of spending my days alongside the medical personnel without necessarily entering an operative relationship of *mutual exchange* became difficult to enact. The attempt to occupy a halfway position, for example trying to sit at the side of the table during the doctor-patient interviews, was not sufficient to make me appear a "third party" subject with whom it was not appropriate to share personal impressions on the conversations with the patients or their families. In particular, in accordance with the topic of the research, the role that the medical personnel attributed to me was above all that of "expert in informed consent". The proposal to take part in a workgroup for the purpose of drawing up a new consent to the donation/receipt of biological materials for the procedures of heterologous artificial insemination; the request for approval with regard to the players to be involved in signing the forms (above all in the case of elderly patients and in the case of minors); the invitation to present the results of the research at a conference destined for the hospital personnel[114] and the request for advice to improve the interactions with the foreign patients are some examples of the cooperation with the hospital personnel. In the majority of cases, the choice to welcome the overcoming of the "classic" role of observer in the field resulted in the progressive transformation of the ethnographic research activities into an *applied anthropology* study that did not end with the period of observation of the hospital space.[115] The meetings for feedback organised with the chief medical officers, my involvement in training courses for the medical personnel, the reference to the results of the research in constructing the new guidelines on informed consent underline the depth of the cooperation born from the meeting between the hospital personnel's desire to reflect critically on their practices and the "enactment" of her skills by the anthropologist.

114 One example is my report on the socio-anthropological aspects of informed consent in the obstetrical-gynaecological area as part of the conference and training course (CME – continuing medical education) *Nuovi test di screening e di diagnosi prenatale: quali informazioni ci danno e quali informazioni diamo alla donna*, organised by Dr Elsa Viora and Dr Tullia Todros on 21st March 2015 in Torino.

115 My current involvement in a workgroup for the revision of the criteria of informed consent in the reanimation area of the Molinette Hospital, or my participation as speaker at the training courses for paediatric nurses at the Regina Margherita Hospital are some examples of the ongoing cooperation with the medical personnel I met during the research project.

3.3 *The relationship with the patients*

In the relationship with the patients, the problematics linked to the hospital garb worn by the anthropologist during the field research were many. As for the medical personnel, the first problem was being mistaken for what one was not. What changes, however, is that the hospital garb worn by the anthropologist did not encourage in many cases the construction of a relationship of cooperation and trust. The perception of the researcher as a member of the hospital team in fact went hand in hand with the attribution of knowledge that did not belong to her. What we generally expect from an interlocutor who, according to the categories of common sense and the semantic codes of the hospital environment, appears to all intents and purposes a member of the medical team, is above all clinical competence. As emerged from the research, the principle expectation towards the anthropologist "dressed as a doctor" was the transmission of advice regarding their illness or the therapy suggested by the members of the hospital team. In the majority of cases, the roles attributed to my figure during the first encounter with the patients were those of postgraduate, nurse, psychologist, or doctor's assistant. This evaluation, probably linked to my age (31 years) and the marginal position assumed during the interviews, resulted in the frequent request for clarifications or technical integrations to what the doctor had said. Also, numerous patients or members of patients' families asked me questions about what to do during the temporary absence of the doctor, for example when he/she left for a few minutes to collect the patient's records or to consult a colleague. The difficulty encountered in clarifying my position in the face of this type of request was only partly resolved by the systematic presentation of my figure, by the doctor, before beginning the interview with the patients. Usually, despite the choice of the healthcare professionals to ask the patients and their families to authorise my presence, each time, giving them a copy of the research project, my figure was constantly associated with the medical team.[116] This fact emphasises the ambivalence of the situations in which the researcher was often involved and leads to a series of ethical questions. In particular, the medical authority attributed to the anthropologist in a healthcare context implies above all careful use of one's language and one's body language. The awareness of being able to influence the choices of the patients or members of their family even only through a glance, a smile or an expression of discomfort during the communication of bad news requires a particular ability in using one's body in a "neutral" manner. The possible interpretation of a smile as a signal of encouragement to begin or continue the treatment is valid, in fact, not only for the hospital professionals, but also for the anthropologist present alongside them. The same can be said for the eye contact often sought by the patients to try to understand what the medical personnel

116 P. Sankar, *Communication and Miscommunication in Informed Consent to Research*, in «Medical Anthropology Quarterly», 18, 2004, pages 429-446.

thinks about the treatment proposed. The reading of messages in the body language and the gestures of all those present at the moment of communication regarding a diagnosis or a prognosis refers to the human dimension of the doctor-patient interactions, in which the researcher is inevitably involved. On the other hand, the need to tell the truth about one's role without for this reason losing the possibility of a subsequent discussion with the patients and their families poses a number of problems. When asked questions such as: "How long have you been working with this doctor? Were other patients satisfied? Does this treatment usually work? Have you had other cases in which problems arose? In your opinion, have I made the right choice?" the answer, "I'm sorry, but I can't answer your questions. As the doctor explained previously, I am not a doctor. I am an anthropologist and I am carrying out research into the way informed consent is gathered", the patients and their families generally reacted with an expression somewhere between surprise and disappointment. In some cases, after a few minutes silence, the patients themselves asked for more information on the research. If this did not occur, I supplied more details about the project, progressively "stripping" the role of healthcare worker that had been attributed to me. The acceptance of my "true" function at the clinics and on the wards did not occur at the same speed and in the same way for all the patients and family members. The work of reciprocal acquaintance proceeded differently each time, according to the profile of the patient (age, pathology, duration of the stay in hospital, Italian or foreign origin) and the characteristics of the family group. In the majority of cases, the understanding (at least in general) of the objectives of the research and the construction of a relationship of trust necessary for sharing intimate and often painful information, required a prolonged effort. The lack of knowledge about the figure of the anthropologist and the anthropological discipline was often compensated by the interest the patients and their families showed in a study on informed consent. What initially appeared to them as a waste of time, useless for their current clinical situation was later described by many of the subjects interviewed as an occasion for offering suggestions and advice to the doctors, starting with their own story. The idea of offering a contribution to the community of patients was emphasised repeatedly during the interviews. As often happens during the course of ethnographic research projects (not only in hospital contexts), the narration by a patient of their participation in the study aroused the curiosity of other patients, allowing a rapid multiplication of the persons involved in the survey. In some cases, together with the individual interviews, it was also possible to carry out group interviews with two or more patients. Generally, these interviews took place in the waiting rooms of the clinics, in the corridors and in the rooms of the wards. Thus, my figure was progressively recognised as "a separate figure" by the patients and their families, and the research saw an increasing participation from the grassroots as the months passed.

The considerations that emerged from the discussion with the patients, the medical personnel and the families of the patients, together with the information gathered through the ethnographic observations and the study of the statistical data, will guide the analyses proposed in this book. The ultimate goal is the proposal of a new approach to the study of the practice of informed consent. As I will emphasise in the next chapters, the need to think about informed consent as a complex course, that cannot be limited to the moment in which the patient (or a member of their family) signs, demands a rethinking of a practice composed of many players and various elements, of which the most important is undoubtedly that of doctor-patient communication.

Chapter Three

Gathering informed consent: limits and complexities of hospital practice

This chapter analyses the difficulties encountered by the medical personnel in responding to their new duty to inform patients about the actions proposed, the risks and the possible alternatives, prior to the execution of any diagnostic test or therapy. The feedback on the factors that hinder the communicative process will be based on the observations carried out at the clinics and on the wards, and on the opinions expressed by the hospital personnel. As we will see, the questions examined in this chapter refer to the transverse or *systemic* problems that are not linked to specific clinical situations. The recurrence of the elements described therefore authorises us to consider them structural or physiological limits, *independent* from the will of the individual healthcare worker. They can be summarised in two macro-categories: 1) the factors linked to the hospital work and 2) the factors linked to the way in which the informed consent should be gathered. In both cases, the researcher will review the principle obstacles to the implementation of the process of informing the patients. The question we will try to answer is to what extent the consent demanded of the patients by the medical personnel *can* be informed.

1. *Methods and timing of hospital work*

1.1 Objectives on the ward and economic considerations of the hospital corporation

The first difficulty encountered by doctors when informing the patients concerns the present management of the hospital environment according to an *industrial model.*[117] According to many of the professionals interviewed, the transformation of Italian hospitals into *aziende ospedaliere* (National Health Service Hospital Corporations) has led to a progressive adaptation of the treatments offered to the rationales of the market. As reported by one of the doctors on the internal medicine ward, despite the apparent defence of health as "a public asset", the medical sector in Italy now presents the characteristics of the free economy. In particular, the need for the companies to respond to specific *market goals* is linked to the competition between hospitals not only in the private sector, but also within the public sector. This has led to the increasing importance attributed to the *statistics* shown each year by the individual clinics and wards and by the entire hospital corporation.

> What counts nowadays in evaluating hospitals is above all the number of patients treated each year. The more we increase the number of admittances and the number of surgical operations carried out and the more the hospital corporation will be recognised on the market as a centre of excellence and the patients will be encouraged to come to us when they have problems.[118]

According to the logic of the hospital corporation therefore, the recognition of value and the position held by the hospitals on the health market depend above all on the *number* of services offered to the patients. The greater the number of objectives centred, the more value the hospital corporation will gain on the market. On the basis of this logic, the statistical indicators are a *hallmark* with respect to other competitor wards and hospitals but they also *act as a draw* the patients: the greater the number of admittances, the diagnostic tests and operations carried out, the greater the trust placed in the hospital corporation by the general public. Consequently, amongst the duties of the medical personnel there is that of increasing the statistical indicators of the treatments offered each year. The valorisation of the *productivity of the hospital* underlies the testimony that follows, in which the importance of the *figures* in the operation of the hospital machine is emphasised.

> In the operating theatre, as soon as we "take down" one patient, we "set up" another. We usually work like this all day. When we turn on a machine it is better to make it work for as long as possible, otherwise it wastes money. However, the economy of the hospital depends above all on the number

117 M. Marzano, *Gli equivoci della razionalità: l'ospedale tra passato e futuro. Razionalità, razionamento, razionalizzazione*, in «I quaderni di Janus», 2006, pages 55-62.
118 Extract from an interview held on 9th May 2014.

> of patients on whom we manage to operate. If this year we overtake last year's figures, in the coming years we will be asked to improve even further. The hospital receives public funding on the basis of these figures![119]

As underlined by the words of this doctor, the importance assigned to the figures depends on their *economic profitability*: the greater the number of operations (or treatments), the higher the budget available to the hospital corporation. In effect, as stressed by a number of doctors, the "rewards" attained each year by the wards, such as the possibility to purchase new materials or technological equipment, depends on the figures transmitted to the management. More generally, the regional and national funding is based on these figures, and this in turn depends on the investments made (or not made) by the pharmaceutical companies; finally, the policies for amalgamation to which the smaller hospitals are now subject also depend on the same figures.

The combination of these trends has strongly affected the work of the hospitals, which now seems to be ever closer to a *high-speed production system.* Thus, some of the sites in which the research was carried out seemed similar to an *assembly line*. The "minimum quota" of patients to be treated each day – a quota established not by the individual operators, but by the hospital corporation they work for – in some cases requires an *acceleration* of the hospital activities. The same is true for the so-called ward objectives established by the consultants for the rest of the hospital team. The attainment of these objectives often keeps step with a *speeding up* of the medical treatments, in accordance with the idea that more is better.

> Each year we have a series of objectives as a team. Our consultant makes it clearly understood that the image of the ward depends on our ability to reach ever-higher objectives. The only way to meet these requests is to work more quickly. If we add the bureaucratic tasks that we have to do on the computer, it is obvious that the investment in the communication with the patients becomes difficult.[120]

As suggested by the opinion of this doctor, the reduction to the bare minimum of the moments destined for doctor-patient communication cannot be separated from the operational methods or, to quote Mary Douglas[121], from the way in which the hospital institution thinks: becoming an organism that is increasingly characterised by *a number-based system of thought*.

1.2 One for all, all for one: the numerical gap between doctors and patients

119 Extract from an interview held on 19th March 2015.
120 Extract from an interview held on 18th September 2014.
121 M. Douglas, *How Institutions Think*, New York, Syracuse University Press, 1986; Italian translation: *Come pensano le istituzioni*, Bologna, Il Mulino, 1990.

In addition to the objectives suggested by the logics of the hospital corporation, it is necessary to add the considerable number of patients accepted by the services: a population that has increased in recent years. The statistical data gathered at the clinics and in the departments emphasises how the number of patients treated every day is often higher than that foreseen for the capacity of the clinics and the wards. This trend is linked to a number of factors. The first concerns the so-called *improper admittances*. As emphasised by many of the doctors interviewed, nowadays an increasing number of patients who do not need immediate treatment are admitted to hospital. On the one hand, the hegemony in our society of a *culture of prevention*[122] has had the effect of increasing recourse to the hospital environment also for minor problems. On the other hand, the increase in the number of patients is linked to the same evolution in society. The reliance on medical knowledge for life events that were previously dealt with outside the hospital environment – for example birth and death[123] – has led to a multiplication of the treatments offered to subjects who were once absent amongst the hospital patients, such as elderly persons[124]; the latter are increasingly present in the services, due to the longer lifespan in our society. Another factor is represented by the increasing offer of assistance to all those subjects who are in disadvantaged conditions or who present situations at risk for their psychophysical safety: a set of situations summarised in the category of what are known as *social admittances*. What prevails in these cases is the "charitable" function and at the same time, the "containment" historically assigned to the hospitals in our society.[125] As emerged during the course of the research project, the high number of patients on the wards of the Città della Salute e della Scienza is also linked to another element, that is the poor functioning, or often complete absence, of cooperation between the hospitals in Torino and the local services where many patients could be looked after.

> Often we have to look after not only our patients, but also those of other services. The local services could do much more but we cannot always communicate with them. Frequently, there is a "buck-

122 M. Foucault, *Histoire de la sexualité*, vol. I, *La volonté de savoir*, Paris, Gallimard, 1976; Italian translation: *Storia della sessualità*, vol. I, *La volontà di sapere*, Milano, Feltrinelli, 1978. I. Illich, *Némésis médicale*, Paris, Seuil, 1975; Italian translation: *Nemesi medica. L'espropriazione della salute*, Milano, Boroli, 2005. U. Beck, *La Société du risque. Sur la voie d'une autre modernité*, Paris, Flammarion, 1986; Italian translation: *La società del rischio. Verso una seconda modernità*, Roma, Carocci, 2000. D. Carricaburu, *De l'incertitude de la naissance au risque obstétrical: les enjeux d'une définition*, in «Sociologie et Sociétés. Revue de l'Université de Montréal», XXXIX, I, 2007, pages 123-144.

123 D. Memmi, *Faire vivre et laisser mourir: le gouvernement contemporain de la naissance et de la mort*, Paris, La Découverte, 2003. Id., *La Revanche de la chair. Quand le corps revient au secours des identités*, Paris, Seuil, 2014.

124 S. Porcu, *Invecchiare in Italia: sviluppo e differenziazione sociale della popolazione anziana*, in *Mosaico Italia. Lo stato del paese agli inizi del XXI secolo*, Milano, Franco Angeli, 2010.

125 E. Goffman, *Asylums: Essays on the Social Situation of Mental Patients and Other Inmates*, New York, Anchor Books, 1961; Italian translation: *Asylums. Le istituzioni totali: i meccanismi dell'esclusione e della violenza*, Torino, Einaudi, 2003. R. D'Alessandro, *Lo specchio rimosso. Individuo, società, follia da Goffman a Basaglia*, Milano, Franco Angeli, 2008. D. Carricaburu and M. Ménoret, *Sociologie de la santé. Institutions, professions et maladies*, Paris, Armand Colin, 2004.

passing" attitude towards the more important hospitals so that we end up treating a lot more patients. Many of them should and could be treated elsewhere.[126]

The opinion of this doctor is confirmed by the results of the anonymous study of the medical records. The patients resident in areas not afferent to the Città della Salute e della Scienza complex, in effect, appeared to be numerous. Amongst these, people resident in other districts of Torino correspond to 30% of the patients treated each year, those resident outside the urban area of Torino represent 15%. Nonetheless, the difficult dialogue with the local services only partly explains this tendency. As emerged from the interviews with the patients and the members of their families, the choice to contact the professionals at the Città della Salute e della Scienza is often based on other considerations. The preference for this hospital complex in many cases derives from the fact that it is one of the historical Torino hospitals where friends or relatives have been treated. For other patients, this choice is part of a "family tradition": all the members of the family group have always contacted this hospital and therefore, although they live far away, they prefer to go there. In yet other cases, this choice is based on the fact that the patients know one of the doctors personally and socially, or they are being treated privately by one of the doctors. Finally, for others, it is a "necessary choice" dictated by the fact that the therapies they need are not offered at the hospitals nearer to their district, or even because they do not trust the hospitals present in their region. Some patients the researcher met on the surgery, paediatric or oncohaematology wards came, for example, from the neighbouring region of Liguria or from various regions in southern Italy – mainly from Campania, Calabria and Sicilia. Amongst them, some were taking advantage of the existence of a relative resident in Torino in order to get treatment.

Apart from the possible analyses of the *economic costs* linked to the assistance of a high number of patients,[127] the aspect that interests us here is above all the *overcrowding* of the hospital. The hours spent waiting to be examined at the clinics, the frequent accommodation of patients in the corridors of the wards, the lack of hospital beds, the exponentiation of the rooms needed for A&E admittances are all elements that underline the difficulties met in managing so many patients. In the face of these trends, another problem that has arisen is the increasing *numerical gap between doctors and patients*: on many of the wards analysed, in fact, while the number of patients treated is constantly increasing, the medical personnel is constantly being reduced. As can be seen from the interview that follows, the increase in the number of patients is not matched, in many cases, by an increase in hospital personnel. On the contrary, in recent years, the healthcare workers have often

126 Extract from an interview held on 3rd September 2014.

127 The analysis of the economic costs of the hospital system is the subject of a study currently underway at the Laboratorio dei Diritti Fondamentali in Torino.

been the object of what are known as *hospital cuts*, with a constant reduction of new jobs above all amongst the new generations.

> The situation we experience nowadays in the hospital is quite paradoxical: the number of patients increases constantly, while we are less and less. The intake of new employees has been blocked for some time, when staff retire they are not always replaced, while previously there were two doctors on call, now there is only one, at night we often have to look after more than one ward in order to cover these gaps. Basically, what is happening is a constant reduction in the medical personnel.[128]

Equal in importance to the objectives of the ward, the growing numerical gap between the doctors and the patients is a factor that influences the therapeutic relationship. In various cases, the difficulty in managing in-depth discussion with the patients was an inevitable consequence of the present *economy of hospital personnel* despite the growing *massification of the patients.* Amongst the sectors analysed, the only exception was represented by the paediatric sector where, for reasons linked to the age of the patients, the subjects to be looked after tend to be less numerous than in the adult wards. Despite this fact, as we will see during the following chapters, the difficulties encountered in the informative process for the paediatric patients are in any case numerous.

1.3 Lack of time to inform patients

Amongst the problems encountered in informing the patients, the *lack of time* is another question often mentioned by the hospital personnel. According to many of the doctors interviewed, in order to adequately inform the patients it would be necessary to do only that, or alternatively, it would be necessary to have twice the time currently available. The high number of patients represents, in their opinion, an important obstacle to the time available for the informative process. As emerged during the observations in the hospital environment, each visit is immediately followed by another one, without interruptions or pauses, until the number of patients foreseen for that day has been seen. Equally, in a system based on the incessant succession of patients, the medical examinations of the first shift (morning) are followed by those of the second shift (afternoon) during which there will be a similar number to examine. The need to get straight to the point was emphasised by one of the doctors at the oncological-haematological service.

128 Extract from an interview held on 21st June 2014.

> You can't run over time. For each patient we have a time slot, if we stop to talk more, if we chat, the entire system slows down. The delay accumulated during one examination cannot be made up because there are so many patients. If we are to keep up the pace, we have to hurry.[129]

As we can see from this testimony, the number of patients to be treated each day is often excessive compared with the time needed to speak in depth to each of them. Another of the doctors interviewed, this time in heart surgery, said,

> There's not much choice. Since we can't cut out the clinical part, what we sacrifice is the time dedicated to information. Often we don't even have time to explain the operation, let alone describe the risks or the side effects of the drugs we will use in the operating theatre.[130]

The high number of patients and the swift pace of hospital work are not, however, the only factors that explain the frequent contrast between *time dedicated* and *time required* for informing the patients. As shown by the results of the research, even on the wards where the number of patients is lower, the time for information is in any case limited. On this matter, it is necessary to emphasise the effort made by the medical personnel to dedicate the right amount of time to the process of informing the patients. One of the facts that emerged from the comparison between the various clinics and wards was in fact the different duration of the informative interviews according to the importance of the news to be transmitted to the patient. The interviews carried out during a first visit – usually being the moment in which the diagnosis is communicated to the patient – is generally longer than the interviews foreseen for the follow-up examinations, where the patients are already aware of their illness. In the same manner, the more serious the situation of the patient, the more time is spent on information.

Nevertheless, the tendency to diversify the duration of the informative interview only partially resolves the problem of lack of time. One example is the conversations with patients who need an organ transplant, to whom it is necessary to explain both the various phases of the surgery, the preparatory procedures for receiving the new organ and the risks linked to the post-operative phase. As remarked by the heads of the transplant centre, if the staff choose to dedicate more time – usually not more than two hours – to informing the patient this is because the explanations to be transmitted are more numerous compared with those to be given for less complex operations, such as an appendectomy. Consequently, despite the greater duration of the informative interviews, the time required for explaining the treatments proposed and the consequences that derive from them is

129 Extract from an interview held on 18th June 2014.
130 Extract from an interview held on 20th February 2015.

in any case insufficient.[131] The lack of time reported by the medical personnel is linked in these cases above all to the difficulty in summarising operations that are complicated from a technical point of view and whose effects could change the life of the patient and their family permanently.[132] On the other hand, as emphasised by many of the doctors interviewed, nowadays many of the patients on the wards are *complex care patients*, that is subjects who are suffering from a number of illnesses at the same time, so that it is necessary to provide information on various levels, regarding numerous forms of treatment.[133]

> Lately, it has become increasingly rare to see patients who have only one pathology. The majority has a number of problems at the same time: oncological, nephrological, diabetes, high blood pressure. The treatments for these patients are more complicated from the clinical point of view, we have to take care with the medicines we prescribe, the tests we carry out, but it is also difficult to explain everything, to speak of all the problems in the time we have available.[134]

While for the doctors, therefore, it is often difficult to manage to explain to the patients the treatments necessary in order to resolve or limit the illness(es), for the patients it is often necessary to take important decisions in a short space of time. The choices are often made swiftly, when in many cases more time is needed to ponder the operations that are more complex or "delicate" operations from a bioethical standpoint – such as modifications of the body linked to some forms of oncological surgery (*ostomy*), the choices relating to the end of life, or decisions regarding therapeutic abortion in the presence of serious foetal malformations – rather than the more simple procedures or those that are routinely carried out in the hospital environment. One example of these trends is the rapid succession of the times with which the diagnostic tests essential for understanding how to proceed are carried out (CAT scan, ultrasound scans, endoscopies, gastroscopies). In view of the high number of patients on the waiting list for these tests, if a space is freed, the personnel at the diagnostic centre informs the doctors on the wards, who in turn speak to their patients in order to avoid losing the opportunity to carry out the test in question immediately. The rapid communication to the patient is therefore determined by the attempt to offer the utmost assistance in the shortest time possible, without waiting days to be called to the diagnostic centre. What happens in most cases, however, is that the patient receives little information from the doctors

131 O. Corrigan, *Empty Ethics: The Problem with Informed Consent*, in «Sociology of Health and Illness», 25, 2003, pages 768-792.
132 M.E. Mitola, *Frammenti di corpi: un'indagine antropologica sui trapianti di cuore*, in «Rivista della società italiana di antropologia medica», 35-36, 2013, pages 309-326.
133 This statement is only partly valid for the paediatric patients hospitalised at the Regina Margherita Hospital. As the professionals encountered at this hospital emphasised, except for children who are born with health problems, the accumulation of illnesses is a phenomenon that tends to increase as the patient ages.
134 Extract from an interview held on 20th July 2014.

on the ward, since they are certain that personnel at the diagnostic centre who carry out the test will supply information. At the same time, the staffs at the diagnostic centre are convinced that the doctors on the ward have already given the patient full information. In addition to highlighting the informative gaps produced by the "many stages" of informed consent (cf. paragraph 2.3), this example underscores the fact than the patients often have little time to consider their choices. Sometimes, to gain time, the doctors may *anticipate* the patient's decision, planning the day on which the diagnostic test or the surgical operation will take place even before the patient has expressed their agreement. As emphasised by one of the doctors on the surgical ward, the planning of the treatments "behind the patient's back" is intended to streamline the hospital machine, ensuring that the operating theatres or the delivery room work efficiently (for example by programming elective caesareans). In the case of hesitation or refusal by the patient, the course planned by the medical personnel does not attain the desired results, with a frequent reaction of disappointment from the hospital professionals.

> Many patients spend days in hospital without doing anything, whenever possible we try to speed things up. Often we (doctors) phone each other to plan the list of patients to be operated on, without going through the booking office. We organise the days and times before informing the patient so that when we get a signature, everything is ready. Of course, if the patient does not agree, or changes their mind at the last minute our efforts are useless, at times there are gaps that we can't always fill in with another patient. Quite honestly, when the patients are a bit uncertain I get rather irritated. In the end, they must make the choice, but if the operation has to be done anyway, what use is it spending so long thinking about it and risking missing your turn?[135]

Therefore, sometimes, in the name of the well-being of the patient, the consent to treatment becomes a confirmation of the course of therapy *pre*-organised by the medical personnel, and is not the result of a reasoned choice, made in their own time by the person in question.

1.4 Emergency situations

At other times, the seriousness of the situation does not allow the transmission of medical information. The most typical example of the impossibility of informing the patients for medical reasons is the case of an emergency. This category includes all those situations in which the patients are admitted as an emergency case – for example following an accident – but also all those cases in which they suddenly feel ill while hospitalised or complications arise during a surgical operation.

135 Extract from an interview held on 16th October 2014.

The onset of complications for the mother or the child during birth, sudden cardiac arrest during an operation, the immediate need for a blood transfusion are all situations in which every minute that passes can be vital for the patient's survival. In all these cases, the medical activity becomes a *race against time* in which it is necessary to do everything possible to save the patient's life and there is no time to explain and inform.[136] In other words, the need to intervene as soon as possible subordinates the informative process to the clinical needs dictated by the patient's *state of need*. As emerged from the observations carried out on the wards, in this kind of situation the solutions adopted by the medical personnel are *posthumous consent* to the therapies, if the emergency is underway, or when there is a need for *wide-ranging consent* to the therapies because they fear there is the risk of an emergency arising. In the first case, since it is effectively impossible to inform the patient, the principle shared by the medical personnel is that they have accepted the treatment since 1) they have chosen to be taken to a hospital, or they are already hospitalised; 2) the treatment proposed is essential for their survival. Some examples are an emergency caesarean section, or an emergency surgical operation. In the second case, the immediate risk of complications is translated into the *preventive request* for general consent that allows the staff to carry out any intervention necessary to keep them alive (anaesthesia, transfusions, implanting of a central venous catheter [CVC]). A further example is the preventive consent that the parents of premature babies hospitalised on the intensive care ward are asked to sign, since there could be the need to carry out interventions or treatments without there being time to speak to the parents; they are informed *following* the procedure carried out on the baby. As one of the doctors interviewed emphasised, the awareness that they are acting *to the best of their knowledge and judgement* operates, in both cases, as an *implicit authorisation* to proceed with the medical act considered necessary, even though they do not have time to inform the patient or their guardian or representative.

> When a sick patient arrives, or when you can see that things are going wrong during an operation, the only thing you can do is trust in your knowledge and your common sense. If we keep these two elements together, any decision we make will be less difficult, because we know that we are doing our utmost for the patient.[137]

On the basis of this awareness, in the majority of cases the professionals manage to take important decisions often in an extremely limited timeframe. According to the protocol of urgency at the A&E major trauma – where patients often arrive already unconscious – the window of time foreseen for establishing whether to proceed with a surgical operation corresponds, for example, to

136 M. Graziadei, *Il consenso informato e i suoi limiti*, in L. Lenti, E. Palermo Fabris and P. Zatti (ed.), *I diritti in medicina*, in *Trattato di biodiritto*, directed by S. Rodotà and P. Zatti, Milano, Giuffrè, 2011, pages 191-288.
137 Extract from an interview carried out on 24th February 2015.

not more than fifteen minutes. In this period of time, it will be necessary to carry out an in-depth examination of the patient, to examine them literally from head to foot, and to enact a series of "life-saving" procedures foreseen by the urgency protocol (artificial ventilation of the patient, test to establish the blood group, any transfusions, hydration of the patient through a drip, implant of the CVC).

1.5 The lack of spaces for informing the patients

Another recurrent topic in the description of the obstacles encountered in the process of informing the patients was the lack of suitable spaces for the construction of a doctor-patient dialogue. As one of the doctors on the gastroenterology ward pointed out:

> Even if we had time, where would we have these conversations with the patients? Our wards are not designed for this type of activity. It's not like abroad, where there are rooms in which you can speak to the patients and the patients' families. Here the patients don't have individual rooms like the American hospitals. In order to speak to the patients for any length of time you would have to completely transform the organisation of the wards and of the hospital spaces.[138]

The words of this doctor emphasise the gap between the organisation of the hospital environment in Italy and the needs dictated by the exportation of a practice – the communicative process aimed at the gathering of informed consent – born elsewhere. The lack of spaces destined for conversation with the patients highlights the relevance of the theories of one of the founding fathers of American medical anthropology, Arthur Kleinman, who insists on the need to consider the *hospital systems* as *cultural systems*.[139] According to Kleinman, the characteristics of the hospital systems, including the organisation of the spaces that compose it, refer to specific systems of values. This theory was applied to the Italian situation by the sociologist Franca Pizzini,[140] who emphasises that the organisation of the hospital spaces in Italy reflects the existence of a frequently insurmountable barrier between two different areas: that dedicated to the patients – and at times to their families – and that "inhabited" by the medical personnel. The application of these theories to the practice of informed consent is of interest for two reasons. On the one hand, the absence of places destined for the communication with the patients testifies to the presence of a system of values very different from that of the United States, where the hospital world responds to rules

138 Extract from an interview held on 3rd March 2015.
139 A. Kleinman, *Concepts and Model for the Comparison of Medical Systems as Cultural Systems*, in «Social Science & Medicine», 12, 1978, pages 85-93.
140 F. Pizzini, *Note sullo spazio nel reparto di maternità*, in G. Colombo, F. Pizzini and A. Regalia, *Mettere al mondo. La produzione sociale del parto*, Milano, Franco Angeli, 1987, pages 198-231.

linked to an *economy of health* centred on a system of private insurance policies and the figure of the hospital patient-client.[141] On the other hand, the difficulty in adapting the functioning of our hospitals to the activities demanded by informed consent – first of all the investment in the communication with the patients – characterises not only the places in which the research took place but also other hospitals in Italy[142] and abroad, for example in France.[143] As shown by the testimony of the first doctor mentioned, the construction of *ad hoc* spaces for the communication with the patients would require a rethinking of the historical division of the spaces between areas dedicated to the patients and those reserved for the activities of the medical personnel. In accordance with this division of the spaces, the informative activity currently occurs in what is seen as the patients' area (the rooms) or in the doctors' area (consultation rooms). Except for the patients who cannot leave their beds for medical reasons, the majority of the interviews that the researcher observed took place with the participants seated around tables situated in the patients' rooms, in the corridors of the wards or in the consultation rooms. In all three cases, these spaces appeared to be *a transit area* in which the transmission of information occurred in very few cases only in the presence of the doctor and the patient. The temporary appearance or the permanent presence of other subjects during the interviews (other patients, members of the patient's family, members of other patients' families, members of the hospital staff) highlighted the extent to which the conditions in which the transmission of medical information does not always guarantee respect for confidentiality and privacy and the opportunity for the patient to speak freely.[144] On the wards where questions considered particularly delicate from an ethical standpoint have to be dealt with – for example, choices regarding end of life – the professionals make every effort to overcome this situation. However, spaces reserved for communication with patients and their families are still lacking. According to one of the doctors on the reanimation ward, where in recent years the families of patients have been received in the entrance hall to the ward – a large area where they have tried to create a "conversation area" installing every day, for a few hours, a table and some chairs – the way in which information is given to the patients (and to their families) is somewhat paradoxical.

141 A.M. Mol, *The Logic of Care. Health and the Problem of Patient Choice*, London, Routledge, 2008.

142 C. Faralli (ed.), *Consenso informato in medicina: aspetti etici e giuridici*, Milano, Franco Angeli, 2012. I. Quaranta and M. Ricca, *Malati fuori luogo. Medicina interculturale*, Milano, Raffaello Cortina, 2012. M. Marzano, *Problemi etici nella ricerca sociale sui malati terminali: consenso informato, comitati etici e differenze culturali*, in «Sociologia e Ricerca Sociale», 75, 2004, pages 157-174.

143 S. Fainzang, *La relation médecins-malades: information et mensonge*, Paris, Presses Universitaires de France, 2006.

144 On the wards of the four hospitals that make up the Città della Salute e della Scienza di Torino, the rooms destined for the patients hold four beds. The only exception is represented by the patients who must remain in isolation for clinical reasons, for example immediately following a bone marrow transplant or other transplants, in the case of patients with infectious or highly contagious diseases, or in the case of patients with serious psychiatric disorders. In these cases the rooms for the patients are, exceptionally, single rooms.

> When the patients arrive at the hospital, we ask them immediately to sign the confidentiality agreement. We try to find out which family members we can speak to, who can be informed and who should not. On the other hand, every time we give information we don't worry about who the people nearby are, we give information in a place of transit and other people can hear what we are saying. To me, this is a paradox: what is the point of having them sign a confidentiality agreement if every single day we behave as though we don't know the meaning of the word?[145]

The context observed at the clinics was different. Contrary to the situation on the wards, the process of adaptation of the hospital spaces to a model of care based on the values promoted by the practice of informed consent seems to have taken place in this case. On the one hand, the clinics seem to be more "protected" spaces for communication between the doctors and the patients, thanks to their characterisation as *closed spaces,* unlike the *open rooms* of the wards. On the other hand, it is important to emphasise the efforts made by the medical staff to introduce "separate places" for the explanations and the gathering of informed consent. These environments, adjacent to the examination rooms are generally *demedicalised places*, more similar to an office than to a hospital room. Here, the patients and their families are received individually. Amongst the services in which it was possible to observe what the professionals themselves call *good practice* we find: the adult oncology-haematology clinics and in the paediatric area, the clinics for the transplant centre and the clinics for the diagnostic and ultrasound scan centre, above all with regard to informative interviews relating to abortions.

2. *The complex organisation of informed consent*

2.1 Oral consent

On the basis of what we have described so far, the high number of patients treated, the speed of the hospital schedule, the rapidity of execution of some procedures according to the clinical needs of the patients, are all elements that limit the informative procedure. The testimony below is particularly significant.

> If we were to ask for a signature for every single thing, we could not do our jobs. Many procedures are carried out as routine. Taking blood samples, putting the patient on a drip, implanting a CVC are procedures that we carry out automatically when the patients arrive in the hospital. If we were to ask for written consent for each procedure, we would spend all our time asking for hundreds of signatures a day, it would be impossible! In the end, if someone decides to come to the hospital because they are not well, they expect these things to happen, right? Otherwise, they had better stay

145 Extract from an interview held on March 13th 2015.

> at home! Without these procedures, we can't do our jobs, they are automatic when you are in hospital, no? That is, if I go to the mechanic's because I have a problem with the car, I expect the mechanic to act in some way, otherwise why would I go there? It's the same thing in a hospital![146]

The words of this nurse emphasise that the patients' need for treatment is seen as a form of *implicit consent* to what are seen as *basic procedures* without which it would be impossible to proceed with medical treatments. Given the impossibility of asking for written consent to any and every *medical procedure*, the prevalent choice is the "automatic" execution of these procedures, taking for granted the agreement of the patient who has chosen to go to a hospital. On the basis of this logic, the principal element taken into consideration is the degree of awareness shown by the patients, that is the fact that they are "lucid and focused". This formula commonly used by the medical personnel in compiling the medical records aims to show that the patient they are treating is conscious of the procedures carried out on their body. This awareness is indirectly "proof" of the consent to the medical act. In the case of resistance, on the other hand, the medical records will show informed refusal of the therapies by the patient. In accordance with the regional guidelines[147], what is requested of the patient prior to the execution of "basic hospital procedures" (taking of blood samples, measuring of blood pressure, implant of CVC, medical examination) is the *oral consent* which will be accompanied by registration in writing of the level of awareness of the medical procedures. It must be said that although the preliminary operations for a complete therapeutic process does not require the patient to sign any documents, the gathering of *oral consent* does not eliminate the duty to inform the patient of the risks linked to the medical procedures carried out "routinely" on all patients. As emerged from the research, however, the information given to the patients is frequently lacking when it refers to "basic procedures" that do not require written consent. In many cases, the prevalent attitude is a trivialisation of these procedures considered, on the one hand, a necessary step in the hospital procedure, on the other hand, a sort of "zero level" of medicine, in which the risks for the patients are extremely limited. In accordance with the little time available, the choice is often that of an *economic* informative process: the greater the risks for the patient, the more information is generally given. On the contrary, the lesser the risks associated with the procedures, the less information given to the patient. In many situations, in fact, it is possible to observe a *continuum* between the level of invasiveness of the test or the procedure proposed, the level of risk and the level of investment in the communication with the patients. This behaviour often leads to the construction of a dichotomy between the situations in which the staff simply operate on the surface and those in which they act inside the body. One example is the

146 Extract from an interview held on 13th May 2014.
147 Azienda regionale per i servizi sanitari (Aress), *Linee di indirizzo per la gestione del processo informativo e l'acquisizione del consenso informato*, Regione Piemonte, 2012.

varying levels of information offered to the patient when it is decided that a peripheral venous catheter (PVC) and that offered to patients for whom it has been considered necessary to introduce a CVC. In the first case, the procedure is considered simply "finding a vein", in the second, a sort of "mini-operation".[148] The same is true for the realisation of a standard ultrasound scan and one with the injection of a contrast medium. In both cases, the greater the invasiveness of the procedure, the greater the attention paid to the gathering of informed consent, which is no longer characterised as *oral consent* but as *written consent.*

2.2 Written consent

Unlike the gathering of oral consent, for which the form varies according to the attention paid to this procedure by the individual healthcare worker, the gathering of written consent is a practice officially regulated by the hospital guidelines. This is based on the signing of certain *printed forms* generally accompanied by an informative leaflet, or a series of pages in which the method of realisation of the procedures proposed and the associated risks are explained. The forms presented to the patients are usually composed of two pages, and may be of five or six pages when complex operations or experimental therapeutic treatments are involved.[149] In the latter case, the forms for informed consent and the informative pages are often accompanied by explanatory brochures supplied by the pharmaceutical companies and handed to the patients by the doctors, together with the other documents.

The first problem that emerged with regard to the gathering of written consent is the effective possibility for the patients to read the forms carefully. This question refers first of all to the amount of time that patients have for this purpose. On the basis of the observations carried out at the clinics and on the wards, the reading of the informative documents appeared in many cases to be an activity *incompatible* with the rapidity of the hospital rhythms. The gap between the time required and the time that it is possible to destine for the reading of the forms is a question debated by many hospital professionals. According to the majority of doctors, it is an activity that requires much more time than that which can be dedicated to each patient. Starting from this consideration, the hospital personnel adopt various solutions. The first is the presentation of the forms as the written version of the interview with the medical personnel: "this is a summary of what we said", as

148 Expressions taken from the interview held on 24th May 2014.
149 U. Felt *et al.*, *Refusing the Information Paradigm: Informed Consent, Medical Research and Patient Participation*, in «Health: An Interdisciplinary Journal for Social Study of Health, Illness and Medicine», 13, 2009, pages 87-106.

many state. Judging by the research, this attitude seems to prevail not only with outpatients at the clinics, but also for those who have been hospitalised for some time on the wards. The permanence of the patients in the hospital environment did not, in other words, seem to be a determinant factor for a difference in the presentation of the consent of the patient. The second solution, on the contrary, consisted of asking the patients not to sign the consent forms immediately, but to take time to consider their choices and decisions. This proposal was quite rare amongst the patients "passing through" the clinics, while it was more common with the patients hospitalised on the wards, where the doctor could return after a few hours, or a few days, to collect a signature. On this occasion, the questions that the patient asks the doctor allow him/her to "verify" the understanding of the activities proposed. While on the one hand the possibility of postponing the possibility of delaying the signing of the consent form for a few hours is linked to the clinical condition of the patient, on the other hand, it depends considerably on the importance attributed to this procedure by the hospital personnel. One example is the explanatory leaflet created *ad hoc* and distributed together with the consent forms to the patients at the transplant centre, generally interrogated by the doctors about the operation they are about to face before proceeding with the signing of a consent form.

> If our consultant realises that the patients have not read the consent forms, he sends them home, asking them to return in a few days time. Sometimes we have let a less urgent patient 'jump the queue' because we realised that the other one had not read any of the material. This question of reading before the operation is part of the 'pact' we make with the patients, we are all involved in the operation, not only us but also the patients who must read [the informative material].[150]

Apart from these exceptions, in 90% of the interviews that the researcher listened to during the year, the signing of the consent form occurred at the time of the informative interview, without the patient or their guardian or representative[151] reading the forms. Typical of this situation is the interaction that follows between the doctor on the paediatric ophthalmology ward and the mother of a child hospitalised with a problem with his eyes, who has been asked to sign the consent form for surgery planned for the following day.[152]

> Doctor: This document serves to show that we discussed the situation. Have you got any questions?
> Mother: (silence)
> Doctor: Well, that means you have understood completely. You can sign without worrying.

150 Extract from the interview held on 26th June 2014.
151 Amongst these, we find family members of patients in the case of terminally ill patients, or patients who are unconscious; the parents or guardians of minors; the parents or administrators of disabled patients incapable of expressing their will. On the role played by the family members in the informative process and the problem of "who to inform" see chapter four.
152 Extract from the interaction observed on 14th October 2014.

This interaction, chosen amongst the others for its cynic sense, summarises what has been described by many doctors as the *reality* of an *ideal system* in which the process of informing the patients clashes with the use of forms that exemplify the *bureaucratisation* of hospital work.

The second problem concerns the *language* used on the forms. Apart from the time available for reading the pages, which are often long, understanding their content appeared to be closely linked to the terms in which they are written. The study of the forms in use in the clinics and on the wards showed that they were written in *technical language*, somewhere between medical terminology and legal lexis. The lack of accessibility of this lexis for the non-experts emerged from the testimonies of many of the professionals interviewed. The difficulty encountered by patients in understanding the forms was summarised as follows by one of the doctors on the gynaecology ward.

> It would seem that these forms were designed so that the patients can't understand them! If the aim is to inform the patients, we are way off the mark. Why should we assume that the patients have medical knowledge or that they know all the laws, for example those regarding abortion? We have to give this information and we can't take it for granted that the patients know everything and that they understand everything. They should use simpler language, not so complicated! If I go to the bank and they ask me to sign a contract where I can't understand a thing, I instinctively don't trust it! If we use the same language when speaking to our patients that we would use with our colleagues, what can they possibly understand? So much for therapeutic alliance! In my opinion, the patients' trust is gained by helping them to understand what we are talking about and not pretending to speak to them in *medicalese*![153]

The opinion of this doctor emphasises the extent to which the lexis used in drawing up the consent forms requires a process of *socialisation* with medical, juridical and forensic language. Together with the linguistic register, another critical aspect is that much of the information offered to the patient is presented in the form of numbers or statistical data. The problem that arises in this case, is the patients' difficulty in foreseeing their own individual situation. At the same time, the gap between the existing knowledge of the overall data – such as the success rate of the treatments, the death rate linked to the operation, the percentages of the side effects of the medicines – and the possible application of these trends to the individual case shows the difficulty that the doctors encounter in giving "valid information" for each individual patient. As various professionals stated, *in passing from the large numbers to the individual cases the logic of probabilities suggested by the*

153 Extract from the interview held on 7th June 2014.

statistics shows all its limits. Hence, the problems encountered in stating that the operation *certainly* does not present complications of any kind, and there will *certainly* not be any post-operative problems, even if the figures presented on the forms stress that these possibilities are almost nil.

The criticisms presented by the professionals regarding the language of the forms clashes, however, with what we observed during the interactions with the patients. In fact, although many doctors tend to emphasise the need to use simpler language, what *actually* happens during the interactions with the patients is the common recourse to scientific vocabulary, very distant from the ordinary language of the layman. In the same way, the reference to statistical data seemed to be one of the main tools used by the professionals for informing the patients. In 90% of the interviews observed, the explanations given to the patients were mainly centred on *technical, statistical and impersonal* information. Therefore the process of informing becomes *'one size fits all'*, that is based on the transmission of universal or universalizable data.

At the same time, the constant repetition of the same type of information, often transmitted by the professionals for a number of times equal to the number of patients seen in a day, transforms what should be the most important moment of the meeting between the doctors and the patients into a routine activity. The case of the anaesthetists charged with informing the patients about the type of anaesthesia that will be used prior to surgery, is typical of this aspect. During the procedure of informing the patients, this explanation should be the link between what other specialists have said – paediatricians, internists, oncologists, for example – and the explanations offered subsequently by the surgeons. The *informative space* assigned to the anaesthetists is consequently particularly limited and always the same in content: the drugs used during anaesthesia, the duration of the effects of the drugs, sensations felt by the patient on waking, possible risks and collateral effects. Generally, this information is repeated many times a day since the number of people to be operated on is always high and the number of anaesthetists who work in the operating theatres is somewhat limited. According to the planning of the operations, the days on which the so-called "minor operations" or operations that require only a short time in the theatre, are carried out the anaesthetists can meet more than ten patients a day, repeating the same explanations each time. The result is a considerable *standardisation* of the meetings with the patients, who are informed in a mechanical way by the anaesthetist, but also a progressive *reduction*, or worsening, of the informative process during the day. Thus, the first patients receive more detailed information and the later ones only the strictly necessary information.

The transformation of the dialogue with the patients into an activity carried out routinely by the professionals leads, not only in the case of the anaesthetists, to a tendency towards *standardisation* of the informative process. In fact, it was only rarely adapted to the individual

profile of the patients. In the majority of cases, if there is a form of *personalisation of informed consent*, this relates to the *clinical characteristics* of the patient. One example is given by the choice made at national level by the operators of the transplant centres, who have decided to adapt the consent forms to the physical condition of the patient. Therefore, within this medical sector there is not just one consent form, but rather various forms for the diverse categories of patient: consent for donors with pre-existent tuberculosis, consent for donors with meningitis or positive bacteraemia, consent for donors with positive HCV and so on. As we will see, the challenges posed by the adaptation of the consent and the informative process also vary according to the *social profile* of the patient (see chapter five).

2.3 The many stages of informed consent

Another critical point, which emerged from both the oral consent procedure and the written consent procedure, is the frequent organisation *in stages* of the process of informing the patient. The choices to advance progressively in transmitting the information, above all when it is a question of information that may be "difficult" for the patient to accept, leads to various problematics. In many of the situations observed, in effect, the *continuity of the dialogue* between the doctors and the patients clashes with the system of hospital shifts. Despite the efforts made by the personnel on the wards, it may be that the patient is informed of the illness or the treatment to be carried out by an operator who will be absent the following day. As the healthcare operators themselves admitted, the *fragmentation* of the informative process brings with it various orders of problems. The first has been summarised by many professionals in the question of *who says what*. In the passage from one doctor to another, or from one nurse to another, on the other hand there is a risk of repeating the same information, and on the other the danger of producing *communicative vacuums*. Not knowing which "bit of information" – as many said – has already been transmitted by the colleagues is often accompanied by the conviction that some explanations come before others, so that they often do not verify whether the patient has already been informed of certain aspects of the illness or the treatment proposed. In a number of cases, for example, the researcher heard conversations in which only at the end it was discovered that the patient had already received the explanation, or on the contrary, that it had not been introduced by another colleague. As shown by the testimony that follows, this type of problem can only partly be explained by the lack of dialogue between the members of the hospital staff.

> At times it may be that one of us begins talking to a patient, another continues and yet another asks for consent. At other times, we start talking to the patient and we continue two days later without knowing what they have been told in the meantime by our colleagues. Usually, we write in the medical records what we have said, to help the person who comes after us. For example, if we know that we are going on holiday for two weeks, we don't even start to inform the patient, it's better if someone else does it directly. The problem is that even if we talk to each other, everyone has their own way of doing things. Some need to start the explanation all over again, so that they can be sure they have said everything, others emphasise certain aspects, yet others insist on further aspects, so it is always difficult to know exactly what has been said and at times we get confused![154]

As this doctor emphasised, the alternation of various players in the informative process may lead to a result that is not always coherent for the patient. Apart from the possible repetitions or the potential gaps in the information, the explanations given by one doctor may conflict with what another has to say, or even what one operator emphasises another may play down, making the patient's choice even more difficult. The segmentation of the informative process appeared to be an element that can negatively affect the construction of a relationship of trust between the doctor and the patient. In a number of situations, it was possible to observe, for example, the reactions of resistance by patients when a new doctor appeared to speak to them on the ward or at the clinic. The experience of Michele is typical of this situation. He was urgently hospitalised on the initiative of his wife Cristina, who was concerned about her husband's worsening stomach pains. During the conversation with the first doctor he met on the internal medicine ward, Michele was worried about the proposal to undergo a gastroscopy to ascertain that he did not have a pancreatic tumour. His fears were linked to the procedure itself, which he thought would be particularly painful, and to the results of the diagnostic test. The explanations given by the first doctor reassured him, however. The emphasis of the advantages of the gastroscopy encouraged Michele to undergo this test. The insistence on the importance of finding out why he had pain strengthened his impression that it was a test necessary for his well-being. In the face of the progressive acceptance shown by Michele, Cristina tried to encourage him further by offering to be present during the diagnostic test. By the end of the conversation, Michele seemed fairly convinced, but he asked for a few more hours in which to think about his decision. The doctor accepted this request and gave Michele the informed consent form to be signed as soon as possible. At the same time, starting from the interest shown by both the patient and his wife, the doctor decided to book the gastroscopy for the following day. As emphasised in the researcher's interview with the doctor, after the conversation with Michele, it seemed unlikely that the patient would refuse the diagnostic test. There were numerous signals, in

154 Extract from an interview held on 3rd July 2014.

his opinion, that allowed him to assume that the patient would undergo the gastroscopy the following day. During the afternoon Michele tried to speak to the doctor again, but was told by a nurse that he had left: his shift was only in the morning. The next day Michele asked again to speak to the doctor, but he was absent again: this time he was on the afternoon shift. In view of the difficulty in expressing his doubts, which in the meantime had become pressing, to the doctor, Michele became discouraged and reacted rather badly when a new doctor came to speak to him. After a few minutes silence, Michele repeated that he was doubtful about the risks linked to the gastroscopy; in particular his impression was that the dangers were much greater than those mentioned by the doctor the previous day. Surprised by these questions, the new doctor discovered that neither the patient nor the colleague on duty the previous day had signed the consent forms and therefore he had to fill in the forms together with the patient. The new description of the risks linked to the gastroscopy increased Michele's concerns, and he appeared even more confused. At this point, the doctor emphasised that it was necessary to decide immediately because the test was booked in an hour's time. This discovery greatly irritated the patient. Despite the attempts of the new doctor to continue the dialogue, the decision to refuse the gastroscopy was now definitive. During the conversation that the researcher had with Michele a few hours later, the three aspects he mentioned repeatedly were: 1) "I felt abandoned by the doctor who explained the test to me, I wanted to talk to him but I couldn't." 2) "The things the other doctor said made me change my mind." 3) "The fact that the doctor booked the test before knowing what I had decided felt like a sort of betrayal." These statements emphasise how the construction of a dialogue between doctors and patients is not always easy. In the story of Michele, the opposition between the search for a *continuative dialogue* and the limits set by the hospital shifts emerges clearly. This story also underlines how far the way in which the information is transmitted can influence the patients' therapeutic decisions. According to the theories of *discourse analysis*[155], the fact of emphasising some aspects of the phenomena described – the advantages rather than the risks of the treatments proposed, for example – and the choice of the adjectives used during the conversations play an important role with respect to the message that reaches the interlocutors. The impact and the interpretation of the information may not be the same and therefore the choices will be influenced in one direction or another. In accordance with these theories, many of the doctors interviewed felt that the *neutrality of the informative process* was a difficult ideal to reach during the meetings with the patients. The implicit transmission of one's ideas in the dialogue with the patients appears, nonetheless, to be an *input* that is difficult to manage for the latter, when the voices to be listened to are more than one and do not always agree. Finally, as the story of Michele shows, the anticipation

155 N. Fairclough, *Critical Discourse Analysis. The Critical Study of Language*, London, Routledge, 1995.

of the patient's choices – a practice that is common amongst doctors, as we said, in order to gain time in the treatment process – may, on the contrary, be associated by the patients with *bad intentions*, or "abuse of power" by the professionals. On the other hand, as it was possible to observe not only in the case of Michele, the completion of the consent forms is not always carried out by the doctor who supplies the patient with information. In many situations, *the person who informs the patient is not the person who signs the consent form,* and *the person who acts on the patient's body is not the person who took part in the informative process*. The lack of coincidence between the person who informs, the person who signs and the person who effectively acts on the patient's body is only partly linked to the problem of hospital shifts. As we will see in the following chapters, the hierarchies between the various professionals – for example between the doctors and the nurses – also play an important role (see chapter five). This aspect is particularly important for the oral transmission of the information to the patients. In the gathering of written consent, on the other hand, the *interchangeability* of the professionals is valid only within the same professional category. Therefore, the consent to chemotherapy can only be signed by an oncologist and information must be given by another colleague on the oncological ward, and the consent to a surgical operation can only be signed by a surgeon and gathered by another colleague on the surgical ward.

2.4. *Multiple consents*

The case of what are known as *multiple consents*, or the therapeutic courses that require the signing of more than one consent form by the patient, are different. In this case, the signing of the consent forms is entrusted to the representatives of the various sectors of hospital medicine. The rule for the treatments in which the various health professionals participate is, in fact, the request for *a number of consent forms equal to the number of professionals involved.* As observed during the research, the number of persons that the patient meets in many cases makes the way in which informed consent is gathered complicated. In addition to the problem of 'who says what', there is the question of the order in which the hospital staff ask the patient to sign the consent forms. In many situations, in effect, the order of the consent forms presented to the patient does not follow the succession of the treatments or the interventions proposed, but the availability of the hospital professionals. Thus, for example, if one of the surgeons has a moment free to meet the patient, the explanation of the operation and the signing of the consent to surgery may take place before the signing of the consent to the use of anaesthesia without which it would not be possible to carry out said operation. In other cases, the first figure that the patient meets is the psychologist charged with

verifying the sustainability, in psychological and emotional terms, of the treatment. The criticism of the often random succession of professionals met by the patient emerges explicitly from the testimony of one of the doctors on the clinical psychology ward, who emphasises that the efficacy of his role depends on the respect for the *correct chronology* of the informative procedure.

> If the patients are not informed first by the doctors or by the surgeons, our work becomes difficult. Our meeting with the patient serves to evaluate whether they have understood the extent of the treatments they are about to face, and therefore we should appear last of all. In many cases, however, we are the first to meet the patients. What counts for the system is that the patients *do the rounds of the professionals* so that if the doctors are busy and we are free – which is almost always the case! – we act first and then the patients speak to the doctors. The problem is that our work does not operate in this way: since we can speak to the patients about the way they are reacting to the information received from the doctors, we often have to explain the therapeutic procedures, practically standing in for the doctors, despite the fact that we do not have their professional knowledge![156]

In other cases, on the contrary, the patient may receive the most important information only at the end of the *round of professionals*, that is after having signed most of the consent forms. One example is the tendency to inform the patients of the oncological risks linked to anti-rejection medicines necessary after a transplant, or the moment in which the patient is asked to sign the *final consent* in order to be added to the waiting list, after having already signed all the consent forms for the transplant (consent to the operation, consent to the anaesthesia, consent to the blood transfusion, etc.). In more than 90% of the interviews observed by the researcher, the transmission of this information did not negatively influence the decision of the patients. The uncertainty produced by the news that the medicines to be taken after the operation carry a risk of incurring a new illness was often balanced by the fact of having waited for a number of months before getting onto the waiting list for a new organ. As some patients said "after everything we have gone through to get this far, it is quite difficult to go back", or "it's better to deal with the illness we have rather than thinking about one that we could have in the future."[157] The pre-eminence assigned by the patients to the immediate need for treatment leaves, however, some questions open: would the information on the possibility of incurring an oncological illness due to the pharmacological treatment linked to new organ have the same weight if it were transmitted to the patient earlier? To what extent does the moment in which this information is given guarantee the freedom of choice within a "lifesaving" procedure or a procedure that is necessary for the survival of the patient?

156 Extract from an interview held on September 6th 2014.
157 Extracts from interviews held on 16th and 17th June 2014.

2.5. *The linguistic barriers in informing foreign patients*

Another limit emphasised by the medical personnel was the difficulty in communicating with patients who are unable to read, understand and speak Italian. As emerged from the observations held during the research project, the *linguistic barriers* encountered by the professionals in informing these patients only partly found a solution in the *linguistic-cultural mediation service* introduced in the hospitals at the end of the nineties, in order to encourage the dialogue between the medical personnel and the foreign patients. The linguistic support offered to the doctors by the mediators still encounters the limits of a service kept "on the outskirts" of the hospital institution, despite the growing number of foreign patients. One example is the obstetrical and gynaecological service where the foreign patients seen at the clinics and on the wards are more numerous than the Italian women.

The first problem that emerged in all the services analysed is the fact that the informative leaflets and the forms distributed to the patients for the signing of the informed consent. As emphasised by the management of the public relations office (URP) – the body officially charged with managing the linguistic-cultural mediation service within the hospitals analysed – the proposal to translate the forms and the informative leaflets into other languages is a project that has been discussed for a number of years by the chief medical officers. As stressed during the interviews, apart from the limits set by the economic cost, one of the questions still to be resolved is which languages to include in the translation project. Unlike hospitals in which the foreign patients show a strong homogeneity with regard to their origin[158], the extreme variety of the countries from which the foreigners resident in Torino originate makes the linguistic choice difficult. The impossibility of covering all the languages spoken in the countries of origin was a recurrent them also with regard to the interpreter service carried out by the cultural mediators during the informative interviews between doctors and patients. The policy shared in all the clinics and on the wards analysed is the recourse to two different categories of mediators: those who work with the most numerically important groups of foreigners and those who work with the minorities. The former represent a *fixed presence* in the hospitals, the latter are only contacted in case of need. In this case it is the doctor who personally informs the management of the URP which could be the most suitable linguistic mediator for the patient, choosing from the list of mediators available[159] according to the agreements established between the hospital and the various social cooperatives who work in

158 C. Falge, C. Ruzza and O. Schmidtke, *Migrants and Health: Political and Institutional Responses to Cultural Diversity in Health Systems*, London, Routledge, 2012. I. Quaranta and M. Ricca, *Malati fuori luogo. Medicina interculturale*, op. cit.

159 Amongst the countries covered by the "occasional" linguistic-cultural mediation service we find: Morocco, Albania, China, Russia, Moldova, Romania, Peru, Philippines, Zaire, Nigeria, Kenya, Spain and Portugal.

various ways with the immigrants.[160] As emphasised by the majority of the professionals interviewed, the need to make contact beforehand with the mediator required, demands a programming of the activities that is not always compatible with the hospital workload and schedules. Equally, as many of them said, the time required for summoning the mediator does not always allow them to make use of this figure for the explanations to be given immediately to the patient and in emergency situations.

The relative availability of the linguistic-cultural mediation service also concerns the so-called "permanent" mediators. We will take as an example the Molinette Hospital; there are four mediators available at present – all women. A mediator for Arabic, one for Albanian, one for Romanian and one for Chinese. The same is true for the Sant'Anna and Regina Margherita hospitals where for the groups of foreigners most numerically important (those who speak Arabic, Albanian and Romanian) there is only one mediator for all the clinics and wards. The possibility for the doctors to use these figures therefore requires further planning of the hospital activities. According to the information that emerged during the observations of the services, in many cases the doctors are forced to renounce the interpreter service, because the mediator is busy on another ward, or the foreign patient is seen during the hours in which the mediator is not on duty. In all the hospitals of the Città della Salute e della Scienza, the presence of the linguistic-cultural mediators is in fact limited to certain hours of the day, the morning and the early afternoon. Some of them, such as the Romanian mediators, work in more than one hospital, and therefore their presence is guaranteed only for a few hours a week.

In some cases, the doctors manage to compensate for these limits thanks to their own knowledge of a foreign language such as English, French or Spanish. In other cases, the doctors enact two main expedients. The first consists of improvising a translation service with the help of representatives of the hospital staff who speak the same language as the patients (Albanian nurses, auxiliaries of Romanian origin, for example). The second, is the translation of the information by a member of the patient's family or, alternatively, by a person from the same country who has a better command of Italian. In both cases, however, this is an *extemporaneous remedy* whose efficacy depends on a series of unforeseeable circumstances – assistance provided by persons belonging to the hospital staff, or not, who speak the same language as the patient. The result is a frequent communicative vacuum produced by the difficult communication between the doctors and the foreign patients.

160 A. C. Vargas, *La mediazione interculturale e la formazione*, in E. Castagnone *et al.* (ed.), *La salute come diritto fondamentale: esperienze di migranti a Torino*, Bologna, Il Mulino, 2015, pages 181-200, also available in English *Health as a fundamental right: A study on migration and healthcare in Turin*; G. Ceccatelli Gurrieri, *Mediare culture. Nuove professioni tra comunicazione e intervento*, Roma, Carocci, 2003.

Another problem frequently mentioned by the hospital staff is that it is impossible to check the information given by the foreign patients and equally by the linguistic-cultural mediators, or the figures employed in their stead. And so, one of the choices adopted by a number of doctors, in order to safeguard themselves legally, is to ask the mediators to sign the forms (or the medical records if it is a case of oral consent) in the role of *witnesses* to the transmission of the information by the medical personnel and the fact that the patients have understood.

> It is impossible for us to know what the mediators say to the patients. They are professionals who have trained to learn medical terminology, so they certainly explain everything in detail. The problem is not that we don't trust them, quite the opposite! The point is that we cannot understand whether the patients have understood or not. Generally, we ask the interpreters this question, but what proof do we have? The only way we could think of was to have the mediator sign a document, or the consent form itself, saying that the patient has understood the explanations. We don't know whether these documents can have legal value, but when we do this we feel a little more protected! [161]

On their part, a number of mediators showed that they are aware that the signing of the informed consent forms is not one of their duties. As the testimony that follows shows, the choice to humour the doctors is often seen as a form of assistance offered to the foreign patients.

> The fact that they have us sign the informed consent forms is a new situation that has arisen in recent years. In our opinion, the doctors are increasingly frightened by this consent and so they have invented this procedure! We know that it is not part of our job, but none of us has ever thought that it is a lack of trust in us. The work with the doctors has always gone well. As far as I am concerned, it is a form of help that I can offer the foreign patient that I am dealing with, together with the doctor. [162]

Thus, the signing of the informed consent form by the linguistic-cultural mediators has rarely been a source of conflict with the hospital personnel, with whom they try to find "grassroots solutions" to cope with the various limits of the practice of informed consent and the dialogue between doctors and patients.

161 Extract from an interview held on 25th September 2014.
162 Extract from an interview held on 6th October 2014.

Chapter Four

Who should be informed and *how*?
Patient autonomy and self-determination in therapeutic choices

The problems described so far represent only some of the obstacles that doctors meet when offering clear, complete and thorough information. As we will see in this chapter, the process of informing the patients is often difficult to apply for two further reasons. The first corresponds to the question of *to what extent* it is possible and correct to inform the patients. The second is represented by the choice of *whom* to inform, together with, or instead of, the patient. As we will see, in both cases these questions show a gap between the principles proposed by informed consent, such as the principle of *autonomy* and that of *self-determination* of the personal choices made by the patient and the aspect of the practical interactions between the doctors and the patients.[163] To what extent is it possible to share what is known about the illness with the patient? Do the doctors always have complete and exhaustive information about the risks linked to the treatments proposed? To what extent does the informative course involve only the doctor and the patient? The aim of this chapter is to give an answer to these questions. The perspective from which we now examine the practice of

163 L.C. Edozien, *Self-Determination in Health Care. A Property Approach to the Protection of Patients' Rights*, Farnham, Ashgate, 2015.

informed consent is no longer that of the structural limits associated with the working of the hospital machine (lack of time, lack of spaces, high number of patients), but rather that of the problems posed together with the content of the information to be transmitted to the patients and the characteristics of some categories of patient.

1. *Telling the truth*

The depth and detail of the information to be given to patients often sets a series of *moral dilemmas* for the medical personnel. Even if, in order to obtain informed consent, the explanations given to the patients should be as complete as possible, in fact *the extent* to which the patients should be informed is not always an easy choice for the medical staff to make. In many situations, the ideal of clear, complete and exhaustive information in fact conflicts with the practical choice to tell patients more or less the truth. This dilemma emerged above all in those situations in which it was necessary to face end-of-life situations.[164] In the majority of cases, the choice to dedicate sufficient time to the dialogue with the patients goes alongside the tendency not to go into detail when describing the situation. In many cases, the medical staffs' decision to increase the frequency of the interviews with the patients does not increase the level of information the patients acquire. In fact, beyond a certain point, the explanations stop. Unlike the situation described in the literature for the United States,[165] the tendency observed on the wards was to always leave the patients with hope. Thus, the decision to not tell the entire truth about the prognosis. This tendency, described by many professionals as a *deliberate choice*, not only characterises the Torino situation, but is also shared elsewhere in Italy and abroad.[166] Arthur Kleinman's theories[167] are once again a useful tool for considering the variability of the amount of information offered to patients in the various countries in which there exists the "culture of informed consent."[168] The evaluation of the extent to which it is possible to inform the patients of the progress of the disease in fact varies according to the *healthcare values* shared by the doctors and the patients. Therefore, the right to information – formally seen as a *universal right* – presents differing characteristics in the North American context, in that of Northern Europe and in that of Southern Europe.[169] If we examine the situation in the light

164 M. Marzano, *Scene finali. Morire di cancro in Italia*, Bologna, Il Mulino, 2004; D. Memmi, *Faire vivre et laisser mourir: le gouvernement contemporain de la naissance et de la mort*, Paris, La Découverte, 2003.
165 A. Fiester, *Neglected Ends: Clinical Ethics Consultation & the Prospects for Closure*, in «American Journal of Bioethics», 15, 1, 2015, pages 29-36.
166 S. Fainzang, *La relation médecins-malades: information et mensonge*, Paris, Presses Universitaires de France, 2006.
167 A. Kleinman, *Concepts and Model for the Comparison of Medical Systems as Cultural Systems*, in «Social Science & Medicine», 12, 1978, pages 85-93.
168 P.I. Kirk and L.J. Kristjanson, *What Do Patients Receiving Palliative Care for Cancer and Their Families Want to Be Told? A Canadian and Australian Qualitative Study*, in «British Medical Journal», 328, 2004, pages 1343-1347.
169 E. Bergman and A. Fiester, *The Future of Clinical Ethics Education: Value Pluralism, Communication, and Mediation*, in A. Akabayaski (ed.), *The Future of Bioethics. International Dialogues*, Oxford, Oxford University Press, 2014, pages 703-711.

of the cultural differences that pass through these areas of the western world, the ethical question posed by the decision not to tell all the truth assumes relative importance. This cannot, in fact, be seen as the denial of the patients' universal right information, but must be interpreted as behaviour dictated by a system of values corresponding to specific deontological principles. On the one hand, in the light of Arthur Kleinman's theories, the tendency of the doctors to share the truth with the patients only in part could be described as *culturally determined* behaviour. On the other hand, this tendency has a therapeutic purpose in many cases. As emphasised by many of the doctors interviewed, giving full information to the patients can be counterproductive for their health. In their opinion, the main risk linked to the decision to tell the whole truth is that of causing impulsive reactions, such as the immediate interruption of the therapies or suicide attempts. According to this logic, the decision to inform the patients only partially is described as a way of protecting them in a moment of physical, logical and emotional vulnerability. The *cultural* and *therapeutic* dimensions of the partial information regarding the prognosis were summarised as follows by one of the doctors on the oncological-haematological ward.

> In Italy, it is not like the United States where the doctors clearly tell the patients that they have only a month to live. Our policy is always to leave a psychological crutch for the patients. Often in oncological diseases, the patients feel well until just before the physical collapse. It is very difficult to tell someone who still feels well that they have only a few months left to live! In the face of this type of information, the risk that the patients fall into depression or stop taking their medicines, therefore worsening the situation, is very high. If we tell them exactly how things stand, it can be counterproductive for the patient's health. If we don't want the patients to give up, it is better to tell only part of the truth. It is not a question of mocking them or telling lies, but rather of not traumatising them with the information, we hold.[170]

In the light of these considerations, the majority of the doctors decide to allow the patient to realise the seriousness of the situation on their own, "allowing it to sink in" – as they say – that nothing more can be done with regard to their illness. Thus, in many of the interviews witnessed by the researcher, the prevalent behaviour amongst the doctors was that of *hints and allusions*: they tried to increase the patient's level of awareness, without deluding them with false expectations, but also without presenting them with the hard truth. The only exception was represented by the situations in which the patients openly asked the doctor for information on the prognosis. In the face of this question, the professionals usually decided to tell the truth, giving explicit forecasts of the number of weeks or months left to the patient. In other words, what prevailed was respect for the

170 Extract from an interview held on 19th May 2014.

right to information of *patients who wanted to know* since they wished to organise this last phase of their life, or because they wanted to deal personally with certain material questions (inheritances, Wills, etc.). As emphasised by many of the doctors interviewed, in these cases it was the patients themselves who *authorised* them to tell the truth, reassuring the personnel of the positive intentions linked to this question. On the contrary, if the patients did not ask for information about the prognosis, the staff drew the conclusion that they *did not want to know* and that therefore telling the truth would be a form of violence against them.

These tendencies emerged during the informative interviews regarding terminal illness, but also during the medical examinations in which patients were informed for the first time of serious illnesses, such as cancer. In addition, in this case, the need to tell the truth often appeared to be in conflict with the fear of traumatising the patients by informing them of the presence of illnesses commonly associated with a risk of death. As emphasised by the theories of *discourse analysis*[171], the register employed by the person responsible for the communicative process – in this case the doctors – varied according to the *intentionality* of the message to be transmitted to the listener – in this case the patients. Through the way the diagnosis is communicated, the discursive choices of the doctors not only influence, but *are intended to influence* the message transmitted to the patients. The intentionality shared by the doctors is usually that of informing the patients without alarming them. This frequently leads to the use of rhetorical figures of speech – in the first place metaphors – or of specific linguistic variations typical of Italian, such as diminutives – during the dialogue with patients. In many of the conversations observed, instead of openly naming the illness (cancer, tumour) the choice was to explain the situation to the patient without actually mentioning the pathology. Amongst the terms most commonly used by the doctors instead of tumour we find "mass", "spot", "little mass", "patch"; or expressions such as "alteration of the organ", "group of cells that are not working properly", "a mass of dangerous cells", "cells that could cause problems". Another element that emerged during the interviews was the variability of what they thought it was possible to say to the patients. As shown by sociological-anthropological literature,[172] the words that frighten patients as soon as they are spoken have changed over time. Some terms that in the past were considered synonyms of immediate exposure to the risk of death – such as "heart attack" – now suggest that the problem can be treated. The evolution of the words that it is considered better to avoid during the conversations with the patients emerges explicitly in the testimony of another doctor on the oncology haematology ward, who emphasised the way the fears associated by the patients with the word, "cancer" have now moved to other terms:

171 N. Fairclough, *Critical Discourse Analysis. The Critical Study of Language*, London, Routledge, 1995.

172 A. Letourmy and M. Naiditch, *L'information des usagers sur le système de soins: rhétorique et enjeux*, in «Revue française des affaires sociales», 2, 2002, *La démocratie sanitaire*, pages 45-60.

> In the 1980s as soon as we told a patient that they were at risk of a heart attack, the first thing they thought was that they could die at any moment. Nowadays, thanks to the progress we have made, the patients know that there are many cardiological or surgical remedies for heart disease and it is possible to talk about heart attacks. In the 1990s, the word that we absolutely had to avoid was 'cancer'. None of us used this term because as soon as the patients thought that they would die after a few months. With the progress, we have made in oncology, the patients have understood that there are various types of tumour: those that can be treated and those that can be more problematic. The result is that now we can mention the word cancer, while the patients are more frightened when they hear the word 'metastasis': many know that if this term is introduced, the problem is serious.[173]

As emphasised by the words of this doctor, the evolution of the "transmissible content" in the conversations with the patients is linked above all to two factors: the scientific discoveries and the process of habituation of the patients with the medical culture. The introduction of new therapeutic remedies thanks to the progress of scientific discoveries often leads to a significant change in the terms that define the diseases. At the same time, the growing familiarity of patients with medical knowledge – a phenomenon often encouraged by the use of Internet where they have access to knowledge once guarded by medical manuals (see chapter five) – is translated into the capacity of the patients to understand, or at least to imagine, the seriousness of the situation according to the terms used by the doctors. Therefore, both the doctors' knowledge of the patients' situation and the patients' understanding of the situation announced by the doctors influences the informative process, affecting what can be said, the terms chosen by the professionals and the words to be used with care, such as the word "metastasis" in the case of oncological patients.

1.1 The unspoken and the taboo of death

These changes in the dialogue between doctors and patients lead to a series of questions that the hospital personnel find it difficult to answer. The first is represented by the "unspoken" or by communicative gaps in the conversations with the patients. One example is the informative leap that is often made when passing from active to palliative treatment for cancer patients. The tendency to avoid making the seriousness of the situation clear has often resulted in the end of therapeutic treatment becoming a sort of taboo, or a complicated topic to deal with, for the medical personnel. In many conversations that the researcher observed, the proposal to continue the treatments at home

173 Extract from an interview held on 3rd May 2014.

or in structures outside the hospital, such as a *hospice*,[174] took place without specifying that the treatment offered in these places is not that offered so far, but the palliative care aimed at accompanying the patient towards a "peaceful death" without suffering. As emerged from the research, the difficulty in admitting that there is nothing more that can be done often goes hand in hand with a series of strategies enacted by the doctors on the ward. A first strategy corresponds to the decision not to mention this topic in the hope that the patients will realise by themselves that the chemotherapy is not giving the results hoped for. In other cases, on the contrary, the doctors decide to propose that the patient continue the treatment, even though they know that they are not responding to the medicines and that the illness is entering the final phase. The decision not to interrupt the treatment and to carry out a further cycle of chemotherapy postpones the moment in which it is necessary to tell the patient that there is nothing more to be done. As stated by many of the doctors interviewed, this choice has the advantage of producing a "placebo effect" on the patient, who will have the impression that they are still fighting the illness. Together with the question of the economic costs of continuing a treatment that is clinically no longer necessary, and whose benefits for the patient are above all of a psychological nature, the other problem that arises is the risk of *therapeutic persecution*.[175]

The often slight difference between the types of support that is offered to the patients and the risk of carrying out some form of therapeutic persecution is a question that emerged repeatedly during the research project. In the case of the terminally ill, the doctors' opinions seemed fairly uniform. In particular, they all emphasised the need to accompany the patients towards a "good death" intervening with palliative treatments. With respect to the patients hospitalised on the intensive care wards, whose lives depend on the machines that replace the vital functions (nutrition, hydration, respiration, etc.), on the other hand, the professionals seemed somewhat divided. According to some, the decision to keep the patient alive despite the limited capability of the body to react to external stimuli is a choice that alters the natural cycle of life, postponing for weeks, months or even years, the moment in which the patient dies. For others, the patient who, thanks to the machines, can continue to perform their vital functions is still alive; to deprive them of the support given by the hospital equipment would be equivalent to a form of euthanasia.

> Some patients after a few days on the reanimation ward die peacefully. Others may remain with us for weeks or even months without moving either forwards or backwards. Thanks to the machines, it

174 Structures that have an agreement with the hospital services and which care for terminally ill patients during the last three months of life. On this topic cf: A. Gusman, *Comuni-care: un percorso sulla comunicazione nel passaggio alle cure palliative*, in «Rivista Salute e Società», 3, 2015, pages 1-14; M.J. Field and C.K. Cassel (ed), *Approaching Death. Improving Care at the End of Life*, Washington, National Academic Press, 1997.

175 D. Capozza and I. Testoni, *Dinanzi al morire: percorsi interdisciplinari dalla ricerca all'intervento palliativo*, Padova, Padova University Press, 2012.

> is possible to reach an equilibrium that may last for a long time, but which could break down at any time. In these cases, we don't know what to do, is it better to let the patients meet their fate or wait until their own bodies decide? How long should we wait? For example, if the patient has been in a coma for months should we continue the treatments even though we can see no improvements? There are no laws or guidelines on this subject that we can refer to, so we look at the scientific evidence and then everyone follows their own conscience. Personally, my philosophy is that as long as there is hope there is life, other colleagues see things differently.[176]

Unlike other European countries, such as Holland, Belgium and Luxemburg, Italy has no laws on what is known as "a living will" or "anticipated directives" and this deficiency tends to lead to the doctor taking a decision on the basis of the individual case, and their personal opinions about whether and when to interrupt the treatments offered to the patients. Although the debate underway in recent years on the bioethical legitimacy of end-of-life treatments has been centred above all on the world of the adults, the evaluation of what to do appears equally complex when it is a question of paediatric patients or new-born babies hospitalised on the intensive care wards. In the majority of cases, unlike the adult world, when it is clear that nothing more can be done for the patients, the doctor's choice is to leave the children to their fate, without asking the parents to make a decision, but informing them once the choice has been made on the basis of the clinical situation.

Apart from the age of the patients, the decision to interrupt the therapies finds consensus amongst doctors when cerebral death is ascertained. As emphasised by many of the professionals interviewed, this phenomenon, which was unknown until a few decades ago, has revolutionised the concept of death in medical literature, shifting the "proof" of decease from the interruption of cardiac activity to the absence of cerebral activity.[177] Having said this, the decease of the patients has been described by many as a subject that doctors still find it difficult to face. The difficulty encountered by many professionals in speaking both about the imminent threat of death, and of the death of the patient after it has occurred, confirms the theory supported by many sociologists and anthropologists that death has become a cultural taboo in our society.[178] The increasing spatial, psychological and emotional distance we place before this stage of life has made conversations on the subject of death difficult for the healthcare workers. As stated by many of the professionals interviewed, nowadays death has disappeared from the discourse of the doctors, the patients and the members of the patients' families: it is a topic that is avoided even amongst colleagues. Speaking with the family of the patients of a subject that has become unnameable, even within the hospital

176 Extract from an interview held on 12th June 2014.
177 On this topic see A. Carol, *Une histoire médicale des critères de la mort*, in «Communications», *Chairs disparues*, 2015, pages 45-56.
178 L.V. Thomas, *Anthropologie de la mort*, Paris, Payot, 1988.

environment, is often experienced as an important challenge by the medical personnel. Judging by the researcher's observations on the reanimation ward, while the communication of the patient's death is in itself a complex subject to deal with, the difficulties faced by the doctors increase when it is necessary to speak of a type of death that is distant from everyday experience, such as cerebral death. The acceptance of the fact that the patient is dead even when the heart continues to beat often presents a problem of communication between the doctors and the members of the patient's family. The querying of the fact that it is a *certain death* even though there are still signs of life in many cases translates into resistance by the family members against the news of the patient's death.[179] This leads to the need for a greater investment by the professionals in the dialogue with the members of the patient's family, in order to help them accept the idea that the death of their dear one is definitive. As shown by the words of this doctor, the supplementary explanations regarding the characteristics of cerebral death extends the duration of the conversations on topics that they would prefer to deal with as quickly as possible, making the situation more trying on the psychological plane for the medical personnel.

> Often it is not easy to make the relatives understand that while the heart is still beating, all cerebral activity has ceased and the patient is dead. For many, if the heart continues to beat, the patient is still alive. In these cases, we are forced to give more detailed explanations about the fact that this person is no longer alive, but has a body that is still apparently alive. These conversations are difficult to deal with. It is difficult for those who have suffered the loss to engage in these discussions, but it is also difficult for us who must face up to death time after time.[180]

Once the information about the decease has been communicated, the hospital staff must face another equally difficult challenge: the request for consent to harvest organs or tissues.[181] Except for the patients who, while they were alive, chose to make an anticipated directive, explicitly communicating their opinion on the *post mortem* donation (also known as a living will), in all other cases it is necessary to ask for the consent of the members of the family before proceeding with the removal of organs or tissues. Although in the absence of any declaration of intention, the rule is to interpret the lack of explicit opposition to donation (dissent) as a form of indirect assent to the donation, the effective possibility of proceeding with the retrieval of the organs *in effect* depends on

179 On this subject, it is necessary to emphasise the difference between the position of some family members who resist the news of a beloved person's death for affective, psychological and emotive reasons and the position shared by the associations – such as the Lega nazionale contro la predazione di organi e la morte a cuore battente (national league for the abolition of the declaration of "brain death" with a still-beating heart as imposed by law for organ transplant purposes) who fight the idea of cerebral death for political or ideological reasons.

180 Extract from an interview held on 12th September 2014.

181 M. Weinstein, K. Overby and A. Fiester, *Addressing the Consent Issues of Donation after Circulatory Determination of Death*, in «American Journal of Bioethics», 15, 8, 2015, pages 3-9.

the opinion of the patient's family. This tendency, observed not only in the case of minors, but also for adult patients, aims to guarantee respect for the *dignity* and the *integrity* of the organism of the deceased person:[182] a body from which it will be possible to use some parts for medical and scientific purposes only if the patient has expressed their approval, or if the family does not dissent following the death.[183] The data gathered on the wards showed that the percentage of patients who choose to express an anticipated directive is generally much lower than the total number of patients treated each year (less than 10%).[184] Consequently, the majority of decisions regarding the donation of organs and tissues are taken by the family immediately following the news that a dear one has died. In some cases, even though there is no explicit declaration by the deceased, a number of elements (conversations with family members, comments on the experiences of other friends, reactions during television programmes on the donation of organs, etc. make it possible to understand what they would wish, thus making the decisions about the treatment of the body *post mortem* easier. In other cases, the relatives may appear undecided, since they are still shocked by the death of their loved one, or because they disagree about what to do. According to the representatives of the Regional Coordination for the Donation and Harvesting of Organs and Tissues, the communicative capability of the medical personnel is essential if the relatives who have suffered a bereavement are to be informed correctly, and may be decisive in situations where they appear confused or uncertain about their choice. The importance attributed to the choice of words used by the hospital staff has led the Regional Coordination for the Donation and Harvesting of Organs and Tissues to draw up a series of *good practices*. The first is represented by strengthening the team, advising the healthcare workers to work in pairs when they inform the relatives of the death of the patient and propose the donation of the organs and the tissues. This information is usually given immediately after the death of the patient, in order to guarantee the maximum "quality" of the organs for the patients who will receive them, often after spending a long time on a waiting list.[185] The other practice is represented by the organization of training courses on the donation of organs and tissues for all the healthcare workers who must deal with this question in their professional activities. These courses last two days and are usually organised more than once

182 S. Novaes, *Respect des personnes et éthique de la transplantation*, in R. Carvais and M. Sasportes (ed.), *La greffe humaine. Incertitudes éthiques: du don de soi à la tolérance de l'autre*, Paris, Presses Universitaires de France, 2000, pages 629-642; M. Touzeil-Divina and M. Bouteille-Brigant, *Le droit du défunt*, in «Communications», *Chairs disparues*, 2015, pages 29-44.

183 A. Giannelli Castiglioni *et al.*, *Manuale del corso nazionale per coordinatori alla donazione e prelievo di organi e tessuti*, VI ed., Bologna, Editrice Compositori, 2008.

184 On this subject, we can mention the informative campaigns carried out in Torino and throughout Piemonte by the Regional Coordination for the Donation and Harvesting of Organs and Tissues. Amongst the activities to raise awareness of the question of transplant and donation of organs and tissues there are courses for the middle and secondary schools, cooperation with the local authorities who wish to inform their citizens about the topic, the publication of informative material – fliers, leaflets and brochures – at the clinics, on the wards and in hospitals throughout Piemonte.

185 As emphasised by the doctors, the life of the organs and the tissues corresponds to about 10 days for the corneas; 72 hours for the kidneys; 18 hours for the liver; 5 hours for the heart and the lungs. If it is not possible to harvest, transport and transplant them in time, they can be used for scientific study, otherwise they will be destroyed with the rest of the organic hospital waste.

during the year. The first part, which generally corresponds to the first morning, is composed of a number of classroom lessons during which the practice of donation is discussed from a medical, juridical and medical-legal standpoint. The remainder of the two days is dedicated to communication and the practical application of certain communication techniques. Pair work and group work is followed by enacting situations in which it is necessary to inform relatives of the death of the patient and in which the donation of organs and tissues is explained. The participation in this *role-playing*, where the staff impersonate the various roles, first being the healthcare worker and then a member of the patient's family, aims to help the professionals to overcome the discomfort that they often experience when proposing an act – that of donation – considered important from a scientific point of view, but problematic from an ethical standpoint. Through this training they practice informing the patient's relatives and acquire new skills for reaching *efficacious professional communication*, abandoning the idea of being the only ones who find it difficult to talk to and to inform the patients' relatives.

> We learn a lot during these courses about an area where we are not specialists, but which often crops up in our work. The most interesting part is that we discuss the difficulties in communication and asking for informed consent with our colleagues. When you talk to the others, you realise that we all have the same doubts, what seems to be only your problem when you are at the hospital, is in fact a common problem. The point is that we never have time to talk to each other, while these courses give us time to compare our experiences. After all, we all feel the need to learn, because no one taught us how to speak to the patients and their families. In my opinion, we should do courses like this for other topics, it is the only way to fill a gap in our medical training. In our profession, we are now required to speak to the patients, so it is better if we do training courses on the subject. Perhaps they should also be included in the medical degree courses, to prepare the new generations.[186]

1.2. *Information on the risks*

The risks linked to the treatment and the procedures proposed to patients are another complex topic that the hospital staff must face. Through the observation on the wards, the researcher tried to answer the question 'to what extent were the patients informed of all the risks linked to diagnostic, pharmacological and therapeutic treatments, and indeed, to what extent is it possible to inform them?' Apart from the problem of time insufficient for in-depth conversations with the patients, the information about the risks often presents a number of difficulties for the healthcare professionals. In the first place, according to many doctors, if they are listed in full, the

186 Extract from an interview held on 24th May 2014.

dangers linked to the procedures promoted for the well-being of the patients could be a deterrent in the therapeutic course, if not an element that could lead to the decision to refuse treatment. As emphasised with regard to the information regarding the terminal phase of life, the idea widely shared by the professionals interviewed is that this type of information can discourage the patients, leading them to abandon or resist the course proposed by the doctors. The result is, in their opinion, the opposite of what is considered the best treatment for the patient. Without arriving at outright lies, the choice not to mention the dangers linked to the medical procedures therefore, once again, has a therapeutic purpose. One example is the way in which the diagnostic tests proposed are explained to the patients. In the majority of cases, the emphasis is on the improvements in the techniques used in the hospital. There is a tendency to minimise or exclude, on the other hand, the iatrogenic risks linked to the procedures, such as the risk of abortion linked to amniocentesis, or the collateral effects of MRI. In the majority of the interviews observed, the conversations between the doctors and the patients were centred on the benefits linked to the diagnostic tests and not on their risks, such as the possibility of endangering the life of a foetus by carrying out a test normally advised for pregnant women in order to ascertain that it is growing properly, in the first case; or the possibility of incurring illnesses produced by the radiations emitted by the MRI in the second case. In the face of questions about this choice, the response is generally that the test proposed is necessary and ~~that~~ the possibility that the patients will incur these risks is very low.

> In any case, it is better not to frighten the patients speaking to them about the risks, which according to the statistics are almost equal to zero. If we feel that a test is important for the patient, it is better to be cautious about this kind of information. As soon as we say there could be risks, even if these relate to 0.0001% of the population, the patients immediately think that there will be problems for them. To be honest, what could create difficulties is mostly the fact that the patients may be hiding information that could increase the risks. This is a complex question, because if the patients don't tell us the truth there really could be dangers.[187]

The difficulty of informing the patients of the dangers linked to the medical procedures emerged in a number of situations observed at the hospitals. As emphasised by the words of this doctor, together with the choice to ignore risks considered close to zero, in some cases, the patients may omit information, thus preventing the evaluation of dangers *effectively* linked to the treatments. Taking the risks linked to MRI as an example, the balance of the risks run by the patient is drawn up on the basis of the answers to a questionnaire distributed by the healthcare workers prior to the signing of informed consent. By compiling this questionnaire, the patients are made

187 Extract from an interview held on 12th October 2014.

aware of the dangers linked to magnetic radiations and the doctors evaluate whether it is possible to subject the patient to the MRI.[188] The impossibility of checking the information supplied by the patient may, however, lead to problematic situations. Typical of this question in the case of Marina, a patient of sixteen years of age, who chose not to inform the doctors of her pregnancy in order to avoid sharing this news with her parents, who were present when the questionnaire was compiled. The omission of this information, discovered later by the staff through a blood test, did not allow the doctors to realise that the patient was not compatible with MRI, nor to inform the patient and her parents of the greater risks of the diagnostic test. The same type of problem emerged in all those cases where the patients, without wishing to hide information from the doctors neglected to give certain information through distraction or forgetfulness. Omitting to take certain medicines, for example, may increase the level of risk for the patients who will not be informed by the doctors of the effective risks of hospital treatment, since the medical staff is not aware of the clinical situation of the patient.

In other cases, on the contrary, the difficulties encountered by the doctors in explaining the risks linked to the treatments concerns the lack of information available to the hospital staff themselves. According to the facts that emerged during the research, the circumstances in which the doctors do not have much information to give to the patients are mainly twofold. On the one hand, the situations in which medical knowledge continues to be partial. One example is the so-called rare diseases, on which medical studies are still underway because the information that can be given to the patients is limited. As many doctors emphasised during the informative interviews, the lack of other similar cases on the ward results in the difficulty in making certain forecasts or announcing to the patients the risks of the therapies or the possible results. One of the topics frequently stressed by the professionals during the interviews was "how can we inform patients about things of which not even we are certain?"[189] On the other hand, the topic of the limits set by the information available to the medical personnel emerged in the situations in which, despite the increase in scientific discoveries, the possibility of having complete control over the patients' situation is still a distant ideal. The proliferation of the medical techniques and technologies aimed at preventing risks linked to pregnancy are typical of this situation.[190] Since the sixties, the techniques used in gynaecology to verify whether the foetus is healthy have become increasingly sophisticated. The colour photographs offered by 3D and 4D ultrasound scans make it possible to have increasingly detailed

188 Amongst the categories of patients considered incompatible with MRI are pregnant women, patients with a pacemaker, patients with heart valves, patients who have any sort of extraneous body implant (IUDs, metal prostheses for previous fractures, dental prostheses, neurostimulators, etc.)

189 Extract from an interview held on 13th February 2015.

190 B. Duden, *Der Frauenleib als öffentlicher Ort: vom Missbrauch des Begriffs Leben*, Hamburg-Zürich, Luchterhand, 1991; Italian translation *Il corpo della donna come luogo pubblico*, Torino, Bollati Boringhieri, 1993. Id., *Die Gene im Kopf, der Fötus im Bauch. Historisches zum Frauenkörper*, Hannover, Offizin Verlag, 2002; Italian translation *I geni in testa e il feto in pancia. Sguardo storico sul corpo delle donne*, Torino, Bollati Boringhieri, 2006.

and faithful images of the development of the foetus. As emphasised by a number of professionals, the constant improvements in the diagnostic tools still has certain limits, for example the fact that, according to the position of the foetus within the uterus, it is not always possible to see the aspects that the doctor would like to examine. One of the doctors interviewed at the diagnostic and ultrasound scan centre emphasised this aspect.

> With respect to when I started, nowadays we can do incredible things with ultrasound scans. For example, if we fear that there is a cardiac problem, we can analyse the form and the movements of the ventricles, the direction of the blood flow. The times when we could only monitor the heartbeat are over, now we can look inside the heart, we can explore parts of the body that are only a few centimetres in length. All this is possible providing the foetus is in the right position. Often we advise the mothers to take a walk along the hospital corridors, in the hope that the foetus will turn, otherwise we can't see anything. This question of the position of the foetus has been a problem since the seventies and it is still an obstacle today. The technologies that we use are more advanced, the clarity of the images has improved, but the ultrasound scan is still an imperfect tool: sometimes we can see that there are health problems, at other times we can see little or nothing.[191]

The transformation of the foetus into a new hospital patient[192] around whom an entire sector of modern medicine has developed – what is known as prenatal medicine – thus finds obstacles in the permanence of situations that remain "beyond the control" of the medical staff. In effect, the techniques with which health problems are avoided for the future child remain limited. Another example of what can be called the *impotent omnipotence* of modern medicine is to be found in the new screening tests and the prenatal diagnosis, generally used to identify any genetic alterations of the foetus. As emphasised by the gynaecologists at the ultrasound scan centre, despite the increasing number of studies on the human genome, the capacity to recognise and prevent the genetic illnesses that the foetus could be carrying are still limited. Without wishing to enter the debate on the so-called "false positives" and the ambivalence of the confines that separate the scientific discoveries aimed at fighting the genetically transmittable illnesses from the risk of eugenics linked to these studies,[193] what we intend to emphasise in this volume is that the possibility of knowing about chromosomic alterations of the foetus thanks to modern screening tests and prenatal diagnosis is still limited. According to various members of the medical staff, in view of the growing number of screening tests, the admission of their limits is often problematic. As in the case of the ultrasound

191 Extract from an interview held on 5th February 2015.

192 C. Pancino and J. D'Yvoire, *Formato nel segreto. Nascituri e feti tra immagini e immaginario dal XVI al XXI secolo*, Roma, Carocci, 2006.

193 J.-H. Yu *et al.*, *Attitudes of Genetics Professionals toward the Return of Incidental Results from Exome and Whole-Genome Sequencing*, in «The American Journal of Human Genetics», 95, 2014, pages 77-84; J. Viberg *et al.*, *Incidental Findings: The Time Is Not Yet Ripe for a Politicy for Biobanks*, in «European Journal of Human Genetics», 22, 2014, pages 437-441.

scan, the fact that it is not possible to completely exclude the presence of problems or anomalies clashes with the expectations of the patients, who are generally persuaded otherwise. The idea that the doctors can now know everything about a pregnancy, guaranteeing the birth of a "perfect" child, or informing the couples regarding the imperfect health of the foetus, does not leave room for grey areas in which no one knows whether the child will be in good health or not.[194] The difficulty in meeting the patients' needs, to which it is not always possible to give definitive answers often goes hand in hand with the lack of acceptance of the fact that there still exists a margin of *unpredictability* linked to this event.[195] The same is true for the moment of birth. The increasing number of checks on the progress of the labour is still accompanied by the impossibility of foreseeing and preventing an emergency due to sudden complications for the mother or the baby. As emphasised by the head of one of the obstetric wards on which the research was carried out, the attempt to control an experience for which every effort has been made to reduce the risks – the considerable reduction in the rates of maternal and infantile mortality is proof of this[196] – still contrasts with the unpredictability of the progress of the procreative process.

> Pregnancy and birth are experiences that always present a certain risk. With the development of modern medicine, the checks have increased and we have managed to eliminate most of the problems that in the past led to the death of the mother and the child. The association of birth with death is something we no longer consider, but that does not mean that this danger has completely disappeared. There are so many things that we can do to help the women, but there can also be situations in which the dangers arise suddenly and we can do very little. In these cases, nature is in command. In cases of placenta praevia, for example, it is impossible to know how long the women will continue the pregnancy, whether the baby will be born at the fifth or the seventh month. In these situations of uncertainty or danger, when informed that there could be risks for themselves or for the child; many patients believe that we are saying this to frighten them. The impression is that many of them do not take this information seriously; they think that we are exaggerating; they are convinced that we can control everything.[197]

The words of this gynaecologist show to what extent the question of risks linked to the birth and the pregnancy raises problems in the dialogue between the doctors and the patients. In the modern culture of birth, the references to dangers and complications often appear to be an

194 N. Press and C.H. Browner, *Why Women Say Yes to Prenatal Diagnosis?*, in «Social Science and Medicine», 45, 1997, pages 979-989.
195 R.C. Fox, *The Evolution of Medical Uncertainty*, in «The Milbank Memorial Fund Quarterly, Health and Society», 58, 1, 1980, pages 1-49.
196 On the reduction of rates of maternal-infantile mortality cf. M. D'Amelia, *Storia della maternità*, Roma-Bari, Laterza, 1997; Y. Knibiehler, *La naissance en Occident*, Paris, Albin Michel, 2004.
197 Extract from an interview held on 13th March 2015.

anachronistic discourse that the patients find it hard to believe. Within this framework, the perplexity shown by the patients when told that there could still be serious complications exacerbates the difficulties encountered by the professionals in giving information on the risks that could arise at any moment, but of which they are not certain.

1.3. *Information on the possible alternatives*

According to the medical deontological code, in order to facilitate freedom of choice, together with the explanations of risks, the professionals must give clear and exhaustive information on the possible alternatives to the treatments proposed to the patients. As for the matter of risks, the question that arises in this case is to what extent it is possible to inform the patients about possible alternatives to the treatments. One example of the complexity linked to this type of information is represented by experimental therapies.[198] As emerged from the results of the research, the possibility of choosing between standard treatment and experimental cures is often affected by the high costs of therapies still being experimented and by the lack of availability of medicines not officially on the market. The outcome of this situation is generally that these therapies are only offered to a limited sample of patients, chosen by the medical personnel, and not to all those who could benefit from them. The fact that these therapies cannot be offered to all the patients is often a dilemma for the doctors. They must choose whether to inform the patients of existence of therapies to which they will not have access at the hospital.

> One doubt that we frequently have when speaking to patients is whether to inform them that we are testing new therapies on the ward. Is it right to inform all the patients of something that we can offer to only a few? Is it better to speak to everybody or only to those that we can include in the study? These are complex questions that do not have a single answer. On the one hand, it seems right to let everyone know that there are new medicines undergoing experimentation, on the other hand, it does not seem fair to raise hopes when we know that we can't treat everyone with the new drugs.[199]

The considerations of this doctor echoed in a number of situations observed on the ward. The case of experimental medicines against the Hepatitis C virus is typical of this aspect. These drugs were introduced into Italy during the period of the research project, which allowed the author to follow the challenges presented by the limited access to the new "life-saving" medicines during the most critical phases. The capacity of these medicines to cure more than 90% of the cases in

198 O. Corrigan, *Empty Ethics: The Problem with Informed Consent*, in «Sociology of Health & Illness», 25, 7, 2003, pages 768-779; R.C. Fox and J.P. Swazey, *Observing Bioethics*, Oxford, Oxford University Press, 2008.
199 Extract from an interview held on 23rd November 2014.

which the patient is affected by the Hepatitis C virus – a disease that until the beginning of 2014 was considered incurable – is limited by the high costs imposed by the pharmaceutical companies who own the patents, above all in the early stages. With regard to this situation, the main criticism that the Associazione Italiana del Farmaco (AIFA) and associations of patients, such as EpaC, have made against the pharmaceutical companies is that by preventing universal access to a revolutionary and essential treatment, they are indirectly contributing to keeping the mortality rate for Hepatitis C high. In the months during which the research was conducted, the costs for the new drugs amounted to approximately €30,000.00 per patient, a sum paid by the national health service. In Torino, as in the rest of Italy, except for the patients who have tried to buy the antiviral drugs independently by going abroad where the costs are significantly lower than in Italy,[200] for many patients the only way to move from conventional treatment based on Interferon – which does not eliminate the illness – to treatment with the new drugs was to be "enrolled" amongst the patients chosen for experimentation in hospital services.

The doubts raised by the doctors concerning the content of the information to be given to the patients also emerged with regard to the inclusion amongst the alternatives of operations that are technically possible, but not particularly beneficial for the patient's health. One example is a surgical operation to be carried out on a geriatric patient. The consideration of costs and benefits for the health of the patient, and for the economy of the hospital, often results in doctors advising against these interventions. Therefore, the burning question is, whether is it right to inform patients that they could undergo a surgical operation when the risks of complications are equal to or greater than the benefits that the operation would offer? Together with the stress linked to the choice of going into the operating theatre, the doubts about how far these operations, which are extremely expensive for the hospital, can improve the situation of the patients appeared to be numerous. In the face of these perplexities, many doctors 'resolve the problem' by not informing the patients of the possibility of an operation.

In other situations, the margin of choice for the patients is limited to two equivalent options relating to the same pharmacological treatment, or the same medical action. Typical of this type of choice is the case of patients who must begin chemotherapy and who are asked which type of catheter they prefer for the injection of the drugs. The alternatives are generally the application of the PICC (peripherally inserted central catheter), that is a venous catheter inserted peripherally in the arm, which lasts six months at most, or the application of a Port-a-Cath, that is a silicone catheter that can be implanted under the skin on the subclavian vein, the jugular vein or the femoral

200 Amongst the neighbouring countries in which these drugs were immediately made available at lower prices are Switzerland, San Marino and the Vatican State. As emphasised by a number of journalistic articles, many patients have now decided to undertake journeys to distant countries, such as India, in order to gain access to equivalent medicines at a lower cost. On this subject cf: M. Gahlot and V. Krishnan, *La salute non ha prezzo*, in «Internazionale», 1151, 2016, pages 42-58.

vein and linked to one or more ports which will last over time. These are the only types of support offered to the patients, although others are available. At the same time, the patient's possible preference for the intravenous injection may meet objections from the medical personnel due to the greater risk of embolism.

In yet other cases, the alternatives for the patients are even more limited, if not absent. The lack of alternatives emerged, for example, in the paediatric sector where the only medicines available for treating the children and babies were the so-called *off-label* drugs, that is medicines not officially registered for use on children. As emerged from the testimony that follows, the difficulties encountered by the professionals in giving information to the parents about these medicines are often numerous.

> The majority of the drugs that we use in paediatrics are registered officially as medicines for adults. All the scientific studies show that, in the right doses, these drugs are suitable for children and babies and all the paediatricians have used them for years in Italy and abroad. The fact is, however, that this is not their official use, so we are forced to call their use on children 'experimental'. Obviously, as soon as we use the word 'experimental', the parents think that these drugs are new and that we are using them for the first time on their children. How can we explain that they are drugs described as 'under experimentation' but that in fact we have been using them for ages? How can we explain to them, in these difficult moments, that we are not using their children as guinea pigs? How can we explain to them, that in any case, there are no alternatives available on the market? To avoid any problems, we speak vaguely and say nothing about why we have to use off-label drugs.[201]

The words of this paediatrician show that the decision to limit the explanations regarding the drugs available for treating the children has a positive aim: to avoid frightening the parents with the description of therapies that could give the impression that they are unsafe for their children. This strategy is intended in particular to attain two objectives: on the one hand to reduce the problems regarding the decision to be made for parents who might not agree to treat their children with medicines that are not officially registered as paediatric drugs; on the other hand, to limit the causes of conflict with the medical personnel. Another problem emphasised by the paediatricians concerns the interviews with the parents who must give informed consent for the off-label medicines to be used, specifying each time the barcode on the packets of medicines to be used for the treatment of each individual patient. This procedure, required of the doctors by the pharmaceutical companies – who are interested in understanding the extent to which these drugs are used in the paediatric field – is difficult to apply in real life. In some contexts, such as the reanimation wards, treatment of the

201 Extract from an interview held on 18th March 2014.

patients requires the use of various medicines, progressively introduced by the personnel according to the needs of the baby or the children. The difficulty in contacting the parents each time it is necessary to change the therapy or proceed with the addition of a new drug finds a solution in the signing of a *single consent form* for the use of off-label drugs, without specifying the names of the medicines.

On the contrary to what we have described so far, it is possible to mention all those situations in which the suggestion of, or the request for alternative procedures to those proposed by the doctors comes from the patients or members of their family. The request for information on the practices suggested by the so-called *parallel medicines* – such as acupuncture as an antalgic remedy for cancer patients, the preference for homeopathic medicines, reflexology and other practices of oriental medicine – are an example.[202] As emerged from the observations on the wards, the presence of various positions and philosophies within the medical staff goes hand in hand with the tendency to let patients do whatever they wish outside the hospital environment, providing they do not abandon the therapies advised by the healthcare professionals. The admission of a course of *integrated medicine* is usually accompanied by the idea that, if used together with the treatments prescribed by the doctors, these remedies can have a placebo effect or a symbolic efficacy[203] on the patients contributing to their well-being. As the doctors said, "if they believe in it, it is better if we let them proceed, these are things that can help the patients to feel better."[204]

There were many situations in which freedom of choice or the proposals of alternatives made by the patients, and members of their families, translated into the request for treatments considered not necessary and at times counterproductive, by the medical staff. Some examples taken from the observations carried out at the clinics and on the wards are the request for a caesarean section when there are no medical reasons, that is from patients who are not presenting any problems and could give birth normally. The request to carry out a surgical operation by the members of the family who cannot accept illnesses linked to the aging of a loved one. The observations carried out alongside the professionals showed that when they feel that the dangers for the patient are greater than the benefits linked to the intervention – for example in the case of geriatric patients –the doctors generally refuse to proceed with the operations requested either by the patient, or by a family member. In other cases, on the contrary, as admitted during the conversations with the doctors, although they do not consider these operations strictly necessary – for example in the case of the caesarean – they tend to accept the patient's request in order to avoid

202 A. C. Begot, *Médecines parallèles et cancer. Une étude sociologique*, Paris, L'Harmattan, 2010.
203 C. Lévi-Strauss, *Anthropologie structurelle*, Paris, Presses Universitaires de France, 1958; Italian translation *Antropologia strutturale*, Milano, Il Saggiatore, 1965.
204 Extract from an interview held on 7th December 2014.

legal risk. It is, as many stressed, an interventionism that goes in the direction of *defensive medicine*.

2. *Whom to inform?*

The question of *the extent to which* it is possible to inform the patients of healthcare procedures, the risks and the possible alternatives is often accompanied by another problematic decision for the hospital staff: which players to involve in the informative process. In fact, although the only person responsible, together with the doctor, for choices regarding their health is the patient, in effect the management of the illness is often characterised as a *shared course* with family members. On the basis of the observations carried out at the clinics and on the wards, it was evident that the doctor-patient relationship was rarely a one-to-one relationship. On the one hand, the professionals involved in informing the patients are numerous and only partly correspond to the medical personnel (see chapter five). On the other hand, except for isolated patients, the representation of the patient as the only person responsible for evaluating whether to entrust their person and their body to the medical treatment clashes the participation of other members of the group during the decision-making process. In effect, as shown by the research project, the patient from whom informed consent should be gathered is often far from appearing the *autonomous individual* or an *individual subject*, separate or separable from the rest of the group.[205] This fact is confirmed by the theories of the sociologist Daniela Carricaburu[206] who emphasises that on the occasion of an illness the paradigm of western individualism or of the so-called society of individuals shows its limits.[207] In some cases, other subjects are called upon to choose *together with* the patient. In other situations, the choice is effectively made by other subjects *in lieu of* the patient. In yet other cases, the involvement of the family in the daily assistance of the patient influences the choices of the sick person. As we will see through the study of various categories of patient, the plurality of the players involved in the decision-making process goes hand in hand with the dilemma of *whom* to inform before carrying out the therapeutic actions.

2.1. *The case of patients incapable of discernment or disabled patients*

The first set of situations on which it is necessary to reflect concerns all those cases in which the consent to treatment cannot be given personally by the patients. The impossibility for the sick

205 C. Charles, A. Gafni and T. Whelan, *Decision-Making in Physician-Patient Encounter: Revisiting the Shared Treatment Decision-Making Model*, in «Social Science and Medicine», 49, 1999, pages 651-661.
206 D. Carricaburu and M. Ménoret, *Sociologie de la santé. Institutions, professions et maladies*, Paris, Armand Colin, 2004.
207 N. Elias, *La société des individus*, Paris, Fayard, 1987; Italian translation *La società degli individui*, Bologna, Il Mulino, 1990.

persons to give their consent, or to indicate dissent, with regard to treatment depends in these cases on the patient's state of health. Amongst the situations observed we find patients who cannot express their opinion due to a temporary clinical condition, but also subjects incapable of expressing their will due to pre-existent physical, cognitive or psychological deficiencies. In the first category are patients hospitalised urgently at the A&E department – for example following a road accident – who are in such pain that they cannot speak, those hospitalised in coma on the intensive care ward, or those on the reanimation ward, or still under anaesthetic after an operation. As shown in the first part of the chapter, in these cases the information on the treatment and the signing of the informed consent involves above all the members of the patient's family, called upon to express themselves on behalf of the patient with regard to choices that are often complex from a bioethical standpoint. The decisions linked to the end of life, or regarding donation of organs and tissues are examples of this. At the same time, as in the case of Luigi, it may be that the patient has given their consent to a surgical operation, but that during the operation the doctors realise that it would be best to extend the operation to other parts of the body. The communication of this possibility, generally encouraged by the doctors to avoid subjecting the patient to another operation, places the family in the difficult position of accepting – as the family did in this case – or refusing the suggestion of the doctors, without being able to ascertain the wishes of the patient. The patient will be informed of what occurred during the operation only when they wake from the anaesthetic.

Problems of this type also emerged in the case of the patients only partially capable of understanding the explanations of the doctors or incapable of expressing their will because they have more or less serious handicaps. Also in this case, the information on the treatments and the signing of the informed consent will see the involvement of the closest members of the family (spouses, parents or children) or guardians where present. As emerged from the research data, these generally coincide with the cases involving a member of the extended family (aunts and uncles, nieces and nephews, or distant cousins). In some cases, they may be subjects outside the family group, nominated by a judge or chosen by the patient to represent them. According to the conversations held on the wards, except for the patients with serious disabilities, such as patients affected by aphasia or almost total paralysis, the dilemmas of the medical personnel concerning the process of informing disabled patients or the patients not capable of discernment are numerous. In particular, the two questions raised by the doctors were 1) how to evaluate the patient's capacity for discernment, and 2) to what extent it is possible to try to involve them in therapeutic decisions. In both cases, recognising that the only possible solution is to proceed case by case was often accompanied by a criticism of the characteristics of informed consent. The lack of reference criteria for evaluating the capacity for discernment of the patients has been described as a limit in the

construction of *other forms of dialogue* with this category of patient. At the same time, the introduction of alternatives to the informed consent forms, such as the use of drawings, photographs or images that explain the message transmitted by the doctors, could facilitate the involvement of these patients, who should be informed, in the opinion of some doctors, without the reading of the forms.

2.2 *The case of psychiatric patients*

The difficulty posed by the patients' capacity for discernment also emerged in another case, that is where the patient is affected by what is known as an *invisible handicap* or *pathology*, such as the illnesses suffered by psychiatric patients. On the basis of the results of the research, the characteristics of the assistance offered to these patients can be described as an exception to the rule. Above all, the informative process for these patients is characterised in specific terms. Unlike the process described for other patients, the tendency to *standardise* the informative process, transmitting information in a way that is equal for all, does not seem possible in this case. As emphasised by the professionals who are responsible for treating psychiatric patients, the construction of a dialogue with subjects affected by this type of problem requires an adaptation of the informative process to the patient's profile. The *personalisation* of the dialogue between the doctors and the patients is linked, in particular, to two elements: 1) the level of understanding of medical information – to what extent the patients can understand the explanations given by their doctor? 2) the tendency to accept the ideas, often distant from reality, held by the patients. Considering that, although there are common pathological traits, mental illness presents in a different manner for each patient and it is necessary to respond to the differing *therapeutic needs*, but also to the differing *dialogical and communicative* needs of the patients. Hence, the choice to adapt the forms of communication with patients according to the codes of interpretation of reality that they prefer. The search for a form of shared dialogue with the patients is described by the professionals in the sector as an essential element for attaining good results on a therapeutic level, but also in terms of the relationship with the patients. The patients' acceptance of the treatment depends above all, in the opinion of the doctors, on the construction of a therapeutic alliance, or the investment in a prolonged dialogue with the patients. Then, as shown by the testimony that follows, they will entrust themselves to the medical care recognising the hospital staff as reference figures on whom they can rely when necessary.

> On the contrary, to what many think when speaking of psychiatry, many patients consider us allies. Many of them have been coming to our ward for years, because they know that they will always find support here. According to how they are feeling, they realise whether the illness is worsening, asking their family to bring them to us at the hospital. The relationship of trust that we manage to build up with our patients is often greater than on other wards. We know well that, apart from the drugs, what counts in psychiatry is the dialogue with the patients and we spend a lot of time talking to them. We are convinced that without this dialogue many of them would abandon the therapies or would refuse to be taken to the hospital when they are not well, they would not consent to the course of treatment we have proposed. Of course, in the situations where the illness is denied, we can always turn to mandatory medical treatment, but before we arrive at this stage, we prefer to try with dialogue.[208]

The words of this doctor underline the way the construction of a relationship of trust in the sector of psychiatric treatment depends on both the professionals' investment in the dialogue with the patients and the patients' recognition of the need for treatment. The consent to the therapies, generally obtained orally during the conversations with the patients, is linked to the patient's recognition of the alteration of their mental health. The negation of the fact that they are ill, on the contrary, prevents them from consenting to treatment.

As emerged from the research data, in addition to the patients who agree to the need to undergo medical treatment, there are many who feel that they do not need help from the healthcare professionals. In these cases, the only possible method for proceeding with medical treatment is to apply for a mandatory medical treatment order. This procedure is ordered on both the medical and the juridical levels and is used above all for patients considered potentially dangerous for themselves and for others. On this basis, they can be hospitalised for at least one week without the need for their consent.[209] The collaboration required in these cases from two institutions traditionally allied in the history of medicine and in the history of western society[210] - medical knowledge and law – highlights the relevance of the function of containment and recovery still entrusted to the hospital environment.[211] As stated by the doctors interviewed, despite the transformations linked to the evolution of the laws on the treatment of mental illnesses – such as the decision to close the psychiatric hospitals or the decision to abolish straight-jackets, electric shock treatment and the mechanical containment of patients[212] - the treatment of psychiatric patients remains a sector in which different rules apply with respect to other patients. Within the panorama

208 Extract from an interview held on 17th October 2014.
209 A. Siracusano, S. Ferracuti and M. Zanasi (ed.), *Il consenso informato in psichiatria*, in «Nóos, Aggiornamenti in psichiatria», 18, 1, 2002.
210 M. Foucault, *Naissance de la biopolitique*, Paris, Gallimard, 2004; Italian translation *Nascita della biopolitica. Corso al Collège de France (1978-1979)*, Milano, Feltrinelli, 2005.
211 E. Goffman, *Asylums: Essays on the Social Situation of Mental Patients and Other Inmates*, New York, Anchor Books, 1961; Italian translation *Asylums. Le istituzioni totali: i meccanismi dell'esclusione e della violenza*, Torino, Einaudi, 2003.
212 R. D'Alessandro, *Lo specchio rimosso. Individuo, società, follia da Goffman a Basaglia*, Milano, Franco Angeli, 2008.

of services analysed, it is in effect the only sector in which the patients do not always have the right to refuse the treatments proposed by the doctors, and the doctors tend to adopt treatments without a consent of the kind required of other patients.

2.3 *The case of minors*

The process of informing the patients appeared to be a particularly complex question in the case of minors. As emphasised by the doctors in this sector, in order to proceed with the treatments of the patients who are not yet of age, it is necessary to obtain the consent of the parents. Where the parents are not present, therapies can be authorised by the guardian nominated by a judge. On the basis of the observations on the wards, these rules often encounter obstacles in their application. One example is the parents' refusal of therapies. As mentioned by many of the paediatricians interviewed, in this case it is often difficult to take the necessary steps in time, above all in emergencies. Blood transfusions to be carried out on minors belonging to the community of the Jehovah's Witnesses[213] are a typical example of this problem. In the opinion of many paediatricians, in fact, the possibility of proceeding with the treatment citing a state of need to some extent frees the parents of the decision whether to infringe the rules of their religious community, but it also often forces the professionals to act before they receive approval from the Juvenile Court.

The difficulty of using the parents as intermediaries when gathering informed consent also emerged in other situations on the paediatric wards. The case of unaccompanied minors or in all those situations in which the health problems depend on the behaviour of the parents who should be responsible for their children's welfare are some examples. As shown by the words of this paediatrician, the number of players involved in these cases in helping the minors – such as the medical personnel, the social workers, the psychologists, the educators and the volunteers present on the wards – clashes with the tendency to recognise the parents as the figures responsible for the health of their children.

> Theoretically, the parents should give us information on the health of their children. However, children and adolescents are often accompanied by the grandparents or by other persons because the parents do not look after them. At other times, which is even worse, the children are unwell because the parents are violent or irresponsible. Frequently, we have become aware of cases of violence against children or other equally serious situations. In these cases, we must deal with the immediate

213 In accordance with the literature on treatment of the Jehovah's Witnesses, in the case of adult patients the choice of the medical personnel is usually to allow the patients who refuse a transfusion for religious reasons to die. In the case of minors, on the other hand, the tendency is to proceed with the transfusions despite the dissent of the patient's parents. On this topic see J. Barbot, *Soigner en situation de risque judiciaire. Refus de transfusion et responsabilité médicale*, in «Revue française de science politique», 58, 2008, pages 985-1014.

> treatment, but we must also work out how we can help these children when they leave the hospital. The fostering system or the guardianship is not always easy, often it takes a long time and the parents never agree, so the case frequently ends up in Court![214]

This testimony emphasises the *social medicine* aspect of the work that the paediatricians are called upon to carry out, starting with the evaluation of the parents' behaviour towards their children.

Another question that emerged on the paediatric wards concerned the possibility of informing the minors directly.[215] Although, in fact, those who are responsible for signing the consent forms are the parents or other legal guardians, informing the protagonists of the treatments is a topic on which the professionals appear to be divided. For some, under a certain age, generally identified around ten years of age, the decision to give medical information to the children leads to risks on a psychological plane. According to others, trying to make the children understand what they must face is a duty for the medical personnel. In both cases, the two questions considered particularly complex to deal with are 1) to what extent it is possible to tell the truth and 2) what language to use to keep the patients informed. In the majority of cases, the choice is that of proposing information "adapted" to the level of maturity of the patient. The attempt to adjust the language code to the needs of the paediatric patient has led to a series of initiatives within the hospital setting. Amongst these, we can mention the involvement of infant school teachers to inform the younger patients. As observed for example on the surgical wards, the information was given in the form of play, through the narration of stories about imaginary characters who went to hospital for the same operations that the children were to undergo. According to the teachers working on the wards, seeing pictures of the operating theatre helps the children to prepare for what they will experience in a few days' time. In the same way, the use of puppets and what is known as "the big book" which the children can read with the teacher, taking part in the construction of the story, will help them to understand the various stages of a surgical operation, from the moment they are admitted to when they are discharged. For the older patients, on the other hand, the informative support proposed by the teachers is an interactive DVD in which the doctors explain to the patients the general working of the hospital, the purpose of the various wards, the roles of the staff, the treatments offered on each ward. Thanks to a browser within the DVD, the children can search for information on their illness and about the treatment.

However, the adaptation of the informative supports to the age of the patients does not eliminate the complexity linked to the assistance of what are known in Italy as the *older minors*, that

214 Extract from an interview held on 15th March 2015.

215 M. Bonnet, *Parler à l'enfant de sa maladie: un long processus jusqu'à l'âge adulte*, in P. Ben Soussan and R. Gori (ed.), *Peut-on vraiment se passer du secret?*, Paris, Erès, 2013, pages 181-196.

is the adolescent patients aged between 13 and 17. The professionals described this age range as a *grey area of informed consent*. Unlike the younger patients, in fact, the evaluation of the level of maturity of the adolescents is considered by many to be a delicate topic on a clinical level, and in medical-legal terms. The lack of universal rules for deciding whether and how far to involve the patients in the informative process and in the decision-making process is translated into the use of various parameters according to the professionals involved. Some base their evaluations on the scholastic conduct of the patients; others prefer to consider all the life experiences of the patients prior to hospitalisation. According to the observations carried out on the wards, the variability of the criteria used by the professionals make the degree of involvement of the adolescents uncertain and their opinion will only be taken into consideration if it is considered possible to treat them "as adults". The absence of explicit rules appeared to be immaterial when the opinions of the patient and the parents coincided. On the other hand, when the patients held a different opinion to that of their parents it was necessary to decide to what extent to take into account the wishes of the patients. Amongst the situations observed during the research we can cite the case of Paolo, aged 15 and hospitalised on the haematology ward. He was against the chemotherapy proposed by the doctors and welcomed enthusiastically by his parents. In the case of Giulia, 16 years old and in the first month of pregnancy, the patient wanted to continue with the pregnancy, but her parents preferred the alternative of an abortion. The importance attributed to the opinion of adolescent patients often goes hand in hand with another delicate topic for the professionals, the decision of whether to speak to the patients in the presence of the parents. Also in this case, the lack of explicit indications in the law on privacy results in a diversity of behaviour amongst the doctors. As some of them emphasised, the risk that they run at times, nonetheless, is that of committing medical errors if the patients choose not to share certain information in the presence of their parents. As described in paragraph 1.2, the story of Marina, who was subjected to MRI without the staff knowing that she was pregnant, is typical of this question.

The conflicts regarding the therapeutic choices may involve the parents and the children, but they can also concern the two representatives of a couple. When this happens, the involvement of the parents varies according to the characteristics of the couple. If the conflict arises between a married couple, the doctors generally try to obtain the consent of both parents. As observed on the wards, in many situations of conflict, the doctor is called upon to play the role of 'referee' to ensure the well-being of the child. On the other hand, in the case of unmarried couples, divorced couples or blended families, the professionals tend to 'settle' as they say, for the consent of one of the two parents, generally preferring the opinion of the person who is most responsible for the minor's health, whatever the degree of blood relationship. Thus, for example, it was observed on the wards

that in some situations consent may be given by the so-called social parent – being the partner in the couple who looks after the child, without being either the father or the mother – and not the so-called biological parent, with whom the child has a direct relationship of kinship.[216] The doctors take into account all the characteristics of the family models when they choose who to contact for informed consent, showing that 'necessity is the mother of invention'. Hence, the relevance of the theory presented by the heads of the paediatric sector, according to which the world of the minors does not represent a small-size version of the world of the adult patients, but is a separate universe, with its own specific characteristics, its own problematics and its own rules regarding informed consent.

2.4. *The sharing of the choice: the consent of couples and the case of geriatric patients*

In the case in which the family are officially called on to take a decision *on behalf of* the patient, their participation in the therapeutic decisions appeared to be a phenomenon transverse to all the situations in the hospital setting. There were many circumstances in which, although the patient was capable of choosing autonomously, the decisions were in any case taken *together* with the family. The examples presented below emphasise the presence of two different tendencies within the services: in the first case, the participation of the other members of the family group was encouraged by the hospital itself; in the second case, it was the patients who asked for the family to be involved in the choices that concerned them personally.

The consent of couples, that is consent forms signed by both partners, for decisions regarding the reproductive process, such as abortion, represents the first tendency. In fact, although, as established by the Italian law on voluntary termination of pregnancy (Italian law N. 194/1975), the right to choose whether to continue with the pregnancy is an individual right of the woman, in the majority of the interviews observed by the researcher the women were accompanied by their partner. This presence appeared to be a constant above all when the abortion was justified for therapeutic reasons, such as the discovery of a physical malformation or a genetic alteration of the foetus. In more than 90% of the interviews observed, the description of the risks linked to the refusal to abort – and the explanations about Down Syndrome, or other handicaps for the child, occurred in the presence of both partners, also when they were not married.[217] In the light of these trends, one of the questions dealt with during the interviews with the medical staff was to what extent the presence of the partner during the interviews affects the women's freedom of choice.

216 S. Grilli and F. Zanotelli (ed.), *Scelte di famiglia. Tendenze della parentela nella società contemporanea*, Pisa, Ets, 2011.
217 D. Manaï, C. Burton-Jeangros and B. Elger, *Risques et informations dans le suivi de la grossesse: droit, éthique et pratiques sociales*, Bern-Bruxelles, Stämpfli/Bruylant, 2010.

According to some doctors, the lack of attention for the subjective dimension of the choices that concern above all the patients can be explained by the growing number of conscientious objectors amongst the medical staff, whose behaviour limits the women's freedom of self-determination. In other cases, the professionals emphasised that the increasing involvement of the partner in the reproductive process has now transformed what should be an *individual choice* into a *couple's choice*.[218] As emphasised by many of them, even in situations where they decide to speak first to the patient and then to the partner, in any case, they ask both members of the couple to sign the consent for voluntary termination of the pregnancy. Should they have contrasting opinions, the contradictions inherent in a process where, at least in theory, it is the opinion of the woman that counts are increased. In fact, as emerged during the observations carried out alongside the hospital staff, in some situations the women fear the opinion of their partner to the point where they dare not express a choice.[219] In other cases, the divergence of opinion may lead to the emergence of a conflict, so that the doctors decide to postpone the decision for a few days.[220] This possibility emerged above all in those cases where the women seemed not to wish to renounce their maternity, or when the doctors could not give certain information on the risks for the foetus.

Again, in the area of reproductive health, another course officially considered a choice to be made by the couple is that of medically assisted procreation.[221] Although it is a process based on treatments that involve above all the female body, the consent to the procedures requires the signature of both members of the couple. As observed at the clinics of the assisted procreation centre, the meetings that precede the phase of ovarian stimulation are characterised by moments in which the partner is also present. The same is true for the successive phase, when the woman is subjected to what is known as *transfer*, the operation that allows the embryo created in vitro to be implanted in the uterus. Once it has been ascertained that the embryo has 'taken' and that therefore a pregnancy is underway, the couple are both present at the subsequent meetings with the doctors. As emphasised by the juridical and anthropological literature, the reinvention of methods through which it is possible to facilitate a pregnancy has represented an important cultural revolution in our contemporary society.[222] The possibility of overcoming the limits of biology thanks to the new opportunities offered by technology – such as the use of biological material belonging to a number

218 L. Boltanski, *La condition foetale: une sociologie de l'avortement et de l'engendrement*, Paris, Gallimard, 2004. P. Charrier and G. Clavandier, *Sociologie de la naissance*, Paris, Armand Colin, 2013.

219 M. Dixon-Woods *et al.*, *Why Do Women Consent to Surgery, Even When They Do Not Want to? An Interactionist and Bourdieusian Analysis*, in «Social Science and Medicine», 62, 2006, pages 2742-2753.

220 This possibility depends on the stage of the pregnancy. Here the most problematic cases appeared to be those in which, despite the conflict between the partners, the decision cannot be postponed because the limits set by the law on abortion have been reached.

221 S. Novaes, *Procréation assistée et génétique médicale: questions techniques, dilemmes éthiques, enjeux sociaux*, in P. Livet (ed.), *L'éthique à la croisée des savoirs*, Paris, Librairie Philosophique J. Vrin, 1996, pages 1-85.

222 A. Gribaldo, *La natura scomposta. Riproduzione assistita, genere, parentela*, Roma, Luca Sossella Editore, 2005. M. Iacub, *L'Empire du ventre. Pour une autre histoire de la maternité*, Paris, Fayard, 2004; Italian translation *L'impero del ventre. Per un'altra storia della maternità*, Verona, Ombre Corte, 2005.

of players – goes hand in hand, nonetheless, with the need to continue to consider the reproductive experience a process based on the desire of two people to have a child. On the basis of this logic, although the techniques of medically assisted procreation *multiply* the players involved in the reproductive process – according to the laws in force in various countries, in fact, there can be *biological parents*, or those who offer the raw material and *social parents*, that is those who care for the child without having contributed, or having contributed only in part to the biological production of the foetus – the tendency is to continue to think of this experience within the framework of the couple. As highlighted by the theories of Marilyn Strathern,[223] recourse to these techniques can be considered by the professionals and by the parents of the children a process in which the "normal characteristics" of the procreative process were reproduced in another form. This theory, applicable in the opinion of the author to all the contexts of the western world, appears particularly pertinent in the Italian case, where until April 2014 the only possibility offered to couples was "homologous artificial insemination", that is a technique based on the union in the laboratory of the eggs and the sperm of the two partners who wished to have a child. As emphasised by the research data, the idea that, despite the recourse to technology, the procreative process is an event shared by the couple finds confirmation in the present characteristics of informed consent to the assisted procreation. One of the questions that it will be interesting to consider in the future is the process of adaptation of informed consent to the techniques of assisted procreation with donors outside the couple, such as heterological insemination, which was recently approved in Italy with Law N. 40/2004.

With regard to the patients' tendency to involve members of their family in decisions that concern them personally, we can mention the case of elderly patients, who are always present in the hospitals. The particularity of this category of patient consists in the common decision to delegate the informative process and the decision-making to other representatives of the family, generally sons or daughters. On the basis of the observations carried out on the wards, this tendency to delegate every decision to their children is often justified by the *relationship of dependency* that binds the geriatric patients to the people who look after them daily and with whom, in many cases, the patients live. The words of Antonio, aged 81, show how the decision to leave all choices to his son is inseparable from the need to receive assistance from him. Taking decisions without knowing the opinion of one's family means imposing a choice that cannot be carried forward on one's own.

> For the most important things I cannot decide on my own. For example, if I decided to have an operation and at that time my son was not able to look after me, if he couldn't buy me my medicines or take me to the hospital for the appointments, what would I do? Every time I speak to the doctors, and they tell me there is a decision to make, I say, "speak to my son, he looks after me." When you reach a certain age, you can't just do what you want. I have been living at my son's house for years

223 M. Strathern, *After Nature: English Kinship in the Late Twentieth Century*, Cambridge, Cambridge University Press, 1992.

and so I have to consider the needs of his family. If I agree to have an operation, the consequences will fall on my son and his family. It's better if he decides directly with the doctors what to do.[224]

The description of the therapeutic choices as *family decisions* and not *individual choices*, emerged not only in the case of Antonio. Many of the elderly patients encountered on the wards had chosen to entrust the decisions regarding their health to the opinions of the family, transforming the request to speak to their children into a *constant* of their hospital care.

The tendency to allow their children to decide is, on the other hand, accompanied by another phenomenon in the case of elderly patients: the family often ask the doctors to inform them of the condition and the therapeutic needs of the patient before they transmit this information to the patient themselves. As emphasised by a number of the doctors interviewed, this request is motivated above all by the desire of the family to protect their loved ones from information that could upset them, worsening the conditions of physical and emotional fragility of the patients. Although, as we said, the first (and only) persons that the doctors should inform about their health are the patients, the families' request not to transmit the more serious news to the elderly patients – or to inform them only after having spoken to other members of the family – once again faces the professionals with the difficult choice of *whom to inform*.[225] Thus, even today, there are situations in which the family of the patients are the only persons to be informed by the doctors about the stage the illness has reached and the possible solutions for the patient, to whom only half-truths are told. As observed on the wards, the construction of a therapeutic alliance or a complicit relationship between the medical staff and the family of the patients can lead to various results. In some cases, the patients can spend the entire period of hospitalisation without being informed that they have certain pathologies (for example a tumour), or they can be discharged without knowing that there was the possibility of undergoing an operation that the family considered too invasive. In other cases, on the contrary, on the request of the family, who are interested in prolonging the life of their loved one, the patients may not be told that it is possible to refuse the treatment proposed by the doctors. The request to carry out surgical operations on elderly patients is an example of this situation.

The involvement of the family is witnessed, in a different way, by the complaints against the medical staff placed with the Public Relations Office. As shown by the anonymous study of the complaints received in 2013, more than 50% of the complaints presented by relatives were from families of elderly patients. In accordance with what has been said so far, the claims made concerned above all the death of the patients following the refusal of therapies that the professionals

224 Extract from an interview held on 25th November 2014.

225 I. Testoni *et al.*, *La famiglia nella comunicazione tra medico e paziente. L'approccio delle medical humanities e la gestione della cattiva notizia*, in «Metis», 16, 2009, pages 118-134.

judged unsuitable on a clinical level, or cases of therapeutic persecution of elderly subjects, often aged eighty or more.

2.5. *The meeting with family and cultural otherness: the case of foreign patients*

Together with the problems of communication linked to the presence of linguistic barriers (see chapter three), another of the difficulties encountered in the assistance of foreign patients concerns the doctors' lack of knowledge of distinctive family models of the context of origin of foreign patients. As emerged on many of the wards examined, the need of the professionals to ensure that the information has been understood and that the patient agrees to the treatment proposed goes hand in hand with dealing with the different family schemes, matrimonial models and intergenerational relationships from those typical of our western society.[226] The lack of recognition of polygamous marriage in Italy, or the role of mediation played by subjects who do not fall within our definition of "close" kinship – such as third or fourth degree cousins or aunts and uncles – are some examples of the different organisation of the relationship of kinship in the decision-making process linked to the illness. This leads to the difficulties sometimes encountered by the medical personnel in identifying the family members with whom they should speak about the foreign patient's health.

In accordance with anthropological literature, the cultural distance that separates the doctors from the foreign patients, often finds expression also in the different representation of the illness and the *risks* linked to the treatments proposed by the hospital.[227] On this matter, the interpretation of the systematic refusal of amniocentesis by Senegalese patients – which is described by the doctors as proof that foreigners do not understand this test – is typical of the gap between our vision of the risks linked to pregnancy and the view shared by the Senegalese mothers. As emerged also in other hospitals in Italy, what the western midwife considers a practice designed to reduce the risks for the foetus, on the contrary, to them appears a way of exposing the child to a number of dangers, above all the possibility of attracting the *dëmm*, or anthropophagous witch doctors, who feed on the waters of the mother's belly, or the amniotic liquid examined during the amniocentesis.[228] Thus,

226 C. Lévi-Strauss, *Les Structures élémentaires de la parenté*, Paris, Presses Universitaires de France, 1949; Italian translation *Le strutture elementari della parentela*, Milano, Feltrinelli, 1969.

227 M. Berg and A. Mol, *Differences in Medicine. Unravelling Practices, Techniques and Bodies*, Durham-London, Duke University Press, 1998. B.J. Good and M.J. Del Vecchio Good, *The Meaning of Symptoms: A Cultural Hermeneutic Model for Clinical Practice*, in L. Eisenberg and A. Kleinman (ed.), *The Relevance of Social Science for Medicine*, Dordrecht, Reidel Publishing Company, 1981, pages 165-196. B. Good, *The Heart of What's the Matter: The Semantics of Illness in Iran*, in «Culture, Medicine and Psychiatry», 1, 1977, pages 25-58. C.R. Teal and R.L. Street, *Critical Elements of Culturally Competent Communication in the Medical Encounter: A Review and Model*, in «Social Science & Medicine», 68, 2009, pages 533-543.

228 C. Quagliariello, *Dal Senegal migrare in Valdelsa. Modelli della nascita a confronto*, in A. Colombo (ed.), *Stranieri in Italia. Figli, lavoro, vita quotidiana*, Bologna, Il Mulino, 2014, pages 117-149.

together with the linguistic barriers, the cultural misunderstandings in the informative process and in the dialogue between the medical personnel and the foreign patients were equally numerous.

Chapter Five

Hierarchies and inequalities in the new healthcare democracy

Unlike the situation described in the first part of the book (see chapters three and four), in this chapter we will consider the characteristics of the information necessary for gathering consent in the light of *dependent* factors, those linked to the profile of the various healthcare workers and the divers categories of patient. Therefore, the analysis proposed here refers to the interpersonal dimension on which the interactions between the healthcare workers depends and the dialogue between the professionals, the patients and the members of their families. As we will see, the investment of the professionals in listening to and informing the patients is closely linked 1) to the hierarchy of the representatives of the hospital staff and 2) the inequalities within the universe of the patients. In the latter part of the chapter, we will examine what the patients think about the behaviour of the doctors and their opinion on informed consent.

1. *The dynamics of hospital personnel*

The way the informed consent is generally gathered can be traced back to a series of dynamics within the hospital team. The investment of the professionals in informing the patients is a phenomenon that does not, in effect, involve all the healthcare workers in the same way. As emerged from the observations on the wards, the time taken for the interviews and the gathering of the consent varies above all according to the position held within the hospital hierarchy. In particular, the more important the position occupied by the doctors, the less time they usually dedicate to informing the patients. Hence, the tendency that emerged on the wards was that of *delegating downwards* the activity of informing the patients. However, this trend did not always find an explanation in the greater amount of time available for the operators who occupy lower positions in the hierarchy. As emphasised in the previous chapters (see chapter three) the lack of time for dialogue with the patients is a structural problem that involves all the hospital staff. The

tendency to assign informing the patient to those who occupy a lower position in the hierarchy seems to be linked above all to the different valorisation of the hospital roles. As stated by many of the doctors interviewed, the time available to the surgeons is considered more precious than that of the anaesthetists, who are in turn considered more important than the internists, and so on. The result of this *vertical hierarchization of time* is the frequent transfer of the informative activity from the surgeons to the anaesthetists, from the anaesthetists to the internists and a common delegation to the nurses, as figures historically dedicated to acting as intermediaries between the doctors and the universe of the patients. On the basis of the observations carried out on the wards, this tendency, representative of the professional asymmetries within the hospital environment, often leads to two situations that are to some extent paradoxical. On the one hand, those who dedicate themselves to the informative process are not always the persons who will carry out the treatments proposed to the patients. On the other hand, although the nurses often contribute in a determinant manner to informing the patients, the signing of the consent forms excludes these figures, assigning it to the doctors responsible for the treatments (see chapter seven). Therefore, the person who informs the patient is often the nurse who will not carry out the treatment or sign the consent forms. In both cases, what prevails is a contrast between the *action* and the *therapeutic relationship*, as complementary areas respectively assigned to various professional figures.

According to the research data, the juxtaposition of the operative dimension and the relational dimension of hospital care transverses the medical staff in a vertical sense, but also in a horizontal manner. While it is true that, of all the various hospital figures, the nurses generally spend more time speaking to the patients, it is not possible to say that all the nurses and all the doctors share the same attitude. The need to avoid a rigid contraposition of *care vs cure* is underlined in all those cases in which the *care* relationship is created by the nurses and the clinical assistance (*cure*) usually guaranteed by the doctors are reversed. In a number of the situations observed, in fact, the nurses simply carried out the treatments on the patient's body without committing to a relational effort, and the opposite was true for the doctors. A number of nurses, on the other hand, emphasised that their work has now become more similar to that of the doctors, describing the relational activity with the patients "another task" to be carried out on the wards. Typical of this question are the two testimonies that follow, the first from a nurse, the second from a doctor, who are both on the staff of the same internal medicine ward.

> There are a lot of patients to care for every day. We administer drugs, change drips, take blood and urine samples, check blood pressure, there is little time left for chatting. The fact that the doctors

delegate the dialogue with the patients to us forces us to *do two jobs* and that is not always possible.[229]

Many of my colleagues do not stop to chat to the patients; they leave it to the nurses to inform them about the therapy. The investment in information is seen as a waste of time, or something that we have to do just to avoid legal risks. Personally, it seems right to me to build a dialogue with the patients. For me medicine is a human science, therefore I always try to relate to the patients first as people, and then as persons who are sick.[230]

As shown by these testimonies, the investment of the professionals in information and the dialogue with patients is linked only partly to the position occupied in the hospital hierarchy. Much depends also on the *professional philosophy* shared and defended by the individual healthcare worker.[231] Thus, an anaesthetist may spend more time than a nurse listening to and informing the patients or it may be the surgeon himself who spends more time than others speaking to the patients about the operation to be carried out in a few days' time. The variable availability shown by the professionals in informing the patients appeared, in other words, to be strictly linked to the heterogeneous nature of the *individual profiles* of the representatives of the hospital body.

On this matter, another interesting fact to underline is the frequent correspondence between the choice to undertake training courses outside the hospital and the greater willingness of the professionals to become involved in the dialogue with the patients. On the majority of the wards observed those who made the effort to find time for in-depth information had usually undertaken professional training other than the 'classic' hospital career. Some of these professionals had chosen to accompany their medical training with a course in philosophy. Others had taken training courses or a master in bioethics. Yet others belonged to associations or non-governmental organisations involved in development projects or humanitarian missions in third world countries, some of which were in African countries where they (doctors, nurses and midwives) had worked and lived for long periods. As emerged from the research, these experiences played a role in the attitude of the professionals with regard to informing the patients. In fact, many of them chose to commit to communicating with the patients, for example, remaining at the hospital after their shifts in order to extend the duration of their interviews with the patients. They described their behaviour as a *political choice* or a *personal decision* that sets them against their colleagues who prefer to spend their time with patients in their private surgeries.

229 Extract from an interview held on 13th June 2014.
230 Extract from an interview held on 26th May 2014.
231 B. Hoerni and M. Bénézech, *La relation humaine en médecine*, Paris, Glyphe, 2010.

Each of us experiences our profession in a different manner. There are those who use medicine to make a lot of money, they have private surgeries and can't wait to get out of the hospital and go to their private patients. Others prefer to make a career in the scientific companies, to have a prestigious position at national level, going to congresses, etc. Yet others, like me, have made a different choice, which is to commit absolutely to public medicine, and hospital work, where the patients count most of all and where it is worth working late to speak to them about their illness and their fears. When you go to other countries, you realise that we have more economic resources than the poorer nations, but there is still a lot to be done on the human level.[232]

The words of this doctor emphasise the importance of the professional choices, and to some extent political choices, of the healthcare workers in the construction of medicine centred (or not) on the various needs of the patients. Thus, the information given to the patients appeared in many cases to be a battleground for the professionals committed to public medicine, whether *humanitarian* or *humanist*, centred on the needs of the person as a whole[233] and those who see the informative activity as secondary to the operative dimension of hospital care and their free-lance work outside the hospital. As emerged from the research, the commitment to dialogical medicine (based on listening to and informing the patients) often goes hand in hand with the interest the professionals show in dealing with ethical questions and welcoming alternative therapies, such as parallel medicines, proposed by the patients (see chapter four).

Together with the professional choices of the healthcare workers, another element that appeared equally important in the investment in informing the patients was the generational question, or the age of the hospital staff. Judging by the observations on the wards, the new generations frequently seemed tied to notional medicine (based on the manuals) in which the relation with the patients is rarely taken into consideration. As emphasised by the doctors who belong to the 'older generations' the capacity for listening to the patients and communicating with them are qualities acquired over time. This led to the frequent choice of the older professionals to assign to the new generations technical activities, dealing personally with informing the patients and gathering informed consent. This division of the tasks according to the age of the professionals was also linked to the lack of trust shown by the patients and members of their families in the new generations of doctors, to whom they preferred not to entrust procedures that could – in their opinion – lead to risks at a legal level.

2. *The need to protect oneself on an emotional level*

232 Extract from an interview held on 7t^{h} October 2014.

233 A. Favretto and F. Zaltron, *«Qui sono come a casa mia». L'umanizzazione delle cure e l'esperienza della malattia nei contesti sanitari*, Bologna, Il Mulino, 2015.

The greater or lesser investment of the professionals in informing the patients appeared, on the other hand, to be linked to the emotional dimension underlying the dialogue on questions relating to life, death and illness. As partly anticipated in the analysis of the content of the information to be transmitted to the patients (see chapter four), one of the needs expressed by the hospital staff was that of maintaining an emotional detachment with regard to the information to be given to the patients and their families. In the majority of cases, this need translates into the decision to reduce as far as possible the exchanges concerning the information that is particularly difficult to manage on the human and interpersonal plane, such as the difficulties encountered in verbalising the passage from active treatment to palliative care in the case of cancer, or the request to harvest organs and tissues following the death of a patient (see chapter four). Other examples of communication that is difficult for the medical personnel are the news that a foetus has died during the early months of pregnancy or the appearance of foetal malformation when the pregnancy is advanced. While on the one hand, as some of the doctors interviewed confirmed, the greater the emotional impact of the information, the more it is diluted over time to avoid traumatising the patients and their families. On the other hand, the more time they spend discussing the situation with the patients and their families and the more the staff risk becoming emotionally involved in the situation. As the staff on the intensive care ward stated, dedicating less time to the dialogue with the relatives helps to objectivise the situation and to keep a certain distance from the bad news. This *need to distance oneself* is often expressed as a communicative protocol formed of standard phrases, applied automatically to all the patients and families with whom the professionals speak, without introspectively considering the information they are transmitting.

Another remedy is the support offered by the figure of the psychologist, who is present during the interviews where it is necessary to give information that is particularly difficult on the emotional plane. In all the interviews observed, the psychologist was immediately introduced to the patients and their relatives as a figure on whom they could count, before, during and after the hospitalisation, or the death of the patient. The tendency to transmit certain information in the presence of other professionals appeared to be and can be described as a good practice. In fact, as certain professionals admitted, many representatives of the medical staff have ‘blocks’ when they have to speak to patients of certain topics. On the contrary, thanks to their training, the psychologists are more capable of finding the right words, and are better prepared for accepting and containing the pain, or the other emotional reactions, of the patients and their families. Starting from these considerations, in many of the sectors analysed, such as the transplant procedures, surgical procedures, cancer treatments or abortions, the psychologists were seen as the *figures that*

complement the dialogue between the doctors and the patients, supporting the former in communicating bad news and the latter in accepting it. However, what happens in some cases is that the recognition of the psychologists' greater communicative skills transforms the sharing of the information process into the delegation by the doctors to the psychologists of the informative process. Therefore, some professionals, using the excuse that the psychologists know better what to say to the patients, allow them to take on the role of informers: some news that should be given by the doctors is in fact given by the psychologists.

Apart from the psychologists' better communication skills, the delegation of the information process is linked above all to two motives. On the one hand, the lack of time for many doctors (see chapter three). On the other, the influence of the individual stories and professional experiences of the individual members of staff. The proximity of the professionals to the experience of illness that the patients are living through can make it more difficult to manage the emotional charge of the information process. As observed on the wards, the weight of the news to be given to the patients is not linked only to their content, but also depends on the current or previous stories of the individual professionals. This leads to the greater or lesser need to protect themselves by delegating to others the communication with the patients, or using *impersonal* language in a situation that is, in fact, very *interpersonal*, since it involves not only the healthcare professional, but also the person or human subject. These considerations are confirmed by the theories of the sociologist Dominique Memmi,[234] who emphasises that, although the psychological and emotional challenges are part of the doctors' work, this aspect of healthcare has been extended because the illnesses suffered by the patients can also affect the doctors, and the numbers facing suffering and death without the assistance of their family have increased. This set of factors explains, in her opinion, the greater need of the professionals to protect themselves from the daily transmission of bad news, as observed on some of the wards on which the research was carried out.

3. *The need to protect oneself on the medical-legal plane*

Finally, giving little information to the patient and their family may, represent the way in which the professionals try to protect themselves on a legal plane. The decision of some professionals to employ a model of *defensive medicine* has an impact on the investment in the communication and the time dedicated to information. As admitted by many doctors, the less time dedicated to information, the less the number of questions to which it is not possible to give a comprehensive answer. The new prenatal screening tests are one example. As stated in the previous

234 D. Memmi, *La Revanche de la chair. Essai sur les nouveaux supports de l'identité*, Paris, Éditions du Seuil, 2014.

chapters (see chapter four), the capacity of these tests to exclude with (almost) absolute certainty the presence of the most common prenatal genetic anomalies does not eliminate the danger of what are known as 'false positives'. This leads to the ongoing possibility of incurring medical-legal risks, despite the use of most up to date tests. In the face of this possibility, some doctors prefer not to offer these tests to the patients, basing their evaluations on amniocentesis, which gives results considered more reliable. More generally, it was possible to identify a correspondence, on the practical plane, between the degree of certainty of the results with the treatments proposed by the doctors and the depth of the information offered to patients. The more the doctors are convinced of the results guaranteed by the actions they propose, the more time they generally take to inform the patients of this procedure, without, in many cases, lingering on the alternatives. The combination of these tendencies therefore shows how the time spent informing the patients depends only partly on working of the hospital machine (see chapter three) or on the investment in the information process and the quantity of time dedicated by the medical personnel. The hospital hierarchies, the professional philosophies, the legal protection and the personal needs shared by the various healthcare workers play an equally important role.

4. *Inequalities within the universe of the patients*

The way in which the patients are informed also appeared to be linked to their individual characteristics. Starting from the observations at the clinics and on the wards, we will attempt to show how the *quantity* and the *quality* of the information transmitted by the medical staff is often linked to the biographical, social and cultural characteristics of the patients. As we will see, the selection of the patients with whom it is considered to be worth involving an in-depth evaluation regarding the therapeutic procedures, the risks and the possible alternatives is typical of the numerous asymmetries that represent the world of the patients. Time to inform the patients does not seem to be lacking for *all* patients. At the same time, although the doctors say that they choose *how far* to inform the patients on the basis of their capacity to accept the content of this information on a psychological level, the social identity of the patient plays an equally important role. As shown by the theories of Pierre Aïach[235] and Didier Fassin[236] for the French situation, together with the content of the information it is necessary to consider the influence of social factors in the process of informing the patients. The study of the many factors that lead to a *lack of equity* in the informative process, such as the degree of education, social class, the network of personal acquaintances or the foreign origin of the patients, will allow us to underline the extent to which the differing

235 P. Aïach, *Les inégalités sociales de santé*, Paris, Economica, 2010.
236 D. Fassin, *Inégalités et santé*, Paris, La documentation française, 2009.

construction of the dialogue between the doctors and the patients is closely linked to the phenomenon of social inequalities within the hospital setting.[237] Hence, the need to ponder the forms assumed nowadays by what is known as *healthcare democracy*.[238]

4.1. *The networks of acquaintance and the social capital of the patients*

The first factor that we can mention with regard to the way in which the process of informing the patients is characterised is the so-called *social capital* of the patients. As it was possible to observe in all the sectors of the hospital in which the research was carried out, the network of personal acquaintances, the fact that the patient worked in the health sector, or had family links with a member of the medical personnel were all elements that facilitated the *quantity of time* and the *quality of the time* spent informing the patients. The limits set for the professionals by the hospital schedule described in the previous chapter (see chapter three), in fact, sees some exceptions. In the majority of cases the colleagues, friends, acquaintances and relatives of the medical personnel represent the categories of patient chosen to receive all the time needed for the dialogue, often finding *extra time* for them with respect to that dedicated to other patients. For example, a number of doctors chose to meet these patients outside their working hours, during the lunch break or in the evening when the activities on the ward are less onerous. Together with the attempt to organise *ad personam* meetings in which to talk to the patient without being interrupted by colleagues or other patients, the level of investment in the in-depth information was particularly important when it was a question of assisting a colleague or patients considered prestigious. Here it is possible to cite the case of a doctor taken to the A&E following a collapse, who was received by the entire hospital team, ready to give detailed information on all the tests to be carried out during hospitalisation. Every question the patient asked (seen by some operators almost in terms of an examination) was met by an increasing degree of explanation. Although, as the doctors said, each patient is "a case apart" and the communication process requires, and implies, different information, in clinical situations with similar characteristics, the socio-professional characteristics of the patient can influence the behaviour of the professionals. In this case, for example, the duration of the informative interviews with the patient were twice as long as those observed for other patients who had been diagnosed with the same type of problem.

4.2. *The opposition between the patients of the hospital and the doctors' own patients*

237 A. Coulter, V. Enstwistle and D. Gilbert, *Sharing Decision with Patients: Is the Information Good Enough?*, in «British Medical Journal», 1999, pages 318-322.
238 A.M. Brocas and G. Le Coz, *La démocratie sanitaire*, in «Revue française des affaires sociales», 2, 2000, pages 9-14.

The degree to which the professionals invest in informing the patients appeared to be linked to the *economic capital* of the hospital users. On the basis of the Italian hospital protocols, on many of the wards examined there are two types of patient, who lie side by side: *NHS patients* who meet the medical personnel for the first time when they are hospitalised and the *doctors' patients*, who already know at least one member of the hospital team because they are cared for privately by this particular specialist. In the majority of the situations observed, the information given to the second category was greater than that supplied to the former category of patients. When interrogated about this choice, a number of doctors emphasised that it was easier for them to speak to patients who had been attending their surgeries for years and who already know the clinical situation. Typical of this tendency is the testimony of this gynaecologist concerning women with a high-risk pregnancy.

> Many patients choose this ward for the birth because they know I am here. It's normal. They already know me, they trust me, and they don't want to meet another doctor at the time of the birth, particularly when a caesarean is necessary. For my part, I try to be with them as much as possible, to make them feel comfortable and give them a positive memory of their hospital stay.[239]

The words of this gynaecologist reflect the theory shared by other professionals on the ward: the more time spent talking to the NHS patients, the more time they detract from their private patients, who expect to be treated with greater care by their specialist.

Often, the previous acquaintance with the patients is accompanied by other factors, which are not always mentioned by the hospital personnel, such as the economic interest underlying the doctor-patient relationship. As emerged from the research data, the patients treated privately represent, to some extent, clients to whom it is wise to dedicate all the time necessary, in order to be able to continue treating them also after they are discharged. This question is valid also for the patients who decide to be treated by professionals who, within the hospital setting, carry out what is known as *intramoenia* (semi-private) activity. Remaining in the field of gynaecology, although the assistance during the birth is generally free of charge for the women on the ward who are registered with the national health service, the costs of treatment within the hospital areas – what are known as *clinics* – in which the *intramoenia* activity is permitted, amounts to some hundreds of euro for the staff. As for the private patients, the tendency observed in these cases is to dedicate much more time to dialogue and to informing the hospital patient-client who, considering the high costs of treatment, expects to be welcomed by the medical staff. What emerged therefore in all these cases was the

239 Extract from an interview held on 12th February 2015.

commercial value of the time dedicated to informing the patients, as a possible source of income for the medical personnel and the hospital itself.

4.3. *The cultural capital of the patients*

Another determinant element is the *cultural capital* of the patients. In many of the situations observed, the more the patient appeared to be highly educated the better the explanations given by the medical personnel concerning the treatment, the risks and the possible alternatives. On the contrary, the less the patient appeared to be educated the less the doctors invested in informing the patient. One of the doctors on the anaesthetic service emphasised this tendency to adapt the degree of the interview to the patient's educational level, a major factor being the capacity to understand the information transmitted by the medical personnel.

> The way the patients act and speak allows us to understand immediately whether we are dealing with someone who has studied, or not. It is above all on the basis of this evaluation that I decide how far to go when describing the anaesthetic. If I realise that the patient has a level of instruction that allows them to understand little of what I am saying, I cut it short and move on to the next patient.[240]

As emerged on the wards, the result of these tendencies is often a reinforcement of the social fragilities.[241] This phenomenon was emphasised in a critical manner by the words of another doctor interviewed, this time on the haematology ward.

> The less well-educated patients are those who need more time, because they are the ones who have less understanding of the hospital system. Often, on the contrary, the patients to whom we give fewer explanations and with whom we spend less time explaining are precisely these ones. This is because for us it is a pleasure to talk to people who can follow our explanations, while it takes more patience to speak to someone who has difficulty in speaking Italian correctly. Unfortunately, not all the doctors want to spend time making these people understand why a certain treatment is being proposed and in the end, they ask them to sign the consent forms without saying much.[242]

The fact that those who need more information are usually the ones who receive less is linked, nonetheless, to another factor. As observed on the wards, the patients with a lower level of

240 Extract from an interview held on 7th December 2014.
241 P. Sankar, *Communication and Miscommunication in Informed Consent to Research*, in «Medical Anthropology Quarterly», 18, 2004, pages 429-446. C. Charles, A. Gafni and T. Whelan, *Decision-Making in Physician-Patient Encounter: Revisiting the Shared Treatment Decision-Making Model*, in «Social Science & Medicine», 49, 1999, pages 651-661. A. Kleinman, V. Das and M. Lock, *Social Suffering*, Oxford, Oxford University Press, 1997.
242 Extract from an interview held on 2nd February 2015.

education generally correspond to a category of patients who give few problems, since they accept what the doctors say without arguing at all. In the majority of the interviews we observed, it was above all the more educated patients who expressed doubts or criticised the treatments suggested by the doctors. Thus, paradoxically, together with a greater opportunity to establish a dialogue with the patients who show better competence in understanding the medical language, the greater tendency of more educated patients to refuse the therapies proposed contributes to the decision to offer them all the necessary explanations. The same is true for possible medical-legal problems linked to nursing care. In the majority of cases, in fact, the more educated patients were described by the doctors as having greater knowledge of their rights. These considerations are confirmed by the anonymous study of the medical records and the complaints against the doctors presented by patients to the Public Relations Office. In effect, more than 50% of the (few) complaints relating to the lack of information given came from persons belonging to a higher social class and with either a degree or diploma.

Together with the level of education, the evaluation of the intellectual capacity of the patients also depends on other factors. The age of the patients is one of these. For example, a number of doctors tend to give little information to older patients who appear confused or affected by more or less serious senile dementia. The decision to speak above all to the family is justified in these cases by the link between the patient's *capacity to understand* and the *capacity to decide*, that is the evaluation of the usefulness of the information given by the doctors in consideration of the self-determination of the patient's choices.

4.4. *The influence of social behaviour on the patients*

In some cases, the characteristics of the process of information refer to the doctors' evaluation of the reasons that have led the patients to contract certain illnesses or a given clinical situation. Considering the patients either *victims* or *perpetrators* of their state of health often appeared to be linked to a *moral classification* of the patients according to the system of values shared by the hospital team or held by the individual healthcare worker. As emerged from the research data, the result of this process is that patients with the same need for treatment are not informed in the same manner. At times, what changed was the amount of information offered to the patients, at other times, the choice was to give the information available only to certain categories of patient. A first example is pregnancy in under-age patients. The information on the abortion process is often diversified in the case of minors who have suffered abuse and those who become pregnant by mistake. In the first case, the girls are immediately entrusted to a psychologist and the

information on the abortion is presented as a form of assistance offered to the patients. In the second case, the attitude of the professionals is to give minimal information about abortion, waiting for the family or the patient themselves to ask for more explanations about the process.

A second example is the information given to couples who ask to undergo medically assisted procreation procedures. During the interviews observed, the level of attention shown by the professionals in informing the young couples (under 35 years of age) with problems of sterility was greater than that given to older couples (more than 45 years old) who did not have any problems of infertility, but had delayed the decision to have a child. As various professionals admitted, the support requested by the first type of patient does not have the same value as the help demanded by those who, for personal reasons, have postponed the decision to become parents. Thus, the first category of patients is considered to have *more right than the others* to the help of the doctors, which is frequently translated into a greater commitment by the doctors to the younger couples, not only in the assistance offered, but also with regard to the information given.

A third example is the selection of the patients who are offered the new drugs against Hepatitis C. As emerged from the survey conducted at the gastroenterology clinics during the most critical phase of the experimentation of these drugs in Italy, that is during the months in which they were introduced and the costs were still so high that availability was extremely limited, the tendency amongst doctors was to inform only certain patients of the arrival of the new medicines. In the majority of cases, the patients chosen to receive this information were those who had contracted the virus by inheritance or due to contagion years earlier, when some patients received a transfusion of infected blood while hospitalised. On the contrary, the patients who were generally not informed of the new medicines were those who had contracted the disease due to illicit behaviour, such as the use of drugs – above all heroin – or alcoholism that had resulted in cirrhosis of the liver. Some of the doctors interviewed lamented the fact that although the guidelines issued by the Italian Ministry of Health state that the drugs should be distributed according to the stage of the illness, the principles that seem to have guided access to information and treatment appear to have been above all the *worthiness* and the *reliability* of the patients. In many cases therefore, together with the clinical needs, the general qualities of the patient were evaluated and information and medicines were preferably offered to those who had shown considerable discipline, that is the patients who had never missed an appointment, who had followed the treatment precisely, who had stopped drinking and smoking, as the doctors requested. And so, as some professionals stated, the lack of information on the new drug was translated into a mechanism of discrimination in the transmission of knowledge, but also with regard to the patients' chance to choose, respectively considering them

"class A patients" or "class B patients" according to their clinical history and their behaviour during hospital treatment.

4.5 *The foreign origin of the patients*

The Italian or foreign origin of patients was another element that counted in the informative process. In the case of the foreign patients who speak fluent Italian, the most problematic questions were the stereotypes and the *ethnic imagery* often applied to these categories of patient. While on the one hand, as stated by many professionals, the foreigners hospitalised on the wards are young patients (between 20 and 40 years of age) and in good general health, on the other hand it is necessary to reflect on the tendency to give them little information about the treatments. The almost complete absence of foreigners amongst the patients involved in experimental treatments based on new drugs, or the low percentage of foreigners included in the transplant procedures,[243] to give some examples, can only partly be explained by their better state of health.[244] As emerged from the observations on the wards, the tendency not to offer the same information as that given to the Italian patients is often linked to the idea that patients of foreign origin are a category not to be trusted. As many professionals emphasised, in a number of cases the patients do not attend appointments, arrive late for appointments, do not remember to book the tests suggested by the staff, do not respect the dosages of the medicines prescribed. In consideration of these errors, many professionals prefer not to inform them about treatments that require strict respect for the prescriptions. This choice is also often linked to an idea shared by many of the doctors, that even though numerous foreigners have been living in Italy for years and speak fluent Italian, they will not in any case understand the medical information. In the opinion of many operators, they are patients who lack the basic skills to deal with medical language. This results in the decision to simplify the vocabulary used when informing them as far as possible or to reduce the interview to the minimum required for gathering informed consent. As emphasised by the literature for other similar cases in Italy and abroad,[245] both these ideas correspond to the *representations* of which the foreign patients are often victims. In the first case, the behaviours criticised by the doctors frequently depend on the living conditions of the foreigners: a category of patients who often find it

243 The only exception to this trend is the paediatric sector where the foreign patients for transplant procedures are numerous. This figure emerged above all for bone marrow transplants, which children usually undergo to treat haematological conditions. Amongst the foreign patients on the wards were children from Venezuela and other Latin American countries, thanks to the cooperative projects that the Regina Margherita Hospital has established with these nations. There were also children born in Italy of foreign parents and children with foreign parents now resident in Italy, who were born and grew up in another country but came to Italy temporarily for medical treatment.

244 E. Castagnone *et al.*, *La salute come diritto fondamentale: esperienze di migranti a Torino*, Bologna, Il Mulino, 2015.

245 J. Pratt and R. Grillo, *The Politics of Recognising Difference: Multiculturalism Italian Style*, London, Aldershot-Ashgate, 2002; Italian translation: *Le politiche del riconoscimento delle differenze. Multiculturalismo all'italiana*, Rimini, Guaraldi, 2006.

difficult to deal with the Italian hospital system,[246] but also a category of patients who, thanks to their social status, often find it more difficult to get time off work to go to hospital appointments. In the second case, the doctors generally seemed to neglect the level of education of these patients, who often have degrees or diplomas. In the same way, although some of them were surprised to have to sign forms in order to gain access to treatment, the professionals did not inquire about the foreigners' understanding of the process of informed consent; a procedure used above all in the western world and often absent in their country of origin.[247]

As described in the previous chapters (see chapter three), in the case where the foreign patients do not speak Italian communication with the medical personnel demands the help of other figures. Whether these are relatives, other members of the community or cultural mediators present (only) during some hours of the hospital services, the result does not change: the time needed for the explanations given by the medical personal must include time for translation of the information and therefore the overall time needed for the interviews increases. In consideration of these tendencies, many professionals complain about the time "wasted" in these interactions. Time, they say, that could be used in other ways, above all in situations where the choices of the patients do not depend on the explanations given by the doctors, but on their religion or cultural background. The next testimony, chosen amongst others for its critical dimension, is typical of this situation.

> Why should I waste all this time speaking to Muslim patients about abortion? At times, we spend hours informing them about therapeutic abortion, even though we know they will not choose it. Throughout my career, I have seen only two or three Muslim women have an abortion, or do tests to find out whether the child is well. For them it is all the will of God, so even if we spend our time informing them, they will do what their religion dictates, in any case. Wouldn't it be better to spend this time on other things, such as informing the Italian patients in more detail, since in the face of the same problems they really need to know what to do?[248]

As emphasised by these words, far from being considered a rule valid for all, informing the patients and the time spent on this activity may seem to the professionals "time well spent" or "wasted" according to the social characteristics of the patients.

To summarise what we have said so far, the factors linked to the identity of the patients all contribute to the informative process involved in the gathering of consent. While the equality of the patients nowadays passes for equal access to medical information, on the contrary, a hierarchy of

246 Laboratorio dei Diritti Fondamentali (ed.), *Guida ai servizi sanitari per immigrati. Edizione 2014*, Regione Piemonte.
247 M. Marzano, *Problemi etici nella ricerca sociale sui malati terminali: consenso informato, comitati etici e differenze culturali*, in «Sociologia e Ricerca Sociale», 75, 2004, pages 157-174. I. Quaranta and M. Ricca, *Malati fuori luogo. Medicina interculturale*, Milano, Raffaello Cortina, 2012.
248 Extract from an interview held on 17th February 2015.

patients within the hospital – those that it is worth informing and those that it is not worth informing, those with whom it is interesting to spend time conversing, those with whom conversation is a waste of time, etc. As shown, this divergence depends both on the intrinsic limits of the social profile of the patients and on the informative choices made by the doctors on the basis of the patients' profiles. Consequently, the ideals of the *healthcare democracy* in which the universal right to health corresponds not only to the *possibility of treatment* but also to the *possibility of choice* does not yet seem to have been reached. When asked about these trends, the doctors seemed divided. As some of them stated, the duty to inform the patients does not always correspond to an improvement in the therapeutic relationship, nor to an increased level of the democratisation of the relationship between the doctors and the patients. What is attained, in a number of cases, is a form of *segregative democracy* based on a series of *institutional discriminations*, to use the words employed by certain doctors. Another group of professionals, tended to stand outside the problem of informative inequalities, emphasising that the increasing bureaucratization of the hospital work meant that there was ever less time to look after the patients, and that the doctors were increasingly concerned with producing documentary evidence. Hence, the reduction of the information process and the request for consent to procedures for legal reasons, and not to effectively increase the dialogue with the patients. What do the latter think about this? How do the patients see the behaviour of the medical personnel with regard to the information given to them? What is their opinion with respect to the practice of informed consent? To what extent do the patients know their rights?

5. *The patients' point of view*

On the basis of what we have said so far, the first question to answer is to what extent the patients met at the clinics and on the wards feel they suffer forms of discrimination with respect to the informative process. Maria, 84 years old, hospitalised on the internal medicine ward, emphasised her perception that the more the doctors feel the elderly patient will have difficulty understanding the information and the more they tend to speak to members of the family, spending little time in "speaking directly" to the patients.

> I am certain that the doctors think I don't understand anything they say. They come here and they explain everything to my sister. Even when it is necessary to sign something, they speak to her first. When I was young, I worked as a nurse in Sardinia, while my sister remained at home and never worked. If there is one of us who can understand the doctors' explanations, that is me! However, the doctors don't know that, they just think that I am old and they prefer to speak to my sister, who is

younger than me. Instead, they should assess the patient's situation more carefully, there are elderly people who are not capable of deciding but there are also people, like me, who would like to say what they think.[249]

Maria's testimony is interesting for two reasons. On the one hand, her words emphasise the way the doctors' expectations change from one patient to another. Unlike the situation described in previous chapters (see chapter four), the doctors' tendency to speak to members of the elderly patient's family is in this case seen as offensive. As Maria stated, in some cases the older patients would prefer to be the first to be informed by the doctors. The pressure exercised by family members to avoid informing the patient and the doctors' decision to speak directly to the relatives were described, in these cases, as a "diminution" of their ability to understand the doctor's explanations. The same question emerged in the case of certain adolescents, who emphasised that the doctors' decision to speak also, or above all, with their parents about the treatment showed a lack of consideration for their capacity to choose (see chapter four). On the other hand, Maria's testimony shows how, according to some patients, the doctors act on the basis of *macro categories*, without evaluating what lies behind the image of the patients – in this case age – to see the specific identity of each individual patient. Thus, in their view, the difficulties encountered by the doctors in informing geriatric patients, above all when it is a question of patients not really capable of understanding the medical terminology, often produces a domino effect, so that *all* elderly persons are considered incapable of understanding the doctors' explanations, even when, as in Maria's case, they have worked in the medical sector in the past.

Except for these considerations on the characteristics of the informative process with respect to age, none of the patients interviewed insisted on the perception of a link between their social profile and the quality of the information offered by the doctors. In particular, the elements previously mentioned – such as the level of instruction, the social class or the foreign origins of the patients – were not described by the subjects interviewed as discriminant factors in the information procedure necessary for consent to treatment. On the contrary, almost all the patients interviewed said they were satisfied with the explanations received from the doctors, even though they appeared *in fact* to be of varying detail according to the social status of the patients. Therefore, the first fact that emerged from the comparison of what was observed on the wards and what was subjectively stated by the patients is that the problematics raised by the ideals of healthcare democracy – such as *equal information for all* – seem to be of only relative importance within the universe of the patients. This emphasised the need to rethink the notion of equality and the notion of democracy, as concepts often taken for granted and automatically considered positive, desired and desirable. The

249 Extract from an interview held on 18th July 2014.

opinions of the patients show how parity of treatment does not seem to capture the relevance of the differences recognised as constitutive parts of their identity by the patients themselves. The varying level of culture or the social class are factors that affect the attitude, the expectations and the requests of the patients, who seemed aware of this heterogeneity. Thus, the varied characteristics of their relationship with the hospital personnel show how the abstract concept of "equality of the patients" clashes with the presence of numerous diversities amongst them. In this framework, the problem is to understand which diversities are considered important by the medical personnel and the significance attributed to the patient's opinion. The efforts of some doctors to bridge the cultural gap, often not seen as a problem by certain patients, like the attempt to apply the same treatment to all the patients whatever their individual characteristics (pretending that this gap does not exist) highlights the difficulties encountered by the professionals in applying, or "imposing" healthcare democracy on their patients.

5.1. *"You are the experts." Delegating choices, or asking the medical staff for advice*

The second question examined is to what extent the new duties of the doctors to inform their patients about the therapies, the risks and the possible alternatives helps to overcome so-called *medical paternalism* in favour of a new model of care, in which it is no longer the doctor who decides on behalf of the patient, but the patient who decides starting from the information given by the doctor. As stated in other chapters (see chapter one), in this model the dialogue between the doctor and the patient is the cornerstone of an alliance or a "therapeutic contract" in which, except for emergencies, the patient has the final word on the starting or continuation of treatment. The recognition of the right of adult patients to self-determination regarding their own body and health, and the possibility of going against the doctors' advice, appeared to be principles distant from what happened in reality. As emerged from the observations in the hospital setting, the behaviour of the patients often goes in the opposite direction. Hence, the first recurrent phenomenon is the delegation of the decision-making process to the medical personnel. However much we talk about *autonomous* patients who are *responsible* for their own decisions, many of them present an attitude of total trust in the medical staff. According to the research data, this tendency concerns above all the less well-educated Italian patients, but also often involves other groups of patients, such as foreigners, or Italian patients with a good level of instruction. Entrusting one's therapeutic choices to the medical personnel appeared to be an element transverse to the universe of sick people, amongst whom delegating to the professionals generally assumed three different forms. In the first case, the choice of the patients was to entrust the entire decision-making process to the medical staff, declaring that

they did not want to receive any information on the success rates, the risks and the possible collateral effects of the therapies and the surgical operations. The choice to 'not know' was translated in these cases into automatic acceptance of the opinion of the medical personnel and signing of the consent forms "on trust". Caterina, age 52, hospitalised on the surgical ward said:

> Personally, I did not feel capable of knowing how many people had survived the operation, what problems might occur during the operation, what the risks linked to the anaesthetic are, before I underwent the operation. I was afraid that I would be too upset and I preferred to sign the consent forms on trust, without hearing all this information.[250]

Though in this type of situation the delegation of the decision-making process depends on the patient's choice not to be informed of the "pro" and the "contro" of the treatment, in other situations the decision to trust in the therapeutic choices of the doctors depends on the recognition of the asymmetry between the personal knowledge and that of the hospital staff. During the interviews observed, when asked to express their opinion regarding the treatment proposed by the doctors, more than 90% of the patients emphasised their lack of competence in the field, and therefore the need to trust the opinion of the doctors. In the majority of cases, the patients listened to the explanations and then said one of the following phrases. "Please tell me what I should do." "You are the experts, not me." "You have more experience in this field." "I trust your opinion." As can be seen, the trust in the medical personnel is often accompanied by the consideration that they have knowledge not available to the patients. In other situations, the prevalent attitude is not so much a delegation to the opinion of the professionals – which can be reassumed in the phrases: "You decide for me," or "Please tell me what to do." – but rather a request for advice from the medical personnel. In this case, when asked to give their own opinion on the treatment, the patients generally say, "What would you do, if you were in my position?" "What would you choose, if it were your daughter?" "How would you behave, if it were your father?" The fear of taking the wrong decision is a question emphasised in many cases by the patients and the members of their families during the interviews. This frequently led to the decision to ask the medical staff for advice, assigning them the role of "guide" in the healthcare decisions. Thus, in many of the situations observed personal choices were made starting from what the doctors thought was best. The decision to trust the doctors, whatever decision they made regarding the treatment and the need to receive advice about what to do, shows the extent to which the principle of self-determination in the patients' decisions is effectively applied.

250 Extract from an interview held on 13th March 2015.

The tendency to consider the doctors figures to whom one's therapeutic choices should be trusted was also seen on the wards. As emerged from the research data, although patients now have the possibility to negotiate the characteristics of their treatment and various tools are available to avoid what the doctors suggest, they are used by patients only in very few cases. The rate of refusal of therapies proposed by the doctors is typical of this situation. During the months in which the research was carried out, the patients (or their families) who refused to give consent to the treatments proposed by the doctors were less than 5% of the patients at the clinics and on the wards. This trend was described by the doctors as normal for the services: an opinion that was confirmed by the statistical data of the last five years, which showed a rate for refusal of treatment equal to or lower than 5%. As shown by this data, the tendency to give consent to treatment does not only involve the more serious pathologies – for which there is often no alternative treatment – but generally, for any therapeutic course. The same is true for the patients who choose to withdraw their consent after beginning the therapies or after agreeing to a surgical operation. This situation did not occur during the months in which the research was carried out. Once again, the comparison between the data gathered during the research and the last five years' statistics of the wards confirm that the withdrawal of consent involved only 5% of the patients. In the light of this trend, the question to be answered is "are the patients at the clinics and on the wards aware that they can refuse treatment and that they can withdraw their consent to therapies at any time?"

The contact with some organisations in the area of Torino who deal with patients' rights, such as representatives of the association Cittadinanzattiva (active citizenship) and the Tribunale dei Diritti del Malato (tribunal of patients' rights), allowed us access to some interesting data. According to the heads of these institutions, which also offer legal assistance, in addition to informing the patients,[251] the tendencies described so far do not reflect, or only partly echo the patients' lack of understanding of their rights. With regard to information and knowledge of the laws, the situation of the patients is not always homogeneous; the general tendency to give consent to treatment depends above all on other factors. The first is represented by the permanence of a hierarchy in the doctor-patient relationship. As stated by the representatives of these institutions, despite the battles won with regard to rights, the prevailing culture amongst patients is that of a vertical relationship in which "the doctors have the knowledge and the patients trust in them", to paraphrase the words of one of the heads of the Tribunale dei Diritti del Malato. The verification of an assistential model in which the various possibilities are evaluated together has occurred only in

251 Amongst the informative material distributed to the patients we find the *Patient's Charter* produced and distributed by representatives of the association Cittadinanzattiva Piemonte (active citizenship Piemonte branch). In recent years, the association has been translating this material into various languages, in order to make the information with regard to complaints against the medical personnel and other hospital staff available to foreign patients, who are usually not amongst the public served by this association and the hospital services – such as the Public Relations Office.

part: in the majority of cases, the patients do as the doctor tells them. At the same time, another reason identified by the representatives of these institutions is the little importance attributed by the patients to the practice of informed consent.

5.2. *Gathering informed consent: a "non-problem" for the patients?*

As anticipated in the previous paragraph, according to the heads of the Tribunale dei Diritti del Malato, amongst the elements that make up hospital care, informed consent and its corollaries – such as the information given by the doctors, the possibility of refusing therapies and the freedom to withdraw consent at any time – do not appear to be central to patients' concerns, nor do they give rise to many criticisms.

> We have the impression that all this debate on informed consent is a *non-problem for the patients*. Certainly, it would be important if there was more information and the patients really felt in a position to choose, but there are other reasons patients complain about healthcare. The problem of lack of information or the correct gathering of informed consent is mentioned in very few cases, while it is emphasised by the lawyers and the insurance companies who stand to gain from it. For the patients who contact our association, the problems that count are above all medical errors and questions linked to overcrowding in the hospitals.[252]

These words are confirmed by the reports patients made to the Tribunale dei Diritti del Malato during the period of the research project. To give one example, 171 complaints were received in 2013 from the patients at the Molinette Hospital. Of these, only nine concerned the information given to the patients by the medical personnel and none of them criticised the way in which informed consent was gathered. On the contrary, the majority of the complaints concerned: 1) the "poor functioning" of the hospital machine, with particular reference to the waiting times at A&E and for access to the clinics; 2) presumed errors in medical practice, in particular doctor's errors during diagnostic tests and errors committed during surgical operations; 3) administrative problems, with particular reference to the cost of public hospital fees.

The complaints made by patients to the Public Relations Office of the Città della Salute e della Scienza showed the same trend. Once again, taking the Molinette Hospital as an example, 521 complaints were received in 2013. Of these, only seven concerned the information given to the patients by the doctors – a figure that corresponds to 1.3% of the complaints – and only in one case, the complaint concerned the way in which the informed consent was gathered. The relative

252 Extract from an interview held on 13th December 2014.

importance of the topic of information compared with other problems reported by the patients and their families does not only concern this hospital, it is a factor that involves all the four hospitals in the Città della Salute e della Scienza complex. As shown by the graphs in the appendix (figures 1, 2, 3, 4), in 2013 the complaints received by the Public Relations Offices of the four hospitals were 805 altogether. Of these, 31% concerned expectations regarding the services; 20% the technical-administrative aspects, with particular reference to the public hospital fees; 18% relational aspects, in particular the courtesy of the hospital personnel; 15% the technical-medical aspects, in particular the errors and inaccuracies of the doctors; 3.3% the lack of information for patients. Finally, in 2015, there were 1,889 complaints altogether. Of these 45.2% concerned waiting times; 9.7% technical-medical aspects; 4.6% lack of information for patients. The result that emerged from the comparison of these figures was the increase in the number of complaints made by the patients. Within this tendency, however, the reports regarding the question of information were always fewer than other complaints by patients.

It is necessary to add to these trends another statistical element emphasised by the representatives of the Public Relations Offices during the interviews: unlike the complaints against the inefficiencies of the hospital and the medical errors, due to which a number of patients take legal action against the hospital and the healthcare workers, more than 90% of the complaints regarding informed consent are resolved through "arbitration" within the hospital. The heads of the Public Relations Offices organise a meeting with the doctor accused of not informing the patient correctly, the consultant on the ward, the head of the Risk Management Unit, the patient and in some cases members of the family and generally, this is sufficient to resolve the question, without legal measures being taken. As stated by the heads of the patient's tribunal and the heads of the public relations offices, in their experience, the identification of harm, and therefore the need to sue the hospital workers, is associated above all with physical problems caused by medical procedures and not by the problems caused by a lack of information for patients. In other words, what seems to interest the patients most is the quality of the care (waiting times) and the guarantee of their physical safety thanks to the efficacy of the treatments proposed (technical-health aspects). On the contrary, the new duties of the doctors, such as the effort made to inform the patients about treatment, seem to be secondary in importance for the patients themselves. The idea of healthcare in which the role of the doctors is above all to look after the patients' health as well as possible was expressed as follows by Mauro, 34 years of age, hospitalised on the surgical ward.

> What I expect from the doctors is that they treat me as best possible, without making mistakes. To be honest, information is the last problem for me. I prefer my doctors to give me little information, but to do their jobs properly, not that they inform me and then make mistakes with the operation or the

> anaesthetic. Of course, the doctors must tell us what is best for us, but in the end, they are the ones who know what must be done for our health.[253]

The contrast in this testimony between the *quality of the treatment* and the *quality of the information* offered by the doctors clearly shows that patients see the information process as relatively unimportant. Scepticism towards healthcare increasingly based on informing the patient also emerged during the interpretation of the practice of informed consent. When asked to describe, in their own words, the purpose of informed consent, some patients emphasised that in their opinion it was an *administrative formality*. Domenico, 69 years old, describes the signing of informed consent as a simple bureaucratic procedure now carried out routinely.

> In the past, when you came to hospital you didn't have to sign anything, now they ask you to read and sign for all sorts of things. We do it automatically without thinking about it. At the beginning, I was a bit diffident about having to sign, but then I realised that it is a paper where they ask before starting treatment. If the doctors don't tell me anything, I ask them whether I have to sign something, because I don't want to have to come back to the hospital just for that reason.[254]

However, the normalisation of informed consent as part of the hospital bureaucracy is not true for all patients. In fact, for other patients the consent forms are not "just any piece of paper" they are documents that have value as proof for the doctors, should it be necessary for them to defend their activities in court. Eleonora, 43 years of age, said:

> In my opinion, informed consent has weakened our relationship with the doctors. This fact that we must sign a piece of paper in which we say that we have understood the risks of the procedures serves to safeguard the doctors, giving the patients part of the responsibility should there be any problems. For me, this form does not bring us closer together, but increases the distance in the relationship with the doctors, it puts us all on the defensive, while the aim should be to better understand what the doctors advise for our own good.[255]

The criticism of the construction of greater therapeutic alliance thanks to the practice of informed consent is a topic that emerged in many of the conversations with the patients following their interviews with the doctors and the signing of the informed consent forms. The question of strengthening defensive medicine often appeared to be accompanied by the perception that, in addition to protecting the doctors, the informed consent was a practice "of little use" for the

253 Extract from an interview held on 17th January 2015.
254 Extract from an interview held on 5th March 2015.
255 Extract from an interview held on 5th March 2015.

patients. In some cases, the patients interviewed emphasised that this practice did not encourage a better exchange with the doctors since the time available for reading the forms was limited and the language used was often difficult for the patients to understand (see chapter three). In other cases, the patients emphasised that recourse to informed consent only partly guaranteed greater freedom of choice, which depends above all on the clinical situation. In yet other cases, the patients insisted on the fact that the level of information given to the patients depends only partly on the explanations received during the interviews with the doctors before signing the forms; much of their knowledge about the illness and the possible treatments comes from other sources, as we will see in the following paragraphs.

5.3 *The many sources of information for the patients*

The last of the elements that emerged from the stories of many of the patients interviewed is the relative value of the doctor-patient communication as a source of information. Except for those who choose not to know, the majority of the patients encountered at the hospitals, as we said, appeared to be committed to seeking information on their illness before, during and after the meeting with the doctors. At all the services analysed, there were few patients who signed the consent forms without preliminary knowledge of the illness and the possible treatments. Consequently, the meeting between the doctor and the patient is a moment that cannot be extrapolated from what went before. In fact, the channels of information for patients were numerous and often diversified in content, and in the players involved. For the sake of brevity, in this analysis they will be divided into two macro categories: channels *outside* the hospital and channels *inside* the hospital.

The first category includes, above all, the information that the patients gather by talking to members of their family or friends to whom they choose to speak of their physical symptoms. It is always this type of subject to whom the patients confide their doubts about the need to see a doctor and undergo treatment. In some cases, the exchange of opinions on the possibility of illness starts with the first-hand experiences of relatives or friends who have experienced the same problem, or another health problem. In other cases, these evaluations are based on the general knowledge of family and friends, and on searches for information on the Internet. The blend of information on the Internet and the general knowledge about the illness, such as "folk medicine" or the cultures of illness shared by foreign subjects,[256] emerged in many of the stories from the patients interviewed. During the early stages of the illness, the consultation of the Internet often involves the patients and

256 W.H.R. Rivers, *Medicine, Magic and Religion*, London, Kegan Paul, 1924. A. Young, *The Anthropologies of Illness and Sickness*, in «Annual Review of Anthropology», 11, 1982, pages 257-285.

their families, interested in discovering together what the problem is and what it is necessary to do to solve it. Surfing the Internet is often accompanied by online discussions between the future patients and persons who have had or are being treated for the same illness. The consultation of blogs, forums and specialist magazines also contributes to giving exploratory information to the patients and future patients, allowing them to understand the diagnostic methods and the treatments.[257] In some situations, the need for confirmation of theories advanced by relatives and from reading on the Internet translates into the decision to consult their GP before turning to hospital services.

The information channels within the hospital also seemed to be linked to a number of factors. First, it is necessary to mention the informative function of the material available to patients in the waiting rooms and the corridors of the wards, which include the informative leaflets on treatments; the posters from scientific organisations and associations involved in assisting patients at home; advertising for organisations promoting various creative activities for patients (art therapy, yoga, creative writing). This informative material is generally distributed with the permission of the hospital management, who decide what can be left in the waiting rooms and on the wards. Despite this, some associations try to carry out their information campaigns without prior authorisation from the consultants and the management. One example is the "informative campaign" carried out by the associations for and against the donation of organs and tissues. The conflict between the arguments sustained by these associations, in the first case in favour of donations *post mortem*, in the second case in defence of the integrity of the person following their decease, emphasises the complexity of some decisions asked of the patients and their families, with respect to which public opinion and society still remain divided. As stressed by many patients, the presence of this material contributes to the process of understanding the illness, but it can also have a negative influence on their choices and the choices made by members of their family when the information available on the wards presents contrasting opinions.

An equally important role is played by the explanations given by the nursing staff. The frequent transformation of the nurses into a source of information for the patients is linked to the fact that, as described in previous chapters, these professionals spend a lot of time with the patients (see chapter four) and therefore have more opportunity to discuss the illness. At the same time, many of the patients interviewed emphasised that the nurses were "less severe" figures compared with the doctors and "closer" to the patients; figures, they say, with whom they feel more comfortable and to whom they are less embarrassed about expressing their doubts. So, on many of

257 M. Hardey, *E-health: The Internet and the Transformation of Patients into Consumers and Producers of Health Knowledge*, in «Information, Communication and Society», 4, 2001, pages 388-405. M. Hardey, *Internet et société: reconfigurations du patient et de la médecine?*, in «Sciences sociales et santé», 22, 2004, pages 5-20.

the wards analysed, the patients' greater confidence in the nurses was translated into a tendency to ask them for confirmation and clarification about the therapies proposed by the doctors. The same is true for other figures outside the medical team, but involved in the process of informing the patients, such as social workers or cultural mediators in the case of foreign patients.

Finally, although the waiting times in the hospital setting are one of the main areas criticised by the patients, the time spent with other persons who are waiting to be called for their appointment – and the hours spent with other patients during treatments at the day hospital – contribute to acquiring information on the illness, the risks and the treatments. During the observations on the wards and in the waiting rooms at the clinics, the tendency to form groups was clear. In both cases, while they were waiting to be seen by the doctors, for example for a biopsy, the patients tended not to remain silent. This extract from a conversation[258] reflects this tendency.

> **Patient 1** (new arrival): How many of you are waiting for a biopsy? This is my first time.
> **Patient 2** (veteran of the service): Anything but the first time! I have already done three. I can tell you, in the end, they are useful, they show how far the disease has attacked our organs.
> **Patient 3** (veteran of the service): That's not all they are good for! They also let the doctors see how to combine the drugs to avoid harm to our system.
> **Patient 2** (speaking to patient 1): Do you hear? If you have any questions ask him (indicating patient 3), he's been here for years and he knows more than the doctors!

As emerged from the research data, the *peer-to-peer discussions* not only anticipate, but often compensate for and substitute the exchange with the hospital personnel. In some cases, it is through these discussions that the patients receive answers to questions they dare not ask the doctors. In other cases, it is thanks to these interactions that they gain access to information that is deliberately omitted or transmitted only in part by the medical staff, such as information regarding the patient's life expectancy.[259] In a number of the patients' stories, the construction of their knowledge of the illness was described as the result of the dialogue with other persons with similar illnesses. The case of Daniela, age 43, is typical of this situation. The perception of increasing respiratory difficulties made her suspicious, but she preferred not to speak to anyone in her family about it. In the evening, however, when her children were sleeping and her husband was out, Daniela began searching for explanations on the Internet. Here she discovered a forum organised by patients who discussed various health problems. Through an exchange of opinions with people she had never met, Daniela discovered that her increasing difficulties with her breathing could be a sign

258 Extract from an interaction observed on 16t^{h} December 2014.
259 D.R. Gordon, *Culture, Cancer and Communication in Italy*, in B. Pfeiderer and G. Bibeau, *Anthropologies of Medicine*, in «Curare», 7, 1991, pages 137-156.

of heart disease, and not a problem with her lungs, as she had imagined. One evening, Daniela was contacted privately by a user of the forum, who told her personal story and advised a visit to the cardiologist. This person was Lucia, 38 years old, who was born with an intraventricular defect and had already undergone a number of operations on her heart. The conversation with Lucia tempered Daniela's fears regarding the possibility of an operation and encouraged her to book an appointment with a cardiologist. While she was waiting at the cardiological clinic, Daniela met Alessandra. The absence of members of her family, with whom Daniela had decided to speak only after seeing the doctor, encouraged an exchange between the two women. Alessandra had been affected by heart disease for more than ten years and her experience contributed to Daniela's store of information on cardiac problems and the possible treatments. As she said during our conversations, much of the information she gathered came from these encounters, even before she met the medical staff. As in the case of Daniela, the *horizontal communication* between patients, both online and offline, can contribute to increasing knowledge in the health sector. In particular, the patients who have been living with an illness for many years can play the role of "expert" with new patients, who are curious to learn from the experiences of others. The tendency to act as "teachers" emerged amongst the chronically ill and ordinary patients, but also amongst new and old patients who shared the same type of treatment. On the other hand, what prevailed in the majority of cases was the influence of numerous sources of information, as complementary resources in constructing a relationship with the illness. The idea of a continuity, and not an opposition, between the various sources of information also emerged from the testimony of Giacomo, 26 years old, who summarised the stages of his informative progress on the illness (leukaemia) which he has been battling for about a year, as follows.

> At first, I looked for information mainly on the Internet, on the websites of specialist journals. It was also very important for me to gather information directly, both from a friend's sister who had had the same problem and from patients on the ward who began their treatment at the same time as me. All these things helped me to understand what I was going through and to convince me of the importance of chemotherapy.[260]

As shown by these stories, the meeting with the doctor is only one of the ways in which the patients gather information. There are many other sources of information, from which the medical personnel is generally excluded. What do the healthcare workers feel about this situation of *informative pluralism* for the patients? As emphasised with regard to other questions concerning the relationship with the patients, also in this case the professionals appeared to be divided. According

260 Extract from an interview held on 18th February 2015.

to some, the patients' search for information in addition to the interviews with the doctors can improve the exchange of opinions on the illness and the treatments. In this case, the recognition of understanding by the patients often goes hand in hand with a positive or negative evaluation of the other sources of information that must be taken into account. In the majority of the cases, the doctors were critical of information gathered on the Internet. In their opinion, in fact, it is a dangerous source of information because the 'facts' presented on blogs and websites do not always correspond to the scientific truth. On the contrary, many doctors said they were in favour of horizontal exchanges between patients in the hospital: a practice officially encouraged on some wards, where, in addition to the discussions with the doctors, there is a tendency to propose peer-to-peer discussion and support. Some examples are: the "woman-to-woman" meetings for oncological patients on the Breast Unit; informative meetings between parents (mainly the mothers) of children who are hospitalised and those who have been discharged from the neonatal intensive care ward; the introduction of the "patient testimonial" on some paediatric wards. According to other professionals, however, the only reliable source of information with regard to therapeutic choices is the doctor. In this case, the idea of a monopoly of scientific knowledge held by the doctors translates into a defence of the model of *unidirectional* communication, from the doctor to the patient.[261] The prevalent perspective in this case was a *doctor-centred* one, in which not only the information from the Internet, but also other sources of knowledge were considered "misleading" – to use the words of the doctors – with respect to the explanations given by the medical personnel. Thus, on the one hand, some insist on the negative effects of information "in competition" with that supplied by the doctors, while other operators say that it is difficult to replace this information with "genuine" medical explanations in the little time available for dialogue with the patients. This diversity of opinions within the medical body underlines that the idea of an asymmetry between the position of the doctors and that of the patients must still be overcome. While on the one hand, numerous patients continue to recognise in the doctors the figures to whom they entrust themselves for treatment and for their choices, some doctors continue to think that the only reliable knowledge for the patients is their own. In both cases, what emerges is an attitude close to the paternalistic medicine of the past, rather than the shared or participative medicine of modern times.

261 B.J. Good, *Medicine, Rationality and Experience: An Anthropological Perspective*, Cambridge, Cambridge University Press, 1994; Italian translation: *Narrare la malattia. Lo sguardo antropologico sul rapporto medico-paziente*, Torino, Einaudi, 1999.

Chapter Six

The requisites of consent to medical treatment

1. *Introduction*

As we saw in the initial chapter, the doctor must acquire the patient's consent to any medical treatment. This consent, in order to be considered valid, must meet certain requisites which are *a*) preventive information; *b*) the consent must be given personally and the patient must be capable of discernment; *c*) the manifestation of consent must precede the start of therapy; *d*) consent must be freely given, without errors and clearly expressed; *e*) the declaration of consent must be actual and can be revoked.

Nonetheless, despite the general uniformity of opinion regarding the characteristics that must theoretically mark consent to medical treatment, many uncertainties emerge when it is a question of verifying that they effectively exist in the medical practices. As we already explained,[262] the difficulties doctors encounter in obtaining consent that effectively has all the requisites previously mentioned often relate not to an attitude of disregard, attributable to the individual operator, but rather to problems that involve the entire hospital complex (such as overcrowding of the wards and, consequently, the lack of time for giving information) or to the peculiarities of the individual patient and the type of relationship that they have established with the doctor.

In this chapter, we will therefore try to highlight the main problems that emerged on the legal plane, where jurisprudence and doctrine had to evaluate the validity of the consent given by the patient, and – where possible – suggest solutions that could be adapted to the effective reality of the healthcare situations in which it was necessary to operate.

2. *Preventive information*

The first of the requisites that consent to medical treatment must have in order to be effectively free and aware is that of preventive information.

With regard to this matter we must emphasise that, in our juridical experience, there is a rooted tendency to excessively extend the confines of the doctors' informative obligations. In fact, it is now accepted in jurisprudence that information must include – as expressly foreseen by Article 33 of the medical deontological code – the prevention, the diagnosis, the prognosis, the existence of

262 Cfr. *supra*, chapter three

any alternative treatments and the advantages and risks of each treatment[263]; but also the complications inherent in the planned treatment, or the series of harmful events that can theoretically be foreseen prior to the operation, but which cannot be avoided even when the operation is carried out correctly.[264] According to Italian jurisprudence, therefore, only atypical, exceptional and improbable consequences are excluded from the informative process, and this is because on the one hand it may be difficult to identify them and, on the other hand, if they are presented to the patient the effects may be counterproductive, inducing them to refuse their consent to routine treatments which, in general, have positive results.[265]

Moreover, we must mention the tendency to include in the information that the doctor must give the patient also warning about the dysfunctions and the inadequacies of the healthcare structure at which the patient is hospitalised, including, for example, the temporary unavailability of equipment necessary for appropriate treatment. This principle was established by the Court of Cassation in the case of a pregnant woman, who was not informed of the temporary absence at the hospital of a cardiotocograph and the greater risks linked to a birth that took place without the availability of this technical equipment. She received compensation after giving birth to a child with irreversible damage to the central nervous system, caused by complications that it was not possible to ascertain due to the absence of the equipment in question.[266] Patients must also be informed of the possibility of being treated at a hospital with a higher level of specialisation when the equipment present on the wards is not adequate for carrying out the diagnosis requested by the patient.[267]

A similar reconstruction of the obligation to inform based on Italian doctrine and jurisprudence is confirmed on a supranational level; in particular, the *Draft of Common Frame of Reference* (DCFR),[268] foresees at Article IV.C.-8:105, that anyone who carries out medical treatment in favour of the counterpart has the "obligation to inform" and that the patient has the right to be informed regarding:

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263 Cfr. E. Guerinoni, *Attività sanitarie e responsabilità civile*, in «Il Corriere giuridico», special edition 2013, pages 41 *et seq.*

264 On the question of "complications" cfr M. Faccioli, *La rilevanza del concetto medico-legale di «complicanze» nei giudizi di responsabilità medica*, in «Diritto civile contemporaneo», 18 October 2015; E. Ronchi, *Il consenso "veramente" informato alle cure mediche e il "peso" della omissione di dati rilevanti nella cartella clinica*, in «Responsabilità civile e previdenza», 1997, page 1310.

265 Court of Cassation, 30th July 2004, N. 14638 in «Responsabilità civile», 2007, page 690, with note by F. Zauli, *Mancato consenso informato: danno conseguenza di per sé non oggetto di risarcimento*, according to whom the information "which extends to risks that are not significant according to the *id quod plerumque accidit*, since it is not possible to ignore that the healthcare worker must contemplate the need for information, while ensuring that the patient should not refuse basic treatment for fear of a remote eventuality; thus avoiding what French jurisprudence calls a *reaction dangereuse* of the patient.

266 Court of Cassation, 16th May 2000, N. 6318, in «Rivista Italiana di Medicina Legale», 2000, page 1300. On this occasion, the Court established that the doctor responsible for the treatment of the patient has the duty to inform them of the possible inadequacy of the structure, due to the absence (also only temporary) of essential equipment for appropriate treatment, or for adequate prevention of possible complications.

267 Court of Cassation, 8th March 2016, N. 4540 in www.ilcaso.it.

268 C. Von Bar *et al.* (ed.), *Principles, Definitions and Model Rules of European Private Law. Draft Common Frame of Reference (Dcfr), Outline Edition*, München, Sellier, 2009. This is a project for a doctrinal framework that would standardise European private law.

a) the patient's existing state of health; *b*) the nature of the proposed treatment; *c*) the advantages of proposed treatment; *d*) the risks of proposed treatment; *e*) the alternatives to the proposed treatment, and their advantages and risks as compared to those of the proposed treatment; and *f*) the consequences of not having treatment. The treatment provider must, in any case, inform the patient about any risk or alternative that might reasonably influence the patient's decision on whether to give consent to the proposed treatment. It is presumed that a risk might reasonably influence that decision if its materialization would lead to serious detriment to the patient.

This said, it is necessary to state that, in effect, in the Italian legislation the extension of the content of the doctors' obligation to inform depends on a series of other variables, which may be summarised as follows:

a) *the nature of the operation*: Italian jurisprudence and doctrine usually differentiate between interventions with a therapeutic purpose and purely aesthetic surgical operations, stating that generally in the latter case the doctor has the duty to inform the patient of even remote possibilities that could prevent the successful outcome of the operation, so that the patient themselves has all the information necessary to decide whether to undergo the operation, and whether to take the risk of a possible worsening of their physical appearance;[269]

b) *the moment in which the communication is made:* from this point of view, the primary consideration is the urgency of the treatment, since it is considered that in the case of treatment that can be postponed, the information must be detailed and complete, while in an emergency the need to inform is significantly reduced, and does not exist in cases where it is necessary to operate immediately and it is impossible for the patient to express their will,[270] presuming that in this circumstance, they would have undoubtedly given their consent to the operation;[271]

c) *the cultural characteristics* of the patient: with regard to this profile it is interesting above all to highlight how the importance of the personal qualities of the patient (in relation to the way the information is given) emerges not only from Article 33 of the code of medical deontology, which foresees that "the doctor should adapt the communication to the patient's capacity for understanding […] taking into account the sensitivity and the emotional reactivity, in particular

269 Court of Cassation, 6th June 2014, N. 12830 in «Danno e responsabilità», 2015, pages 246 *et seq*.., with a note by L. Mattina, *Chirurgia estetica: la Cassazione tra consenso informato e "dissenso presunto" del paziente*. This solution is also accepted in C. Von Bar *et al.* (ed.), *Principles, Definitions and Model Rules of European Private Law*, op. cit., at Article IV.C.-8:106 (*Obligation to inform in case of unnecessary or experimental treatment*). Here it is foreseen that" if the treatment is not necessary for the preservation or improvement of the patient's health, the treatment provider must disclose all known risks".

270 C. Von Bar *et al.* (ed.), *Principles, Definitions and Model Rules of European Private Law*, op. cit., Article IV.C.-8:107, confirms this principle stating that "the obligation to inform need not to be performed where treatment must be provided in an emergency. In such a case the treatment provider must, so far as possible, provide the information later".

271 In this situation, the lawfulness of the medical activity is justified by the state of necessity. Cfr. Court of Cassation, 9th February N. 2847, in «Corriere giuridico», 2010, pages 1201 *et seq*., with note by A. di Majo, *La responsabilità da violazione del consenso informato*; Court of Cassation, 6th June 2014, N. 12830, in «Nuova giurisprudenza civile commentata», I, 2014, with note by I. Pizzimenti, *Responsabilità civile del medico per violazione del dovere d'informazione: il crinale della necessità dell'intervento*.

in the case of adverse diagnoses", but is also emphasised by some recent sentences (including those of the Court of Cassation). When dealing with a patient who also has a medical qualification, the Court states that the characteristics of the patient may affect only the *quomodo* of the information, not the *an* of the same, therefore excluding that the patient's specific technical competencies can completely exonerate the doctor from fulfilling their informative obligation.[272]

Having said this, it appears necessary at this point to observe how a complex regulation of the informative duty for the doctor – which could to some extent represent a model also for our legislation – was introduced in Germany by the "law on the improvement of patients' rights (*Patientenrechtegesetz*) dated 20th February 2013 (which came into force on 26th February 2012).[273] The new paragraphs 630a – 630h Bgb, dedicate a specific discipline to the contract of healthcare (*Behandlunsgvertrag*). In particular, the new rulings assimilated respectively at paragraphs 630c and 630e Bgb, reflect the traditional distinction made by German doctrine between two categories of information: therapeutic information (*therapeutische Aufklärung*), with which the doctor clarifies the basic characteristics of the treatment for the patient, and self-determining information (*Selbstbestimmungsaufklärung*), which represents a condition for the manifestation by the patient of valid consent to (or refusal of) the medical treatment.[274] The main difference between these two types of informative duty lies in the fact that while the violation of the former is simply a non-fulfilment by the doctor of the healthcare contract, the infringement of the second determines, in addition to this consequence, a criminal offence.[275]

Moving on from the therapeutic information, it is necessary to report that paragraph 630c Bgb, at subparagraphs 2 and 3, foresees a wide-ranging duty to inform, establishing that the doctor has the duty not only to explain clearly to the patient, at the start of the treatment itself and, if necessary, during the course of treatment (in particular the diagnosis, the presumable development of the state of health, the therapy and the measures to be taken to improve the outcome of the treatment), but also to communicate the circumstances that could cause a medical error;

272 Court of Cassation, 20th August 2013, N. 19220 and Court of Cassation 27th November 2012, N. 20984, both in «Giurisprudenza Italiana», 2014, pages 275 *et seq.*, with note by F. Salerno, *Consenso informato in medicina e qualità soggettive del paziente*. In the second of these sentences it is stated that "there are therefore ways – that is the *quomodo* of the information that the doctor must supply – which may vary according to the patient's specific degree of knowledge; the consent, however, cannot be presumed, it must be effective".

273 *Gesetz zur Verbesserung der Rechte von Patientinnen und Patienten*, in «Bundesgesetzblatt», I, 2013, pages 277 *et seq.*

274 C. Katzenmeier, *Patientenrechte und Arzthaftung*, in E. Lorenz (ed.), «Karlsruher Forum 2013»*: Patientenrechte und Arzthaftung*, Karlsruhe, Karlsruhe Verlag Versicherungswirtschaft, 2014, page 20.

275 Cfr. L. Thole and M. Schanz, *Die Rechte der Patienten – transparent, verlässich und ausgewogen*, in «Rechtsdepesche für das Gesundheitswesen», 2013, page 66; J.F. Stagl, *La «legge sul miglioramento dei diritti del paziente» in Germania*, in «Nuova giurisprudenza civile commentata», II, 2014, page 38, who emphasises that the treatment of a patient without their consent constitutes a personal injury pursuant to paragraph 223 of the criminal code (*Strafgesetzbuch*), according to which the consent of the patient has an exonerative function.

additionally, if the doctor knows that the costs of the treatment are not covered by the national health service, they must inform the patient of the presumed cost before starting the treatment.

In this particular research, of most interest is the nature of the self-determining information, in fact, paragraph 630e Bgb appears of considerable importance, since on the one hand it sets out the *content* of this information and, on the other hand, it disciplines the *way in which* the information must be given.

With regard to the first aspect, the paragraph – in a similar way to Italian jurisprudence – foresees that the doctor is obliged to inform the patient of all the basic circumstances necessary to give consent. These generally concern the type of treatment chosen, its invasiveness, the procedures, the possible consequences, the risks, and the necessity, urgency, suitability of the treatment and, finally, the success rate of the diagnosis or the therapy, the alternative treatments and whether they involve other problems, risks and possibilities of recovery.

Instead, with regard to the methods of information, subparagraph 3 of paragraph 630e Bgb establishes three fundamental principles.

Firstly, the regulation emphasises the principle of *orality*, establishing that the information must necessarily be given verbally, even though the doctor has the possibility of referring to a written formula, which must also be given to the patient.[276] The German doctrine states that the printed informative material must complete and must never substitute the conversation between the doctor and the patient, which plays a central role in the informative process.[277] It is also important to emphasise that the rulings in question foresee an extension, compared with Italian legislation, of the subjects who can fulfil this obligation, including not only the doctor who will carry out the treatment, but all those who, in theory, have sufficient training to allow them to carry out said treatment.[278] This extension operated by the German legislator appears comprehensible since it certainly reflects the everyday situation, if we consider that often, in practice, the information is given to patients by different doctors, effectively determining the segmentation of the informative process.

Secondly, the ruling regulates the *timing of* the information process, foreseeing that information must be given with sufficient notice to allow the patient to take a pondered decision.[279] The introduction of a similar regulation in Italian legislation is to some extent desirable, since often

276 Paragraph 630e Bgb, subparagraph 2, N. 1, in fact states that «*Die Aufklärung muss 1. mündlich durch den Behandelnden oder durch eine Person erfolgen, die über die zur Durchführung der Maßnahme notwendige Befähigung verfügt; ergänzend kann auch auf Unterlagen Bezug genommen werden, die der Patient in Textform erhält*».

277 L. Thole, *Das Patientenrechtegesetz – Ziele der Politik*, in «Medizinrecht», 2013, 31, page 147; C. Katzenmeier, *Der Behandlungsvertrag – Neuer Vertragstypus im Bgb*, in «Neue Juristische Wochenschrift», 2013, page 818.

278 In fact, part of the German doctrine does not exclude that, on the basis of this ruling, the informative duty can be delegated to non-medical personnel: U. Preis and A. Schneider, *Das Patientenrechtegesetz – eine gelungene Kodifikation?*, in «Neue Zeitschrift für Sozialrecht», 2013, page 284.

279 Paragraph 630e Bgb, subparagraph 2, N. 2, states that *«[die Aufklärung muss] so rechtzeitig erfolgen, dass der Patient seine Entscheidung über die Einwilligung wohlüberlegt treffen kann»*.

– also in non-urgent situations, there is not sufficient time to inform the patient comprehensively due to the nature of the operation; also, given the hectic hospital routine, it appears quite difficult to dedicate sufficient time to informing the patients. Foreseeing at normative level the patients' need for sufficient time to consider their options before taking a decision could ensure that it becomes common practice to give the patient informative leaflets and the consent forms, after they have spoken to the doctor, leaving them time to read them at home or at the hospital and making a further appointment with the doctor to discuss any questions or doubts that may arise. In effect, this procedure has now been adopted on some wards.[280]

Finally, the third principle of paragraph 630 Bgb expressly states that the information must be given in a manner that is *comprehensible* to the patient,[281] in this aspect being substantially similar to the content of Article 33 of the Italian code of medical deontology, mentioned above.

However, although this requisite is theoretically required by both legislations, we have already noted that there are often, in daily hospital practice, serious operational limits that prevent the patients from fully understanding the information they are given. Amongst these are knowledge of scientific and legal terms and, even before this, for foreign patients, a poor level of understanding of Italian. The latter is an obstacle that it is difficult to overcome, both due to the lack of sufficient cultural mediators in the hospitals and due to the fact that the informed consent forms are only available in Italian.[282] This means that the requisite of *comprehensibility* abstractly required is often completely lacking in everyday hospital procedures. In the light of this, it is undoubtedly desirable that (instead of merely stating theoretically that a requisite of valid consent is the comprehensibility of the information) "corrective practices" be adopted to effectively guarantee it, for example, by ensuring the presence of a greater number of linguistic mediators in the hospitals.

3. *The capacity to validly express consent: the minor*

Moving on now to deal with the second of the requisites mentioned at the start of this chapter, it is known that, since Italian legislation lacks a general ruling on the capacity to express consent to medical treatment, the problem is that of establishing whether, in order to validly give

280 On this point the guidelines *Linee di indirizzo per la gestione del processo informativo e l'acquisizione del consenso informato 2011* drawn up by AReSS Piemonte for use in the regional and accredited healthcare structures appear to be relevant. The declared purposes are: "a) to define the essential content to be transmitted through written and/or oral information; b) to define the basic content for drawing up a specific procedure for acquiring informed consent; c) to encourage the mapping of clinical practices for which informed consent should be acquired in writing; d) to draw up an example of a standard form for acquiring informed consent and dissent from the patient; e) describe the flow of the informed consent process; f) support the healthcare professionals in the correct behaviour to be adopted in particular cases." *Ibidem* (page 12) it is, in fact, stated that the patient must be allowed sufficient time to express their consent, time in which they can consider the information they have received and if they wish consult their own doctor for clarification.

281 «[Die Aufklärung muss] für den Patienten verständlich sein».

282 Cfr. *supra*, chapter three.

consent, it is necessary to have capacity to exercise rights (full legal capacity, *capacità di agire*) or whether it is simply sufficient to have capacity for discernment (*capacità naturale*).

With reference to this question, although a first theory, stating that consent must be qualified as a legal act in the strictest sense, considered sufficient the *natural capacity* of the subject who expresses it,[283] the prevalent tendency in doctrine and in jurisprudence continues to be that, starting from the premise that the patient's consent should be traceable in the negotiation records and therefore considering applicable the general theory of legal transactions, for the consent to be valid, the patient must necessarily have full legal capacity. A logical corollary of this reconstruction is that when the patient does not legally have the capacity to exercise their rights, the consent to medical treatment must be expressed by their legal representative or guardian.[284]

Various arguments have been presented in support of this predominant theory. Above all, in the absence of a precise discipline on the capacity to express consent in the medical field, the general rule set out in Article 2 of the Italian Civil Code should be applicable. This states that "On attaining the age of majority the individual acquires full legal capacity to exercise those rights for which a different age is not specified." There is then, in Article 37 of the Italian code of medical deontology, a specific prevision dedicated to the legally incapable subject, which states, "The doctor, in the case of minors or patients not capable of discernment, shall acquire the informed consent or dissent from the legal representative." Finally, it has been shown that the solution in question makes it possible to avoid carrying out inquires case by case into the subject's effective capacity for discernment and thus to reach the highest level of legal certainty regarding the validity of the consent expressed by the patient.

Nonetheless, this opinion, according to which the subject who is legally incapable of discernment cannot manifest valid consent to treatment, has been increasingly criticised in recent years by those who have pointed out that the reference to the category of legal incapacity is wholly inadequate in this sector. It has, in fact, been emphasised that, on the one hand it does not take into account the peculiarities that each concrete situation may present, or the degree of autonomy that a subject legally incapable of discernment may possess and, on the other hand, it does not consider that the code on legal capacity is based on the acts of a patrimonial nature, while the consent to medical treatment involves other and highly personal assets (such as the right to self-determination and the right to health).

283 M. Dogliotti, *La potestà dei genitori e l'autonomia del minore*, in *Trattato di diritto civile e commerciale*, directed by A. Cicu and F. Messineo, Milano, Giuffrè, 2007, pages 297 *et seq.*

284 Cfr. L. Lenti, *Autodeterminazione e consenso nell'incapacità e capacità non completa. Il consenso informato ai trattamenti sanitari per i minorenni*, in L. Lenti, E. Palermo Fabris and P. Zatti (ed.), *I diritti in medicina*, in *Trattato di biodiritto*, directed by S. Rodotà and P. Zatti, Milano, Giuffrè, 2011, pages 417 *et seq.*

It is in fact necessary, if we consider in particular the case of minors, to emphasise that in the presence of 'juveniles' – that is subjects who have not yet come of age, but are capable of understanding the effects of their decisions[285] – the need to guarantee them some degree of decisional autonomy has been felt for some time and therefore it has been questioned whether their consent (or dissent) regarding treatment should in some way be taken into consideration. Therefore, part of the doctrine, adhering to the aforementioned opinion, according to which in order to validly express consent it is necessary to have the capacity to exercise one's rights, considers it not necessary to attribute any legal importance to the choices expressed by the minor, without distinguishing whether they lack capacity for discernment, or are a juvenile.

Nonetheless, according to another opinion, which is increasingly prevalent, it must be possible to say that minors with a capacity for discernment – capacity that must be ascertained case by case – should see their power to exercise (at least) those rights that express the fundamental rights of a human being, amongst which the manifestation of consent to medical treatment undoubtedly falls.[286]

Numerous normative rulings have been presented in support of this theory (both national and supranational) which, not only with reference to medical treatment, but also more amply in other sectors, show that the importance of the minor's wishes is recognized.[287] We can consider, just to give one example, the UN Convention on the Rights of the Child[288], which at article 12 says, "States Parties shall assure to the child who is capable of forming his or her own views the right to express those views freely in all matters affecting the child, the views of the child being given due weight in accordance with the age and maturity of the child." Also the rulings on matters regarding abortion, which foresee that within the first ninety days of pregnancy or in the case of emergencies this operation can be carried out on the request of the female minor, independently of the assent of the person(s) who exercise parental rights.[289] Article 35 of the code of medical deontology, states that "the doctor shall bear in adequate consideration the opinions expressed by the minor in all decisions that concern him or her"; or Article 250 Italian Civil Code which forbids the legal recognition of a fourteen-year-old child without their consent; or yet, Article 348 Italian Civil Code, which foresees that the minor who has attained twelve years of age must be heard before a guardian is chosen.[290] Later, the reform of the Italian laws on lines of descent dated 2012, in the new Article

285 Cfr. in particular, on the question of the capacity for discernment of minors G.C. Turri, *Autodeterminazione, trattamenti sanitari e minorenni*, in «Minorigiustizia», II, 2005, pages 125 *et seq.*

286 Cfr. L. Lenti, *Autodeterminazione e consenso nell'incapacità e capacità non completa*, op. cit., pages 420 *et seq.*; G. Casciaro and P. Santese, *Il consenso informato*, Milano, Giuffrè, 2012, page 276.

287 Cfr. C. Crocetta, *I diritti e l'autonomia decisionale del minore in ospedale*, Basel, Helbing Lichtenhahn, 2014, pages 314 *et seq*

288 New York, 20th November 1989, ratified with Italian Law N. 77 on 20th March 2003.

289 Cfr. Article 12 Italian Law N. 194, 22nd May 1978, *Norme per la tutela sociale della maternità e sull'interruzione volontaria della gravidanza.*

290 On this point see also E. Avezzù, *Il consenso del minore ai trattamenti sanitari. L'intervento del giudice e del pubblico ministero minorile*, Incontro di studi organizzato dal Consiglio Superiore della Magistratura, Roma, 9th-11th May 2011, page 4.

315-bis, paragraph 3 Italian Civil Code, was accompanied by a new ruling of a general nature which established that "the minor who has attained the age of twelve, and also younger if the capacity for discernment has been ascertained, has the right to be heard in all questions and procedures that concern them."[291]

Therefore, having examined all these considerations, which are undoubtedly the expression of the progressive valorisation of the minor in the context of the family and the society, the principle was established – although it is not yet recognised, given the lack of a specific legislative ruling in this sense – that the minor capable of discernment has the right to self-determination *in the fullest sense*, that is to say, the right to autonomously express informed consent to medical procedures. There is however a right to self-determination *in the weak sense,*[292] and this would mean that the minor had the right to be heard and involved in the procedure that led to the formation of the consent and that their wishes should be taken into account during the medical decision-making process, especially when it is a question of refusing the treatments, given the impossibility of practising the same therapies by force.[293]

The recent jurisprudential and doctrinal trend, explained above, appears undoubtedly preferable and more suited to the needs of medical practice than the theory that fixes the possibility of manifesting consent on attainment of majority, since this does not take into account that in everyday life the minor – in particular the adolescent – often demands information about the treatment or the therapy they are undergoing and expresses their wishes on the matter. The opinion that it is necessary to ascertain the maturity of the individual minor, on the other hand, has the merit of trying to respond to the needs of a differentiated tutelage of the minor and takes into account their specificity.

Having clarified this aspect, the fact remains that the subjects involved in the choice relating to the medical intervention on the minor are numerous: on the one hand there is the minor themselves, in relation to whom there is the problem of how to assess their natural capacity; then there are the parents, who not only have a duty but also a right to take care of the subject without capacity of discernment; finally, there is the doctor, who, from the moment the relationship of care begins, must answer for the health of a patient without full legal capacity.[294]

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291 Italian jurisprudence is of the opinion that this is a subjective right: see Court of Varese, 24th January 2013, in *Corriere del merito*, 2013, pages 619 e*t seq.* with note by B. Paparo, *L'ascolto del minore non è solo un dovere del giudice ma un diritto soggettivo del figlio.*

292 The expression is taken from G.C. Turri, *Diritto alla salute, minorenni e libertà di cura*, in «Questione giustizia», 1999, pages 473 *et seq.*

293 Starting from the premise that no medical treatment can be forced on a person capable of discernment, because this would be a violation of private rights, it is considered that the mature minor (juvenile) holds the right to oppose any form of enforced treatment involving their body. See Juvenile Court of Brescia, decree 22nd May 1999, in «Nuova giurisprudenza civile commentata», I, 2000, pages 204 *et seq.* with note by G. Grifasi, *Potestà dei genitori e scelte terapeutiche a tutela della salute dei figli minori*). On this question see also M. Piccinni, *Il consenso al trattamento medico del minore*, Padova, Cedam, 2007, pages 314 *et seq.*

294 M. Piccinni, *Il consenso al trattamento medico del minore*, op. cit., page 257.

The existence in practice of these many centres of interest have imposed on jurisprudence and doctrine the need to resolve the conflicts that have in some cases arisen between these figures. It is, therefore, opportune to consider the numerous doubts that the interpreters have had to face:

a) when consent must be given by both parents and when the consent of only one parent is sufficient, and what happens when the parents disagree about the medical decisions to be made on behalf of the minor;
b) what tools are available to protect the minor if the parents' wishes are in conflict with the therapeutic proposals made by the doctor in the best interests of the under-age patient;
c) precisely what is the role of the minor's wishes, since they must, as we said, be involved in the decision-making process.

The first question requires us, as we said, to establish who has the power/duty to give consent in the name of and on behalf of the minor, and that is whether both parents must make the decision, or whether the choice of one of them is sufficient.

The norm to be taken into consideration in answering this question is Article 320 Italian Civil Code, which states that "The parents jointly, or the parent that has exclusive parental rights, represent their children, born or to be born, until the age of majority or emancipation in exercising their civil rights." This article also states that "acts of ordinary administration may be carried out separately by each parent."

Therefore, the norm – which is now considered applicable also to safeguarding personal interests and not only assets – in cases where *both parents have parental responsibility*, distinguishes between ordinary and extraordinary administrative procedures, requiring the consent of both parents only for the latter, since, vice versa, it is sufficient for only one of the parents to give consent for ordinary administrative procedures.

Nevertheless, the question posed by the interpreters was how to establish what is meant by ordinary and extraordinary administrative procedures in the medical field. So, under this profile, the doctrine proposed to include in procedures of ordinary administration only the routine treatments (for example, medications or compulsory vaccinations) and to consider all other interventions extraordinary, so that in the majority of cases it will be necessary for both parents to give their consent.[295]

This said, it is nonetheless necessary to state that even when the consent can be expressed separately, it must still correspond to the directives and the intentions that the parents have established by agreement, by virtue of the principle of joint exercise of parental responsibility, to be

295 L. Lenti, *Autodeterminazione e consenso nell'incapacità e capacità non completa*, op. cit., pages 429 *et seq.*

found in paragraph 1 of Article 316 Italian Civil Code, which foresees that "Both parents have parental responsibility which is exercised jointly."[296]

Thus, it is necessary to ask ourselves how the *contrasts* that may arise between the parents (both with parental responsibility) regarding the therapeutic choices to be taken to safeguard the health of the minor can be resolved. On this matter the doctrine states that, since the decision regarding the health of the minor is to be included amongst the "questions of particular importance", it is possible to apply the procedure foreseen by paragraphs 2 and 3 of Article 316 Italian Civil Code, and that each parent therefore has the right to turn to the court, without particular formality, so that the judge decides what is in the best interests of the child, after hearing the child's opinions and wishes. Then, should the suggestions thus formulated not be accepted by the parents, the judge, on application from the parents, can attribute the decision-making power to the parent who, in the individual case, seems most suitable for the protection of the interests of the minor.[297]

Of course, while a similar procedure can certainly be applied in the case of non-urgent interventions, it is not appropriate in situations where the parents disagree about a therapeutic decision that must be taken urgently and cannot be postponed. In such a situation – since the legislative decree D. Lgs 154/2013 eliminated the norm that attributed to the father the power to adopt urgent and unpostponable measures every time there was an immediate danger for the child – it must be considered that, at least with reference to medical treatment, the decision to intervene in the most suitable way in order to safeguard the child's health is delegated to the doctor.

Having clarified this point with reference to the situation in which the responsibility is exercised by both parents, in the case where *only one parent* exclusively exercises this right (for example because a ruling has been issued that the parental responsibility of the other parent is null, or because one of them has been banned) the consent must undoubtedly be expressed only by the parent who exercises responsibility, pursuant to Article 317 Italian Civil Code, which in paragraph 1 states "In the case of the absence, incapacity or other impediment that makes it impossible for one of the parents to exercise parental responsibility, this shall be exercised exclusively by the other parent."

However, with regard to the identification of the subject who has the right to express consent, it is necessary to state that, in practice, the medical staff cannot effectively ascertain the juridical situation of each individual case involving the patient and the parents. The doctrine has

296 The doctrine has stated that if the consent is given illegitimately, that is by one parent without consulting the other parent, in cases where the decision must be taken jointly, the parent excluded can apply to the courts for a ruling that limits the other parent's parental responsibility, pursuant to Articles 316 and 333 Italian Civil Code (*ibidem,* page 433).

297 For a comprehensive examination of the procedure foreseen by Article 316 Italian Civil Code, see G. De Cristofaro, *Sub art. 316*, in G. Cian (ed.), *Commentario breve al codice civile*, Padova, Cedam, 2014, pages 392 *et seq.*

therefore tried to give criteria that will help the doctor to assess the validity of the consent, or dissent, expressed by the person who exercises parental responsibility.

The simplest case appears to be that in which the intervention is of a routine nature, since this – based on what we have just said – can be carried out by the doctor with the consent of only one parent.[298]

The case – in effect infrequent in practice – where the parent who expresses the consent holds the documentation that confirms that they are the exclusive representative of the minor is easy to resolve,[299] given that, even in these situations, the doctor could act in the presence of the sole consent of the parent who has been attributed guardianship, without having to ascertain that the decision has been agreed with the other parent.

Much more complex is the situation, relatively frequent, in which the parent does not have documentation of this kind. Therefore, in an emergency, the doctor can carry out the treatment even if there is the consent of only one parent, considering that, in such a situation, he or she can operate without consent, since the activity is in any case justified by the state of necessity.

However, if this urgency is such that the time necessary to acquire the consent of the other parent, where there is doubt, could expose the patient to greater risks for their health than those existing at the time of hospitalisation (for example the case of a child taken to A&E by one parent while the other is absent or cannot be reached), the doctrine considers that the doctor can legitimately act on the basis of the consent of the parent present, since the safeguarding of the child is a priority.[300]

Finally, if the treatment can be postponed, the medical staff can be considered completely certain of the legitimacy of their intervention only after attaining the consent of both parents. The doctrine, moreover, realising the difficulty for the doctor who has to ascertain the intentions of both the mother and the father each time, states that the medical personal can consider sufficient the consent of one of them in all cases where they can, in good faith, believe that the parents would agree, that is, in a situation that leads them to reasonably assume that the parent present is giving consent not only on their own behalf, but also on behalf of the other parent.[301]

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298 Moreover, also in this case it is necessary for the consent expressed by only one of the parents to correspond to the directives and the guidelines agreed by both: if this is not the case the intervention is not necessarily invalid or inefficacious, but it may lead the other parent to apply to the courts in accordance with Articles 316 and 333 Italian Civil Code (G. De Cristofaro, *Sub art 316,* op. cit, page 391).

299 It could be, for example, that this parent has a court order that attributes them the power to decide in the specific case or that grants them exclusive custody of the child.

300 Cfr. L. Lenti, *Autodeterminazione e consenso nell'incapacità e capacità non completa*, op. cit., page 436: "When there is an *urgency* – but not an *emergency*, that justifies in itself the immediate medical treatment also without consent – so that it is a risk for the doctor to remain inactive while awaiting the consent of the other parent, it is reasonable that he or she act on the basis of the consent of the parent present, in order to avoid the time spent waiting to warn or consult the other parent transforming the urgency into an emergency." On this matter, the guidelines *Linee di indirizzo per la gestione del processo informativo e l'acquisizione del consenso informato 2011*, op. cit., page 19 propose that, in order to overcome this phase, the parent can fill in and sign under their own responsibility the declaration in lieu of affidavit, stating that the other parent is absent or cannot be present.

301 L. Lenti, *Autodeterminazione e consenso nell'incapacità e capacità non completa*, op. cit., page 437.

With reference to the second problem mentioned, that is the case in which the child can ask for a guardian to be appointed because the parents do not act in his or her interest, for example refusing the therapy proposed by the doctor and suitable for improving the patient's state of health, it seems opportune to make a distinction between urgent interventions and long-term interventions.

In the urgent and necessary interventions, in the presence of dissent expressed by the parents and prejudicial for the minor, the doctor may, in fact – based on a general canon – overrule the parents' wishes.[302] This choice is, in effect, expressly foreseen by Article 37 of the code of medical deontology, which instructs the doctor to report this opposition to the competent authorities and, in any case, to carry out the essential and urgent treatment necessary for the child's health.

However, in the case of non-urgent or long-term treatments that, as such, require the cooperation of the minor, Italian legislation foresees that the juvenile court,[303] when applied to by the parents or by the public prosecutor,[304] shall take the "necessary measures" in the interest of the minor (in accordance with Articles 333 and 336 Italian Civil Code), or in the more serious cases, shall declare the forfeiture of parental responsibility (in accordance with Article 330 Italian Civil Code).

A measure of the first type was adopted, for example, in a situation where the parents of a little girl with leukaemia had interrupted the treatment with a probability of recovery equal to almost 80%, replacing it with an alternative method of treatment for which there was no scientific proof of efficacy. The Juvenile Court of Brescia, following a report from the public prosecutor based on a testimony given by the hospital, decided that the parents' decision involved a serious risk for the child's health and ordered that the treatment interrupted should be reinstated immediately.[305]

Lastly, to come to the third of the problems set out above, that is the role that should be attributed to the wishes of the juveniles in the medical decision-making process, it is above all necessary to observe that there are a series of treatments, legally standardised, that the doctor can carry out *only* on the request of the minor, including, for example: an abortion, when the judge has authorised the minor to decide whatever the opinion of the parents; treatment of serious urgencies; or therapeutic or rehabilitative treatments when the minor takes drugs.

Apart from these cases, which are considered compulsory, it is felt that the involvement of the minor in the decision-making process implies above all the obligation to inform them of the

302 M. Piccinni, *Il consenso al trattamento medico del minore*, op. cit., page 280.

303 On the question of the competence of the juvenile courts and the ordinary courts in matters of parental responsibility, following the reform of filiation see V. Montaruli, *Qualche punto fermo sullo scivoloso riparto di competenze tra tribunale ordinario e minorile?*, in «Corriere giuridico», 2015, pages 1227 *et seq.*

304 This claim can be made on the basis of a report from either the doctor (who under Article 37 of the code of medical deontology has the duty to report to the competent authority the parents' opposition to a treatment considered necessary) or from the minor in person.

305 Juvenile Court of Brescia, 28th December 1998, in «Nuova giurisprudenza civile commentata», I, 2000, pages 204 *et seq.* With note by G. Grifasi, *Potestà dei genitori e scelte terapeutiche a tutela della salute dei figli minori*.

therapy and the treatment proposed. Secondly, at least in the situations where there is no urgency, the doctor must try, where possible, to obtain the shared consent of the parents and the minor to the medical treatment proposed in the interests of the minor.

Should the attempt fail there may be various outcomes. If there is disagreement between the patient and the parents regarding the treatment to be carried out, which leads to the assent of the minor to the therapy proposed by the doctor and the simultaneous refusal by the parents, the doctor can only, once again, inform the public prosecutor's office at the juvenile court so that a ruling of limitation of parental responsibility (in accordance with Articles 333 and 336 Italian Civil Code) can be evaluated.

In the case where it is a juvenile who refuses the medical treatment, an increasing part of the jurisprudence states that also in this case the principle set out in Article 32 of the Italian Constitution must be applied. According to this Article, no medical treatment can be imposed on a person capable of discernment, who makes an informed choice to oppose the treatment, because otherwise personal harm would be caused under the specific profile of freedom of self-determination in the management of one's own body. This means that the minor capable of discernment could undoubtedly exercise *the right of veto* with regard to the treatment, that is, the right to refuse any form of compulsory treatment concerning their body.

This was the measure adopted, for example, by the Juvenile Court of Venezia when dealing with the case of a girl aged nine, affected by leukaemia with a declared probability of recovery equal to 70%, whose therapy was suspended in order to experiment the Multitherapy Di Bella. Despite the fact that this choice determined a considerable reduction in the patient's probability of recovery, the Court decided not to limit the parental responsibility, emphasising above all the fact that the child (who understood her illness and the point to which it had degenerated) opposed the therapy and therefore deciding that her wishes should be heard and taken into consideration.[306]

4. *(Continued) The interdicted subject and persons with a court appointed guardian*

If we now consider the patient who, despite having attained the age of majority, is still legally incapable of discernment, it appears opportune to analyse the situation regarding the interdicted subject and persons with a court appointed, in order to try to understand whether they, from a legal standpoint, have the capacity to autonomously express their consent or dissent to medical treatment.

306 Juvenile Court of Venezia, 7th October 1998, in «Diritto e Famiglia», 1999, page 690. For other cases, cfr. C. Crocetta, *I diritti e l'autonomia decisionale del minore in ospedale*, op.cit., pages 320 *et seq.*

With reference to the *interdicted* patient, it is necessary to separate the case in which they are, in addition to being legally incapable of discernment, also naturally incapable (that is not able to determine and understand their own choices) from those in which the patient is not able to act, although at least partially capable of discernment.

In the first of these two hypotheses, the fundamental problem that the interpreters of the law have set is that of establishing whether, in order to exercise fundamental rights, such as the right to health, the guardian or legal representative can operate on their behalf.

Italian jurisprudence has been dealing with the question since the well-known case of the young woman who had been in a permanent vegetative state for seventeen years, following a road accident, until artificial nutrition and hydration was interrupted, on the request of her father who was also her guardian, a procedure ruled to be admissible by the Italian Court of Cassation following a lengthy judicial process.

With the well-known sentence N. 21748/2010[307], in fact, the Court gave the question regarding the legitimation of the guardian to express the dissent to medical treatment on behalf of the interdicted and naturally incapacitated person a substantially positive response, stating that, if the substitution of the guardian or representative in exercising these very personal rights, such as the right to health and therapeutic self-determination, were to be excluded the person not capable of discernment would in effect be "deprived" of these rights, since they are not capable of exercising them autonomously.[308] However, at the same time the Court stated that the power of the guardian to act on behalf of the patient in a state of total incapacity with regard to their health is subject to a twofold limit: on the one hand, it must be in the strict interest of the patient; on the other hand it must conform to the patient's presumed wishes,[309] reconstructed on the basis of the lifestyle and the convictions expressed before falling into a state of unconsciousness.[310]

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307 Court of Cassation, 16th October 2007, N. 21748, published, amongst others, in *Nuova giurisprudenza civile commentata*, I, 2008, pages 83 *et seq*, con nota di A. Venchiarutti, *Stati vegetativi permanenti: scelte di cure e incapacità*.

308 The Court of Cassation thus reinterpreted the traditional conception of very personal acts as acts that cannot be carried out by subjects other than the person concerned (Cfr. A. Falzea, *Capacità (teoria generale)*, in *Enciclopedia del diritto*, Milano, Giuffrè, 1960, vol. VI, page 28; Court of Cassation., 12th October 2004, N. 20164, in *Foro italiano*, I, 2005, c. 3419). On this point see also M. Azzalini, *Tutela dell'identità del paziente incapace e rifiuto di cure: appunti sul caso Englaro*, in *Nuova giurisprudenza civile commentata*, II, 2008, page 336.

309 Both these limits to the representative power of the guardian have, in fact, a precise normative reference. The first is Article 6 of the Convention of Oviedo, which orders to correlate to the *benefice direct* of the person concerned the therapeutic choice made by the guardian. The second is Article 5 of the legislative decree D. Lgs. N. 211/2003, which orders that the consent of the guardian to clinical experimentation must correspond to the presumed wishes of the person not capable of discernment (Cfr. A. Costanzo, *L'osservatorio di merito. Amministrazione di sostegno*, in «Famiglia, Persone e Successioni», 2012, page 710).

310 The parameter of evaluation to which, according to the Supreme Court, the legal representative must refer when giving a voice to the person incapable of discernment must imitate that proposed by North American doctrine: on the one hand the *best interest*, in which the solution objectively most suited to the needs of the patient is adopted, on the other hand the *substituted judgement*, in which the substitute behaves in the way they believe that the person represented would have behaved if they had been capable of discernment. On this point see G. Gennari, *Esiste un consenso informato per l'incapace di intendere e di volere?*, in A. Farneti, M. Cucci and S. Scarpati (ed.), *Problemi di responsabilità sanitaria*, Milano, Giuffrè, 2007, page 79. Similar criteria are foreseen by the French *code de la santé publique* at Article R 4127-37, which states that the decisions on the interruption of artificial nutrition and respiration must be taken by the doctor responsible for the treatment, after completing a collective procedure, that takes into consideration the intentions previously expressed by the patient, particularly (but not exclusively) those included in the anticipatory directives, and the opinions expressed to the *personne de confiance*, who may also be nominated in writing, or by the family. The

Within this framework, the role of the doctor remains that of checking that the choices made by the guardian are not contrary to the interests of the patient.[311] Nonetheless, when a conflict that cannot be resolved arises between the doctor and the guardian about what is in the "best interests" of the patient, the doctor cannot prescind from the evaluation of the legal representative, but they can ask for the intervention of the legal authorities,[312] who, on the basis of Article 384 Italian Civil Code, have the power, after hearing the doctor, to suspend or remove the guardian who has abused their power or who has been shown to be incompetent in exercising this power.

In the second of the hypotheses mentioned above, that in which the interdicted patient maintains even a reduced capacity for self-determination, the question of who the subject legitimated to manifest the desire for treatment is (whether the interdicted person or their guardian) is even more complex. Although also in this case the possibility that it is the interdicted subject who expresses their consent or dissent to medical treatment seems to clash with the formal limit of the incapacity to exercise rights,[313] an increasing part of the interpreters – as we have seen for the subject who has not reached the age of majority – has considered that it is possible to draw from the systematic reading of a series of rulings enforced by Italian legislation the principle that consent to treatment should in fact come directly from the patient.[314]

Amongst these we can mention, for example, Article 13, paragraph 3, of Italian Law N. 194/1978 on the voluntary interruption of pregnancy, which requires the "confirmation" of the interdicted woman if the request was presented by the husband or the guardian; Article 5 of the legislative decree D. Lgs. N. 211/2003[315] on the question of clinical trials of medicines on adults not capable of validly expressing their consent, which also foresees the duty of the experimenter to take

compatibility of this procedure with Article 2 of the CEDU, which safeguards the right to life, was ratified by the European Court of Human Rights with the CEDU pronouncement, *Lambert and others v. France*, 5th June 2015 (on which C. Casonato, *Un diritto difficile. Il caso "Lambert" fra necessità e rischi*, in «Nuova giurisprudenza civile commentata», II, 2015, pages 489 *et seq.*).

311 See the ruling of the Italian Court of Cassation N. 21748, 16th October 2007, which states, "in cases where the patient is not capable of discernment, the medical duty finds its legitimacy in the constitutional principles inspired by solidarity, which allow and order the urgent interventions that are in the best interest of the patient to be carried out. However, even in such a situation, once the urgency of the intervention deriving from the state of necessity is over, the personalistic instance of the principle of informed consent and the principle of parity of treatment between individuals, whatever their capacity for discernment, requires the recreation of the dualism of the subjects in the process of elaborating medical decisions: between the doctor who must inform regarding the diagnosis and the therapeutic possibilities, and the patient who, through their guardian, can accept or refuse the treatments proposed."

312 M. Piccinni, *Autodeterminazione e consenso nell'incapacità e capacità non completa. Relazione terapeutica e consenso dell'adulto "incapace": dalla sostituzione al sostegno*, in L. Lenti, E. Palermo Fabris and P. Zatti (ed.), *I diritti in medicina*, op. cit., page 382.

313 According to an earlier trend, in fact, it was always the guardian who had the task of expressing informed consent on behalf of the patient, even if they were naturally capable. This theory was, in effect, based on Article 357 Italian Civil Code, drawn up for the minor, but extended by Article 424 Italian Civil Code to the interdicted, according to which "the guardian has the care of the person of the minor, represents them in exercising their rights and administers their assets." (Cfr. App. Milano, 31st December 1999 in *Foro Italiano*, I, 2000, paragraph 2022)"

314 See for example, Court of Reggio Emilia, 29th June 2011, in «Famiglia, Persone e Successioni», 2012, pages 714 *et seq.* where it is stated that, since the expression of consent to medical treatment does not fall within the area of a process of negotiation and since the interdicted person retains a residual power to decide about their own body, the guardian must verify whether there is a residual intention of the interdicted person, in order to understand whether they are capable of expressing aware and free consent, or whether the impairment of the psycho-physical sphere that afflicts them prevents them from making specific choices regarding treatment and care.

315 D. Lgs. N. 211, 24th June 2003, *Attuazione della direttiva 2001/20/CE relativa all'applicazione della buona pratica clinica nell'esecuzione delle sperimentazioni cliniche di medicinali per uso clinico*.

into account the "specific wishes of a subject in experimentation capable of forming their own opinion and […] of refusing to participate in the trial or to withdraw from the trial at any time"; but also – more generally – Article 11 of Italian Law N. 180/1978,[316] which recognises the active electoral capacity of persons who are interdicted due to mental illness. These rulings, according to this opinion (which appears substantially acceptable in its results), show how legal lack of capacity for discernment operates only with reference to rights of a patrimonial nature, while the interdicted person preserves the right to autonomously make decisions of a personal and existential nature, which includes the manifestation of consent or dissent to medical treatment.

Having discussed the interdicted person's capacity to express consent, and moving on, instead, to consider the condition of the person who has a *court appointed guardian*, it is necessary to state that also in this case the problem has emerged with regard to the possibility that the guardian could substitute the patient in the process designed to acquire consent to medical treatment even when the person preserves part of their autonomy, since otherwise it is necessary to extend to the person totally incapable of understanding the effects of their decisions the results reached for the interdicted by the jurisprudence formed after the aforementioned Englaro case.[317]

With reference to this problem, it is opportune to state that the question concerning the manifestation of informed consent by the guardian comes into play only when the tutelary judge, in the decree that nominates the guardian, has attributed to them the power to represent or assist the beneficiary also for acts that concern personal care.[318] Vice versa, if the nomination was made only to manage interests of a patrimonial nature, the principle that the beneficiary retains full capacity to exercise all rights in relation to which the representation or assistance has not been ordered persists, so that the person could legitimately express their consent to treatment, without any kind of limitation.[319]

So, while the guardian, in accordance with the decree of nomination, has the duty to pursue the personal interests of the person incapable of discrimination, trying to understand how the consent to medical treatment must be manifested, it is also possible to consider the ruling that orders the guardian to exercise their powers "taking into account the needs and aspirations of the

316 Italian Law N. 180, 13th May 1978, *Accertamenti e trattamenti sanitari volontari e obbligatori*.

317 This was, in fact, the solution adopted by the Court of Reggio Emilia, 25th July 2012, in «Famiglia, Persone e Successioni», 2012, pages 709 *et seq.*, which established that when the patient is not capable of autonomously expressing their opinion on the therapeutic procedures to be followed, it is the duty of the court appointed guardian first of all and of the tutelary judge to reconstruct the wishes of the patient regarding the therapeutic decisions.

318 Although in the past the question was quite controversial, it is now accepted that the guardian (or legal representative) can be nominated also to assist or represent the beneficiary in exercising rights of a personal nature. See on this point, S. Delle Monache, *Introduzione Capo I, Titolo XII, Libro I: § I-III*, in G. Cian (ed.), *Commentario breve al codice civile*, op. cit., page 500.

319 This principle is ratified by Article 409 Italian Civil Code, which states that "(1) The beneficiary preserves the capacity to exercise their rights for all acts that do not require the exclusive representation or assistance of the guardian. (2) The beneficiary of guardianship can in any case exercise the rights necessary to satisfy the needs of their daily life."

beneficiary" and that, where reference is made to the wishes of the person being safeguarded, the guardian appears particularly suited to operate precisely in the extra-patrimonial area.

Having said this, the requirement that the manifestation of the patients' wishes be duly considered in reaching a therapeutic decision undoubtedly means that the guardian cannot unilaterally exercise the power of representation merely in order to overcome the refusal of certain medical treatment manifested by the patient, where they are capable of taking autonomous decisions.[320]

On the other hand, in cases where a disagreement between the guardian and the beneficiary arises, regarding the possibility that the latter should undergo given medical treatment, Article 410 Italian Civil Code would seem to apply. This Article foresees that the beneficiary themselves, the spouse or the closest relatives and the public prosecutor can appeal to the tutelary judge asking for suitable provisions to be made. In such a situation, therefore, the tutelary judge could, for example, authorise the guardian to carry out the act despite the beneficiary's dissent or, vice versa, order the suspension of the guardian from their position.

Therefore, while in the area of guardianship, the tendency is to safeguard as far as possible the autonomy of the patient, it is opportune at this point to report some jurisprudential rulings regarding the abovementioned hypothesis (in which non-urgent treatment is to be carried out on a subject who is capable of understanding the effects of their choices) since they tend to differentiate between situations in which a court appointed guardian has been nominated and those in which no guardian has been nominated.

In the first case, jurisprudence has established that the public prosecutor, on indication of the doctor, cannot ask for a guardian to be nominated merely so that they can overrule the patient – who is weak, but still capable of discernment – in their manifestation of consent, because if this were to happen, "the guardian nominated, in the hypothesis of the patient's contrary wishes, could not in any case give valid consent to therapeutic treatments or rehabilitation suggested by the doctor."[321]

The Court of Modena came to the same conclusion, according to which respect for the patient's right to self-determination requires "support for the person, substituting them in the right/duty to express informed consent to therapeutic surgery exclusively when, having acquired all the elements, also scientific, it is certain that the dissent is based on a conscious critical evaluation of the situation."[322]

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320 See, for example, Court of Roma, 24th March 2010, in «Famiglia e diritto», 2010, pages 2021 *et seq.* with note by E. Falletti, *Amministrazione di sostegno e consenso informato a terapia sperimentale del beneficiario sofferente di Alzheimer*, which, in the decree nominating a guardian, starting from the premise that the intention expressed by the patient conformed to her genuine wishes, attributed to the guardian only the task of "supporting the beneficiary in the present expression of this will and, subsequently, given that the illness was a degenerative pathology, of informing the doctor of the beneficiary's wishes regarding the experimental treatment proposed."

321 Court of Torino, 22nd May 2004, in *www.personaedanno.it.*

322 Court of Modena, 28th June 2004, in *Famiglia e diritto*, 2005, pages 85 *et seq.*

On the other hand, in the case where the guardian has already been nominated to deal with (also or exclusively) needs of a personal nature, the autonomy of the patient is preserved, because the substitutive powers and power of assistance that the guardian can and must exercise must be considered not exclusive and they therefore have the duty to conform to the wishes of the patient, in the case where there is at least partial natural capacity. This decision is based on the previously mentioned Article 410 Italian Civil Code, which requires the guardian, in carrying out their duties, to take into account the needs and the aspirations of the beneficiary, on penalty of the possibility that the patient may ask for the guardianship to be revoked.[323]

In view of what we have said so far, it would seem possible to state that in the case of non-urgent interventions concerning a patient whose intellective faculties are not wholly compromised, the overwhelming trend in doctrine and jurisprudence seems to be that of imposing respect for the patient's wishes, when they have suffered limitations to their capacity to exercise their rights. This solution should be imposed for both the cases examined, for reasons that even precede the arguments set out above, pursuant to Article 32 of the Italian Constitution, which forbids compulsory healthcare except in cases foreseen by the law, since any intervention carried out against the wishes of the patient who is in fact capable of discernment should be considered such. Therefore, only when there is a founded doubt about the effective, free and unconditional will expressed by the interdicted person should the intervention of the tutelary judge be requested, so that the capacity for self-determination with regard to the treatment can be assessed.[324]

5. (*continued*) *Incapacitated persons*

It remains, to conclude, to examine the hypothesis in which the patient has not been either interdicted or assigned a guardian, but whose intellective or cognitive faculties are considerably reduced: for example the intoxicated patient, someone who is affected by serious depression, or, in some cases, the elderly.

In this situation the patient, although formally capable of exercising their rights, finds himself or herself in a situation of weakness, which means that their consent may not respect the minimum canons of awareness, and consequently of freedom, which are necessary if the consent is

323 Cfr. S. Delle Monache, *Sub art. 410*, in G. Cian (ed.), *Commentario breve al codice civile*, op. cit., page 516, who states that "with regard more specifically to the weight to be assigned to the dissent manifested by the beneficiary regarding the decisions taken by the guardian, from the first paragraph of the article in question we can see that […] such a dissent becomes a legal impediment to the act that the guardian intends to undertake, obliging the latter to bring the matter before the tutelary judge. Said consequence would occur, however, only in the case of dissent from a subject with sufficient capacity for discernment in relation to the act planned by the guardian."

324 See Article 44 implementing provisions Italian Civil Code, in which it is stated that the tutelary judge can summon the legal guardian, the deputy guardian, the trustee and/or the administrator in order to gather information, ask for clarification and evidence regarding the management of the guardianship, trust or administration, and give instructions concerning the moral and patrimonial interests of the minor or the beneficiary.

to be considered valid. In the light of these considerations, it is important to understand who should give the informed consent (or dissent) to non-urgent medical treatment in such cases.

Clearly, since the situation has not in effect been expressly disciplined by the legislator, part of the doctrine has stated that on the basis of a series of rulings scattered throughout Italian legislation – such as, for example, those that cover the duty to give food, or Article 77 Italian Civil Code – there exists a general principle according to which the position of the persons close to the patient assumes particular importance, nominating them *natural protectors*, who would in fact be (whatever the specific legal relationship) in a position to safeguard the patient, and according to which they not only have the duty to protect the person incapable of discernment, but also the power to adopt decisions regarding the care of their person.[325]

Moreover, it is necessary to note that the task of "protecting" the patient should fall first of all to the doctor, who is in a particularly strong position with regard to the patient and their treatment.

However, in the presence of a number of figures with a duty to protect the disabled patient, the question has arisen as to which subject is effectively legitimated to decide about treatment on their behalf. The doctrine[326] has answered this question by stating that the responsibility for the final decision – that is the responsibility that the solution proposed is the one that best meets the interests of the disabled person – should be taken by the doctor, since he or she is the "protector" with the competencies necessary for making the best choice. Nonetheless, the doctor also has a duty to involve the other natural protectors, so that they can confirm, on the one hand, the patient's wishes (either hypothetical or previously expressed)[327] and on the other hand, the effective value of the medical decision for that specific patient.[328]

At present this question is still to be resolved, since Italian legislation lacks a ruling comparable to that existing, for example, in France, which expressly foresees that if the person in question is not capable of expressing their wishes, the doctor, except in cases of necessity, cannot proceed without consulting a member of the family, or in any case, a person close to the patient.

6. *The actuality of consent or dissent to medical treatment*

325 M. Piccinni, *Autodeterminazione e consenso nell'incapacità e capacità non completa. Relazione terapeutica e consenso dell'adulto "incapace": dalla sostituzione al sostegno*, op. cit., page 384. These natural protectors are the members of the family, the cohabitant, or the subject who, for example, has temporarily taken charge of the incapacitated person.

326 M. De Acutis, C. Ebene and P. Zatti, *La cura degli interessi del malato*, Padova, Cedam, 1978, page 144, where it is stated that it is necessary "not to forget […] the profile for which, in effect, the protagonist of the medical *decisions* (and not only the medical *treatment*) remains *in primis* the doctor themselves."

327 U.G. Nannini, *Il consenso al trattamento medico. Presupposti teorici e applicazioni giurisprudenziali in Francia, Germania e Italia*, Milano, Giuffrè, 1989, page 349.

328 M. Piccinni, *Autodeterminazione e consenso nell'incapacità e capacità non completa. Relazione terapeutica e consenso dell'adulto "incapace": dalla sostituzione al sostegno*, op. cit., page 384.

In conclusion, it is opportune to briefly consider the requisite of *actuality* in consent and dissent to medical treatment.

Italian jurisprudence has been forced to emphasise this premise, amongst other things, when deciding on the validity of the dissent manifested above all by Jehovah's Witnesses who, when unconscious, have expressed their refusal of life-saving blood transfusions by means of a card saying "no blood".

The question that obviously arises in this circumstance is whether this dissent – both formally and chronologically – can be considered valid and whether, consequently, the doctor must abstain from carrying out a transfusion or, vice versa, ignoring the wishes of the patient, is legitimated in carrying out the operation.

To be precise, on this point it is not possible to identify a truly majoritarian opinion in the Italian doctrine and jurisprudence; therefore, it appears opportune to present the two opposing solutions advanced on the matter.

A first orientation – widespread above all in jurisprudence – considers the transfusion carried out against the wishes of the patient legitimate when there is a serious and irreparable danger for their physical well-being. On this matter, we have noted, in particular, how in this circumstance it is necessary to carefully verify whether the dissent is manifested in a clear, informed and current manner. In the case in point, the refusal of the transfusion lacks the requisite of actuality and that of information, being expressed at a time when the patient was not aware of the seriousness of their clinical situation. Therefore, when it is impossible to verify the "ongoing nature" of the religious convictions in the face of a sudden danger for health, the doctor should be able to carry out the treatment necessary to save the life of the patient without risking a liability case and, above all, being able to invoke the legitimate state of necessity.[329]

However, this first guideline is opposed by another, which, leveraging the fact that there is no legal obligation to healthcare in Italian legislation, considers that the patient's right to self-determination should always prevail over the doctor's duty to intervene.

The supporters of this second hypothesis state, above all, that the solution presented contrasts with the interpretative results reached by jurisprudence in the Englaro case previously mentioned, since to consider the refusal of a patient in coma valid, the jurisprudence – as we said before – in that specific case considered sufficient a much less explicit and actual expression of will

329 Cfr., for example, Court of Cassation, 23rd February 2007, N. 4211, in «Danno e responsabilità», 2008, pages 27 *et. seq.* with a note by G. Guerra, *Il dissenso alla trasfusione di sangue per motivi religiosi* and Court of Cassation, 15th September 2008, N. 23676, in «Nuova giurisprudenza civile commentata»,, I, 2009, pages 170 *et seq.*, with note by G. Cricenti, *Il cosiddetto dissenso informato*, who states that "in a situation of serious and immediate threat to the life of the patient, the dissent should be an expressed, unequivocal, actual, informed manifestation of intent. That is, the patient must express not an abstractly hypothetical manifestation, but an effectively ascertained one; an intention not merely programmatic, but specific; a knowledge of the facts that is not merely "ideological", but the fruit of specific information with regard to their medical situation.

than that contained in the phrase "no blood", so that it would be necessary to clarify the reasons for which, although in two very similar situations, the hypothesis of the Jehovah's Witness's anticipatory directive should not be considered effective.

Furthermore, it has been shown that the jurisprudential opinion appears to contrast with both the ruling in Article 9 of the Oviedo Convention,[330] according to which "the previously expressed wishes relating to a medical intervention by a patient who is not, at the time of the intervention, in a state to express his or her wishes shall be taken into account" and with the guideline expressed by the national committee for bioethics, which in the document entitled *Dichiarazioni anticipate di trattamento*[331] (anticipatory directives regarding treatment) stated that "it is preferable to allow the indications expressed by the person in question, when they were still in possession of their faculties, and therefore presumably coherent with their concept of life, to prevail, rather than ignoring them by appealing to the possibility of a presumed (but impossible to prove) change of opinion in the time since they lost consciousness.[332] In the light of all these considerations, this guideline states therefore that, in the presence of a "blood card", the intention of the Jehovah's Witness to refuse the transfusion should be considered still actual and remain worthy of respect until the patient themselves unequivocally changes their mind.

Chapter Seven

Civil liability for infringement of the rule of informed consent

1. *The juridical nature of the liability of the doctor for omitted or insufficient informed consent*

From the previous chapters it was clear that – apart from the exceptions that will be examined below – no medical treatment can be given without previously acquiring the informed consent of the patient.

Therefore, since the informed consent of the patient to the treatment represents an assumption of the lawfulness of said treatment, it is clear that the doctor could be considered liable

330 Although Italy is not yet part of the Convention, since the legislative decrees with further rulings necessary for adapting the Italian juridical system to the norms of the Convention were not passed (see Article 3, Italian Law N. 145/2001) and given that the ratification measures were not filed with the European Council (Cfr. C. Casonato and F. Cembrani, *Il rapporto terapeutico nell'orizzonte del diritto*, in L. Lenti, E. Palermo Fabris and P. Zatti (ed.), *I diritti in medicina*, op. cit., page 56), the jurisprudence has established that this international source can and must be used in the exegesis of internal norms, in order to guarantee a reading as far as possible in line with the content of the Convention (Court of Cassation, 4th October 2007, N. 21748, in «Corriere giuridico», 2007, pages 1676 *et. seq.*, with note by E. Calò, *La Cassazione "vara" il testamento biologico*).

331 Comitato Nazionale per la Bioetica, *Dichiarazioni anticipate di trattamento*, 18th December 2003.

332 G. Facci, *I medici, i Testimoni di Geova e le trasfusioni di sangue*, in *Responsabilità civile*, 2006, pages 938 *et seq.*

not only when they carry out treatment or therapy in a negligent or an incompetent manner,[333] but also when, although the medical treatment was carried out correctly from a technical standpoint, they neglect to acquire prior informed consent from the patient.

Before examining the assumptions and the content of liability due to omitted or insufficient informed consent, it is necessary to make a few brief comments regarding the *juridical nature* of said liability, since the reconstruction adopted by the jurisprudence and by the doctrine has strongly conditioned the regime applied, above all with regard to the sharing between the parties of the burden of proof.

Therefore, on the nature of the liability of the doctor we have seen considerable debate, which has concerned the qualification as 'tort liability' or 'contractual liability' first the medical liability overall, and then, within this, the liability that derives specifically from the infringement of the duty to inform.

With reference to medical liability in general, the traditional opinion, while it pacifically qualifies as *contractual* the liability of the doctor operating as a private individual, vice versa tended to consider the liability of the doctor employed by a hospital *a tort liability*.[334] The basis of this reconstruction is that the doctor is extraneous to the contract established, following examination at the hospital or hospitalisation of the patient, between the patient and the hospital as an institution. This contract is traditionally qualified as an atypical contract of hospitalisation, having as its object not only procedures of a strictly therapeutic and diagnostic nature, but also the provision of equipment, instruments and furnishings.[335] Given, therefore, the lack of an obligatory direct relationship between the patient and the doctor, the negligence of the professional in carrying out their work could only supplement – according to this first guideline – a tort pursuant to Article 2043 Italian Civil Code.

However, at the end of the nineties, jurisprudence inaugurated a different interpretative tendency, which was not contradicted for some time, and which tended to consider the liability of the doctor employed by a hospital as *contractual*.[336] The classification of medical liability within this specific form of liability was justified, not so much by a pre-existing obligation of treatment (in

333 On liability for medical malpractice, also pursuant to Italian Law N. 189, November 8th 2012 (known as *Legge Balduzzi*), cfr. recently, M. Bilancetti and F. Bilancetti, *La responsabilità penale e civile del medico*, Padova, Cedam, 2013, *passim*; M. Paladini, *Linee guida, buone pratiche e quantificazione del danno nella c.d. legge Balduzzi*, in «Danno e responsabilità», 2015, pages *881 et seq.*; A. Panti *et al.*, *«Decreto Balduzzi» e responsabilità del medico: un traguardo raggiunto o un quadro in movimento?*, in «Diritto penale e processuale», 2015, pages 735 *et seq.*; G. Visintini, *La colpa medica nella responsabilità civile*, in «Contratto e impresa», 2015, pages 530 *et seq.*

334 Cfr., *ex multis*, Italian Court of Cassation, N. 2428, March 26th 1990, in «Giurisprudenza italiana», I, 1, 1991, c. 600, with note by D. Carusi, *Responsabilità del medico, prestazione professionale di speciale difficoltà e danno alla persona*; Italian Court of Cassation., N. 2750, March 13th 1998, in «Responsabilità civile e previdenza», 1999, pages 272 *et seq.*

335 A. Thiene, *La Cassazione ammette la configurabilità di un rapporto obbligatorio senza obbligo primario di prestazione*, in «Nuova giurisprudenza civile commentata», I, 2000, page 345.

336 For an analysis of the factors that have determined this evolution in the field of medical liability cfr. V. Zeno-Zencovich, *Una commedia degli errori? La responsabilità medica fra illecito e inadempimento*, in «Rivista di diritto civile», 2008, pages 297 *et seq.*

effect never assumed by the medical staff with regard to the patient), but rather by the infringement of the duty of care for the safety of others (obblighi di protezione), which is based on the patients' trust, giventhe professional *status* of the doctor. According to this guideline, therefore, when a patient entrusts themselves to a doctor for medical treatment, a 'qualified social contract'[337] is reached between the doctor and the patient, which, pursuant to Article 1173 Italian Civil Code, generates obligations, which if not fulfilled, give rise to liability specifically of a contractual nature.[338]

The establishment of the theory set out above has therefore led to the application of all the rules existing in the field of contractual responsibility also to medical liability, including, in particular, those drawn up by the jurisprudence of legitimacy with reference to the sharing of the burden of proof. In effect, this implies that, while it is the duty of the patient/the person harmed to prove the existence of the contract (the so-called 'social contract') with the doctor, the damage caused and the causal link; the doctor only has the duty to prove that there was no non-fulfilment of said contract, or that in any case there was no causal link between his/her actions and the damage suffered by the patient.[339]

Hence, once the liability of the hospital doctor towards the patient was identified as contractual, the jurisprudence and the doctrine also asked themselves whether the same regime of liability could be valid also for the specific case in which the doctor infringed the obligation to inform the patient in order to acquire informed consent to a given treatment.

With reference to this question, previous jurisprudence (based on the consideration that the obligation to inform existed only in the phase *prior* to the consent to medical treatment) stated that the lack of information gave rise to a liability of a pre-contractual type (where – as is known – it is mainly framed by the interpreters in the area of tort liability), since it supplemented a hypothesis of infringement of the duty to behave in good faith during negotiations (Article 1337 Italian Civil Code).[340]

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337 For a criticism of the theory of the so-called 'social contract', cfr. A. Zaccaria, *Der aufhaltsame Aufstieg des sozialen Kontakts. La resistibile ascesa del «contatto sociale»*, in «Rivista di diritto civile», 2013, pages 77 *et seq.*

338 This approach was inaugurated with the ruling of the Italian Court of Cassation, N. 589, January 22nd 1999, published amongst others in «Danno e responsabilità», 1999, pages 294 *et seq.*, with note by V. Carbone, *La responsabilità del medico ospedaliero come responsabilità da contatto*; in «Corriere giuridico», 1999, pages 441 *et seq.*, with note by A. Di Majo, *L'obbligazione senza prestazione approda in Cassazione*; in «Contratti», 1999, pages 1007 *et seq.*; in «Responsabilità civile e previdenza», 1999, pages 661 *et seq.*, with note by M. Forziati, *La responsabilità contrattuale del medico dipendente: il contatto sociale conquista la Cassazione*.

339 These rules, established in general by the Italian Court of Cassation N. 13533, October 30th 2001, commented amongst others by G. Villa, *Onere della prova, inadempimento e criteri di razionalità economica*, in «Rivista di diritto civile», II, 2002, pages 707 *et seq.*, were then extended to the sector of medical liability by the Italian Court of Cassation N. 577, January 11th 2008, in «Responsabilità civile», 2008, pages 397 *et seq.*, with note by R. Calvo, *Diritti del paziente, «onus probandi» e responsabilità della struttura sanitaria*.

340 Italian Court of Cassation, N. 10014, November 25th 1994, in «Nuova giurisprudenza civile commentata», I, 1995, pages 937 *et seq.*, with note by G. Ferrando, *Chirurgia estetica, «consenso informato» del paziente e responsabilità del medico*; Italian Court of Cassation, September N. 9617, 10th 1999, in «Danno e responsabilità», 2000, page 730, with note by R. Natoli, *Consenso informato e obbligazioni di risultato tra esigenze di «compensation» ed esigenze di «deterrence»*.

The majority of the interpreters, however, tend to consider medical liability an infringement of the duty to inform, that is to say, a liability of a contractual nature, since the explanation to the patient of the methods and the consequences of the therapy or the procedure falls within the executive phase of the medical treatment which began at the time of the diagnosis, and therefore constitutes an obligation typical of the contract stipulated by the medical institution with the patient, that is, an obligation in any case inherent to the so-called social contract that the jurisprudence – as already mentioned – generally sees as the basis for the obligations of the doctor who works in the aforesaid medical institution.[341]

This classification of the liability of doctors due to omitted informed consent differs, moreover, from that which was recently accepted by the French *Cour de Cassation* in a well-known ruling of June 2010.[342] In this ruling the Court, in identifying the basis of this liability in Article 1382 *Code Civil*, and that is in the key norm on matters of tort liability,[343] rather than, as previously occurred, in Article 1147 *Code Civil*, which disciplines contractual liability,[344] has been seen to base the infringement of the duty to inform within the former, that is to classify it as a *responsabilté délictuelle,*[345] or, according to part of the doctrine, *quasi-délictuelle*,[346] descending from the harm to the fundamental right consisting in safeguarding the dignity of the human being.[347]

It is partly also in the light of these interpretative tendencies in French jurisprudence that the attempt made by Italian legislators to return to a tort regime of medical liability appears not wholly preposterous. In fact, it is necessary to observe that, in Italian legal procedures, the framework relating to medical liability briefly set out above, had remained largely unaltered until the Law N. 189, November 8th 2012 came into force (the so-called *Legge Balduzzi*). This law, which specified in Article 3 regarding the liability of the medical personnel, the "obligation set out in Article 2043

341 Cfr. C. Castronovo, *Profili della responsabilità medica*, in *Studi in onore di Pietro Rescigno*, vol. V, *Responsabilità civile e tutela dei diritti*, Milano, Giuffrè, 1998, page 127; R. Omodei Salè, *La responsabilità civile del medico per trattamento sanitario arbitrario*, in «www.juscivile.it», 12, 2015, page 800.

342 Cour de Cassation, June 28th 2010, Bull. Civ. I, N. 20. For a comment cfr. P. Sargos, *Deux arrêts «historiques» en matière de responsabilité médicale générale et de responsabilité particulière liée au manquement d'un médecin à son devoir d'information*, in «Dalloz», 2010, pages 1522 *et seq.*

343 The article states that: «*Tout fait quelconque de l'homme, qui cause à autrui un dommage, oblige celui par la faute duquel il est arrivé à le réparer.*»

344 Article 1147 of the Code Civil states: «*Le débiteur est condamné, s'il y a lieu, au paiement de dommages et intérêts, soit à raison de l'inexécution de l'obligation, soit à raison du retard dans l'exécution, toutes les fois qu'il ne justifie pas que l'inexécution provient d'une cause étrangère qui ne peut lui être imputée, encore qu'il n'y ait aucune mauvaise foi de sa part*».

345 S. Porchy-Simon, *Revirement de la Cour de cassation quant à la sanction du défaut d'information du patient*, in «La Semaine Juridique Edition Générale», 2010, page 788.

346 J.S. Borghetti, *La sanction de la violation par le médecin de son devoir d'information, ou les limites de la réparation intégrale et systématique*, in «Revue des contrats», 2010, page 1236, according to whom the reference made by the Court to Article 1382 traces the medical liability to legal liability, deriving from the infringement of the doctor's duty to inform, pursuant to Article L 1142-1 Csp (*Code de la Santé Publique*), which in paragraph 1 foresees that : «*Hors le cas où leur responsabilité est encourue en raison d'un défaut d'un produit de santé, les professionnels de santé mentionnés à la quatrième partie du présent code, ainsi que tout établissement, service ou organisme dans lesquels sont réalisés des actes individuels de prévention, de diagnostic ou de soins ne sont responsables des conséquences dommageables d'actes de prévention, de diagnostic ou de soins qu'en cas de faute*».

347 Cfr. F. G'sell-Macrez, *Medical Malpractice and Compensation in France. Part I: The French Rules of Medical Liability since the Patients' Rights Law of March 4, 2002*, in K. Oliphant and R. Wright (ed.), *Medical Malpractice and Compensation in Global Perspective*, Berlin-Boston, De Gruyter, 2013, page 139.

Italian Civil Code,"[348] has had the effect of restarting the debate on the nature (contractual or extra-contractual) of medical liability, including, therefore, that deriving from omitted or insufficient informed consent.[349]

In fact, the law has been interpreted by some as an expression of a refusal by the legislator of the theory of the so-called social contract of jurisprudence and as a return to the tendency to say that for the doctor to respond in the civil courts, it is necessary to show that there was negligence or incompetence, or in other words, malpractice, pursuant to Article 2043 Italian Civil Code.[350] According to an opposing and majority view, on the other hand, despite the reference made by the *Legge Balduzzi* to Article 2043 Italian Civil Code – a key norm in matters of tort liability – a reference that should in fact be seen in a non-technical sense, as a generic reference to *all* the kinds of civil liabilities, and therefore also to contractual liability alone, or in alternative to the extra-contractual one, according to the general principle of the cumulation of the two remedies.[351]

In view of the uncertainty that still exists regarding this extremely delicate question, we can only present the arguments that could support the thesis, which seems preferable, according to which the *Legge Balduzzi* expresses a desire to return to the (less serious) extra-contractual regime of liability of the hospital doctor. The literal tenor of the regulation certainly militates in favour of this solution, since the reference to the same made by Article 2043 Italian Civil Code can certainly not be interpreted, according to the principle of conservation of the law,[352] as a mere *oversight* of the legislator, and as such unsuitable to modify the jurisprudential formulation that was consolidated from the nineties onwards and which aims to attribute the liability of the hospital doctor to contractual liability.

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348 Article 3 specifically foresees that "Medical personnel who in the line of their duties follow the guidelines and good practice accredited by the scientific community do not answer under criminal law for minor negligence. In such cases, however, Article 2043 Italian Civil Code applies. The judge, also in determining compensation for damages, shall bear in mind the behaviour as at the first paragraph."

349 For an examination of the jurisprudential evolution on the nature of medical liability cfr. A. Borretta, *Responsabilità medica da omesso o insufficiente consenso informato e onere della prova*, in «Responsabilità civile e previdenza», 2014, pages 898 *et seq.*

350 Court of Torino, February 26th 2013 and Court of Varese, November 26th 2012, both in «Danno e responsabilità», 2013, pages 367 et seq., with note by V. Carbone, *La responsabilità del medico pubblico dopo la legge Balduzzi*; Court of Milano, June 14th 2014 and Court of Milano, July 17th 2014, both in «Danno e responsabilità», 2015, pages 47 *et seq.*, with note by L. Mattina, *«Legge Balduzzi»: diventa extracontrattuale la responsabilità del medico?*; G. Visintini, *La colpa medica nella responsabilità civile*, in «Contratto e impresa», 2015, page 532.

351 This second theory was supported, for example, by the Italian Court of Cassation N. 8940, April 17th 2017, in «Responsabilità civile e previdenza», 2014, page 803; Italian Court of Cassation, N. 4030 February 19th 2013, and Court of Arezzo, February 14th 2013, both in «Danno e responsabilità», 2013, pages 367 *et seq*, with note by V. Carbone, *La responsabilità del medico pubblico dopo la legge Balduzzi*; Court of Enna, 18 maggio 2013, N. 252, in «Danno e responsabilità», 2014, pages 74 *et seq.*, with note by D. Zorzit, *La responsabilità del medico alla luce del «Decreto Balduzzi»: un viaggio tra nuovi e vecchi scenari*; Court of Brindisi, July 18th 2014, in «Danno e responsabilità», 2015, pages 47 *et seq.*, with note by L. Mattina, *«Legge Balduzzi»: diventa extracontrattuale la responsabilità del medico?*; B. Grazzini, *Responsabilità dell'esercente le professioni sanitarie e rischio clinico nel c.d. «Decreto Balduzzi»*, in «Corriere giuridico», 2013, pages 1238 *et seq.*; M. Faccioli, *La quantificazione del risarcimento del danno derivante da responsabilità medica dopo l'avvento della legge Balduzzi*, in «Nuova giurisprudenza civile commentata», II, 2014, pages 102 *et seq.*

352 For the application of the principle of conservation also in matters of interpretation of the legal norms cfr., amongst others, C. Grassetti, item *Conservazione (Principio di)*, in *Enciclopedia del diritto*, Milano, Giuffrè, 1961, vol. IX, page 173.

Essentially, the effectiveness of this interpretative solution is confirmed also by the observation that the declared intent of the legislator in adopting this legislative measure was that of "containing the phenomenon of so-called defensive medicine"[353] and "promoting the development of the country through a higher level of safeguards for health" through the adoption of a regime of liability, both criminal and civil, that was less severe for the doctors and the hospitals: an intent which, in the option between the reconstruction of this liability as, alternatively, contractual or extra-contractual, should undoubtedly lead the interpreter to prefer the second.

Finally, also the new bill *Disposizioni in materia di responsabilità professionale del personale sanitario*[354] (guidelines on professional liability for medical personnel) seems to confirm the intention of the legislator to return to the regime of extra-contractual liability of the hospital doctor, in force prior to the previously mentioned jurisprudential changeover, expressly stating at Article 7 that the person who exercises the medical profession within a public or private medical institution, or under contract to the national health service "responds for their behaviour in accordance with Article 2043 Italian Civil Code."

2. *The civil liability of the doctor: damage to health*

Thus, having stated the juridical nature of the doctor's liability for malpractice, it is now necessary to further analyse the types of damage that can derive from the omitted or inadequate information for the patient.

As we mentioned in the first chapter, constitutional jurisprudence has long stated that, in Italian law, informed consent constitutes the synthesis of two fundamental rights of the person: firstly, the right to health (safeguarded by Article 32 of the Constitution, which establishes in particular that, "no one can be forced to undergo medical treatment, except where legally required") and secondly, the right to self-determination (recognised by Article 13 of the Constitution, which states that "personal freedom is inviolable").[355] Starting from this assumption, the doctrine has therefore emphasised that the non-observance of the obligation to acquire the informed consent of the patient could harm both these rights, causing both damage to the health and harm due to the violation of the right to self-determination,[356] which we will deal with in more detail in the next paragraph.

353 Cfr. illustrative report on the D. L: N. 158/2012.

354 The bill was approved by the Italian parliament on January 28th 2016.

355 Italian Constitutional Court N. 438, December 23rd 2008, in «Giurisprudenza italiana», 2009, pages 2382 *et seq.* in «Giurisprudenza costituzionale», 2008, pages 4945 *et seq.*, with note by R. Balduzzi and D. Paris, *Corte costituzionale e consenso informato tra diritti fondamentali e ripartizione delle competenze legislative*, by D. Morana, *A proposito del fondamento costituzionale per il «consenso informato» ai trattamenti sanitari: considerazioni a margine della sent. n. 438 del 2008 della Corte costituzionale*, and by C. Coraggio, *Il consenso informato: alla ricerca dei principi fondamentali della legislazione statale*.

356 G. Miotto, *La «struttura» dei danni da omissione del «consenso informato»*, in «Diritto civile contemporaneo», July 21st 2015, page 6; R. Omodei Salè, *La responsabilità civile del medico per trattamento sanitario arbitrario*, *op. cit.*, page 801.

Starting precisely from the first of the two prejudices mentioned, it is necessary to state that they occur when the medical procedures, carried out without informed consent, although respecting the *leges artis*, have caused a worsening of the patient's state of health.

In reality, although some interpreters state that the incomplete information supplied by the doctor *automatically* gives the patient the right to be compensated for the damage to their health, even if the doctor is not guilty of incompetence;[357] the thesis that considers it essential to ascertain each time the link between the omitted (or incomplete) information and the harm to the patient's health seems undoubtedly preferable.[358] This would avoid situations where the patient's claim not to have been adequately informed could become an excuse for obtaining compensation not otherwise due to him, since the doctor acted according to professional standards.

More precisely, under this profile it is stated that, since the omission is illegal (lack of information for the patient) in order to ascertain whether there is a causal link, it is necessary to proceed according to specific rules for this type of offence and therefore carry out an counterfactual, hypothetical inquiry, asking whether, if the patient had been fully informed, they would have agreed to the treatment. Only when it is shown that the patient, where informed, would have opposed the procedure and would therefore have avoided the events that effectively caused the damage to their health (that is the procedure itself), is it possible to conclude that the lack of information was in effect the cause of the damage.[359]

The need for the interpreter to carry out the aforementioned verification was emphasised with particular force by a sentence of the Italian Court of Cassation of 2010, which stated that:

[…] it is necessary to ask, as in every hypothetical, counterfactual assessment, whether the omitted conduct could have avoided the event if it had taken place: whether, that is, the fulfilment by the doctor of his informative duties would have produced the effect of the non-execution of the surgical operation from which, without blame, the pathological condition derived. And since the surgical operation would not have been carried out only if the patient had refused it, in order to identify the causal link between the infringement of the right to self-determination of the patient (caused by the doctor's omitted duty to inform) and the harm to the patient's health due to the, blameless, negative consequences of the operation […], it must be possible to state that the patient would have refused the operation had they been adequately

357 Cfr. Court of Cassation N. 9374, September 24th 1997, in «Rivista Italiana di Medicina Legale», 1998, pages 821 *et seq*., with note by F. Introna, *Consenso informato e rifiuto ragionato. L'informazione deve essere dettagliata o sommaria?*: "The lack of request for consent constitutes an autonomous source of liability should the procedure have a harmful or even mortal outcome for the patient, and the fact that the procedure itself was carried out in the correct manner has no effect on the matter" and subsequently, Italian Court of Cassation N. 5444, March 14th 2006, in «Corriere giuridico», 2006, pages 1243 *et seq*., with note by S. Meani, *Sul danno risarcibile in caso di mancato consenso all'intervento eseguito correttamente*. The assumption on which this conclusion is based is that since the procedure, carried out without the prior consent of the patient, is illegal, the doctor should bear all the harmful consequences deriving from it.

358 Cfr., for example, U. Carnevali, *Omessa informazione da parte del medico, danno da trattamento terapeutico e ipotetica scelta del paziente*, in «Responsabilità civile e previdenza», 2010, pages 2181 *et seq.*

359 *Ibidem*; E. Palmerini, *Il danno non patrimoniale da violazione del consenso informato*, in E. Navarretta (ed.), *Il danno non patrimoniale. Principi, regole e tabelle per la liquidazione*, Milano, Giuffrè, 2010, pages 535 *et seq.*

informed, since otherwise the positive behaviour omitted by the doctor (information, for the purpose of acquiring informed consent) would not in any case have avoided the event (damage to health).[360]

Having said this, the further aspects regarding the question of compensation for damage to health on which we must linger concern, *a*) the sharing between the parties of the burden of proof regarding the causal link between the behaviour and the harm and *b*) the criteria to be followed when compensating damage of this kind.

The first of these interrogatives can be answered quite swiftly, if we consider that – as we said – the liability of the doctor is now considered mainly a contractual liability and that the jurisprudence agrees that, within this liability, it is the creditor who has accused the other party of non-fulfilment who must show the existence of the contract (the so-called social contract) with the doctor, demonstrate the harm caused and the causal link between the non-fulfilment and the harm, while the doctor must prove that there was no non-fulfilment.[361]

That it is, therefore, the patient who must prove the causal link (i.e. if they had been adequately informed, they would have refused the treatment) results, amongst other things, in addition to the aforementioned general principles of *onus probandi,* also from another series of considerations, which the jurisprudence has considered necessary to justify this solution, and which leverage the fact that the element to be proven (the fact that the medical treatment would have been refused) consists in a subjective choice of the patient, since the principle of "proximate cause", in consideration of which the burden of proof lies with the party closest to the source of the proof should be applied. Furthermore, the determination according to which the decision of the patient to ignore the doctor's advice represents an eventuality that does not correspond to the *id quod plerumque accidit.*[362]

Except that, as we previously mentioned, the doctor can avoid liability if he can demonstrate that he fulfilled his duty to adequately inform the patient, or that, in any case, he was not to blame for the omission of information.[363] Under this profile, the aspect that, at present, is undoubtedly the

360 Court of Cassation N. 2847, February 9th 2010 in «Nuova giurisprudenza civile commentata», I, 2010, pages 786 *et seq*., with note by S. Cacace, *I danni da (mancato) consenso informato*, and by A. Scacchi, *La responsabilità del medico per omessa informazione nel caso di corretta esecuzione dell'intervento «non autorizzato»*; and in «Corriere giuridico», 2010, pages 1201 *et seq*., with note by A. di Majo, *La responsabilità da violazione del consenso informato* (from which the following quotations are taken).

361 Cfr. *supra*, paragraph 1.

362 Italian Court of Cassation, N. 2847, February 9th 2010, *cit.*, page 1203. Moreover, it is opportune to point out that the doctrine and the jurisprudence allow that the proof in question can be given by the patient also by means of recourse to presumptions. In particular, when the operation was of an aesthetic nature, and a blemish or defect more serious than the one that it was intended to eliminate or attenuate resulted, the particular nature of the result pursued by the patient and the fact that it cannot be considered in the usual terms of safeguarding of health would allow us to presume that the consent would not have been given if the information had been supplied and would therefore make the ascertainment superfluous – while it is essential in the case of a necessary operation, correctly carried out, but prejudicial to health – on the decisions the patient would have made if they had been informed of the possible risks (see Italian Court of Cassation N. 12830, 6th June 2014, in «Nuova giurisprudenza civile commentata», I, 2014, pages 1171 *et seq.,* with note by I. Pizzimenti, *Responsabilità civile del medico per violazione del dovere d'informazione: il crinale della necessità dell'intervento*).

363 U. Carnevali, *Omessa informazione da parte del medico, danno da trattamento terapeutico e ipotetica scelta del paziente*, *op. cit.*, pages 2181 *et seq.*

most delicate, relates to the way in which the doctor can provide this type of proof. On the one hand, the declaration the doctor makes in court cannot be taken as evidence, since no party can testify in favour of themselves,[364] and, on the other hand, the printed forms generally given to the patient to sign before an operation, having a generic and impersonal content, are considered by the judge not capable of integrating the correct fulfilment of the aforementioned obligation to inform.[365] The method open to the doctor would therefore seem to be only that of drawing up a detailed and personalised document, or, as proposed by part of the doctrine, to document the doctor-patient interview with an audio-visual recording.[366]

It is therefore necessary to examine the last aspect referred to above, concerning the criteria for compensation for damage to health following defective informed consent, harm that, in the absence of malpractice, can be compensated, according to the above considerations, only where the patient can show the causal link between the non-fulfilment of the informative duty and the harm itself.

So, since what is being considered is damage to health (that is biological damage), the discipline contained in paragraph 3, Article 3 of the so-called *legge Balduzzi* should find application also in this circumstance:

Biological damage resulting from the activities of a person exercising the medical profession is compensated on the basis of the tables set out in Articles 138 and 139 of the legislative decree D. Lgs. N. 209, September 7th 2005, where necessary integrated with the procedures set out in paragraph 1 of the aforementioned Article 138 and on the basis of the criteria in the articles cited, to take into account situations that they do not foresee, relating to the activities dealt with in this article.[367]

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364 Italian Court of Cassation, N. 24109, October 24th 2013, in «www.dejure.it».

365 Italian Court of Cassation, N. 2177, February 4th 2016, in «www.personaedanno.it»; Court of Cassation, N. 24853, December 9th 2010, in «Responsabilità civile», 2011, pages 829 *et seq.*, with note by G. Miotto, *La prova del «consenso informato» e il valore di confessione stragiudiziale delle dichiarazioni rese nel «modulo» di adesione al trattamento terapeutico*; R. Omodei Salè, *La responsabilità civile del medico per trattamento sanitario arbitrario*, *op. cit.* page 802. This in the light of the principle according to which the methods and the content of the information should be adapted to the personal characteristics of the patient; cfr. Italian Court of Cassation, N. 19220, August 20th 2013, in «Giurisprudenza italiana», 2014, pages 275 *et seq.*, with note by F. Salerno, *Consenso informato in medicina e qualità soggettive del paziente*. In cases where the consent can be gathered orally, the proof of fulfilment of the obligation to inform can be given by any means (for example, also by testimonial proof): cfr. G. Miotto, *La prova del «consenso informato» e il valore di confessione stragiudiziale delle dichiarazioni rese nel «modulo» di adesione al trattamento terapeutico*, *op. cit.*, page 831.

366 F.H. Miller, *Health Care Information Technology and Informed Consent: Computers and the Doctor-Patient Relationship*, in «Indiana Law Review», 31, 1998, pages 1019 *et seq.* Under French law, although article L1111-2 Csp (*Code de la Santé Publique*) foresees that the proof of having communicated adequate information to the patient – which must be given, as in Italy, by the doctor – can be given "*par tout moyen*", it is considered opportune for the doctor to prepare a document signed by the patient which includes the information provided to the same (cfr. F. G'sell-Macrez, *Medical Malpractice and Compensation in France. Part I: The French Rules of Medical Liability since the Patients' Rights Law of March 4, 2002*, *op. cit.*, page 140).

367 On the problem of determining the *quantum* to be paid in the case of medical liability, cfr. M. Faccioli, *La quantificazione del risarcimento del danno derivante da responsabilità medica dopo l'avvento della legge Balduzzi*, *op. cit.*, pages 103 *et seq.*

This ruling substantially extends to the sector of medical liability the tables used in calculating liquidation of biological damage for injuries deriving from road accidents foreseen by Articles 138 (for damage not of a minor nature) and 139 (for damage of minor nature) of Italian insurance legislation.[368] These tables – as is known – were integrally issued by the legislator only with regard to minor injuries, so that for more severe injuries, reference should be made to the judicial tables drawn up by the Court of Milano, to which the Court of Cassation has repeatedly attributed national value.[369]

This said, it also appears of interest to briefly examine the guidelines that have developed within the French jurisprudence with regard to the criteria under which it is possible to compensate for damage to health, where this derives from lack of, or defective, information, given that some of the solutions set out therein could be – at least in part – imported into the Italian system of liability for arbitrary medical treatment.

It is in fact necessary to state that, in this legal system, the jurisprudence – unlike Italian law – usually excludes total compensation for this type of damage, simply applying the concept of *perte de chance* (loss of an opportunity), already elaborated with reference to the compensation for damage deriving from the incompetence of the doctor when carrying out the treatment. In this case, the Cour de Cassation, since the nineteen-nineties, has established that the non-fulfilment by the doctor of the obligation to inform the patient deprives the latter only of the opportunity to avoid, through a decision other than the one effectively adopted, running the risk (which in effect resulted) of suffering damage to their health.[370] In the light of this reconstruction, it is therefore necessary to verify whether the patient, if adequately informed, would have refused the medical treatment and, subsequently, compensate the damage in a measure proportional to the fraction of the lost *chance*.[371]

Therefore, although a part of the Italian doctrine has already expressed an opinion contrary to this solution,[372] it would seem, in effect, possible to apply also to the Italian system the compensation mechanism based on the loss of opportunity, at least in cases where the patient cannot

368 The Italian Constitutional Court recently declared unfounded the doubts about the constitutional legitimacy of this ruling in the part that foresees a legal limit to compensation and allows the judge to increase it by only 20% where the special circumstances of the individual case require it: cfr. Italian Constitutional Court, N. 235, October 16th 2014, «Corriere giuridico», 2014, pages 1483 *et seq.* with note by M. Rossetti, *Micropermanenti: fine della storia.*

369 Italian Court of Cassation, N. 14402, June 30th 2011, in «Corriere giuridico», 2011, pages 1081 *et.seq.*, with note by M. Franzoni, *Tabelle nazionali per sentenza, o no?*

370 Cour de Cassation, Bull. Civ. I, N. 39, February 7th 1990. The Court stated that the doctor, in infringing his duty to inform the patient «*a seulement privé ce malade d'une chance d'échapper, par une décision peut-être plus judicieuse, au risque qui s'est finalement réalisé, perte qui constitue un préjudice distinct des atteintes corporelles*». Precisely because the patient was deprived of the opportunity to make a different decision, the compensation is completely excluded when in the presence of necessary treatment for which it was impossible to acquire prior consent from the patient (cfr. Cour de Cassation Bull. Civ. I, N. 40, February 4th 2003).

371 Cfr. Cour de Cassation, N. 302, Bull. Civ. I. December 7th 2004, according to which «*la violation d'une obligation d'information ne peut être sanctionnée qu'au titre de la perte de chance subie par le patient d'échapper par une décision peut être plus judicieuse, au risque qui s'est finalement réalisé» e «le dommage correspond alors à une fraction des différents chefs de préjudice subis qui est déterminée en mesurant la chance perdue et ne peut être égale aux atteintes corporelles résultant de l'acte médical*».

372 E. Palmerini, *Il danno non patrimoniale da violazione del consenso informato*, *op. cit.,* pages 536 *et seq.*

present evidence in court of the causal link.[373] In this way, the recourse to probabilistic criteria would facilitate the patient, allowing them to obtain a (partial) compensation of the damage to their health when it is not certain that they would have refused the operation, if they had been informed of the risks it involved.[374]

3. *(continued) The damage from infringement (only) of the right to self-determination*

Once we have examined the conditions for compensation for damage to health, it is necessary to consider the other damage that we have seen can derive from the non-fulfilment of the doctor's duty to inform, and that is the damage to the right to self-determination.

The situation to which it is necessary to refer is that in which the treatment, carried out by the doctor in the absence of valid consent from the patient, has had a positive result, bringing an improvement in the health of the patient in question. In this circumstance, we must therefore ask whether the damage to the right of self-determination, in the absence of damage to health, is compensable or not.

Well, according to the first interpretative guideline, which is being steadily abandoned, the omission by the doctor of a sufficient supply of relevant information that would allow the patient to take an informed decision is not, in itself, a source of liability; but would become so only if the treatment had caused damage to the health of the patient, to the (sole) safeguard to which the obligation to inform is, in fact, instrumental.[375] In consideration of this first approach, therefore, no compensatory obligation could be brought against the doctor when the treatment, carried out without consent, leads to an improvement in the health of the patient, since the damage to the right to self-determination "is consequential to a compensable damage not *ipso iure*, but only in cases where the health asset (with respect to which the obligation of information is necessarily instrumental for the purposes of fulfilling the care contract) was harmed".[376]

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373 U. Carnevali, *Omessa informazione da parte del medico, danno da trattamento terapeutico e ipotetica scelta del paziente*, *op. cit.*, pages 2181 *et seq.*

374 Since the legal asset damaged, consisting of the loss of the possibility to have a different outcome, must be kept separate from the damage to the right to health, it is necessary to consider that if the person harmed intends to claim compensation for the damage to the loss of opportunity (*perte de chance*), they must do so expressly, since it is not foreseen by the claim for compensation of the damage to health (cfr. C. Garufi, *L'obbligo di informazione del sanitario e la c.d. perdita di «chance»*, in «Giurisprudenza di merito», 2011, pages 2100 *et seq.*

375 G. Montanari Vergallo, *Il rapporto medico-paziente. Consenso e informazione tra libertà e responsabilità*, Milano, Giuffrè, 2008, page 236; in jurisprudence cfr. Court of Roma, May 10th 2005, in «Giurisprudenza di merito», I, 2005, page 2621.

376 A.V. Gambaro, *La responsabilità medica nella prospettiva comparatistica*, in AA.VV., *La responsabilità medica*, Milano, Giuffrè, 1982, pages 41 *et seq.*

A different jurisprudential and doctrinal position,[377] vice versa, considers that, even when there is no damage to health, the infringement of the duty to inform may in any case give the right to compensation, providing it is possible to configure a prejudice (so-called causal link) patrimonial or not, which the patient – according to the usual sharing of the *onus probandi* – must demonstrate.[378] If, in fact, it were to be considered that the patient has the right to compensation in virtue only of the infringement of the right to self-determination, we would be legitimating a return to the thesis that considered restorable the mere 'damage-event' concept intrinsic in the infringement of the protected interest, a theory that Italian jurisprudence abandoned some time ago.[379]

This second approach, undoubtedly preferable, starts in particular from the statement that – as previously emphasised – the non-observance of the obligation to acquire the informed consent of the patient integrates an aggravated crime, which, as such, harms not only the right to health, but also the other juridical asset protected by the rule of informed consent, and that is the right to self-determination.

On balance, that the infringement of the right to self-determination brings the right to compensation is a principle now becoming common also in other European countries. This is true, for example, for the French legislation, which in the past denied compensation relating to "pure" informed consent damages[380], but which has in recent years seen affirmed, in the jurisprudence of the *Cour de Cassation*, also the approach according to which the prejudice suffered by the patient who did not receive adequate information prior to the treatment must *always* find reparation,[381] thus integrating the infringement of the duty to inform about a damage "in itself"[382], qualifiable – as the

377 Cfr. for example, Italian Court of Cassation, N. 2847, February 9th 2010, *cit.*; Court of Firenze, December 2nd 2008, in «Responsabilità civile», 2009, pages 899 *et seq., with note by* C. Mighela, *Trasfusioni eseguite contro la volontà del paziente e risarcimento del danno da lesione della libertà di autodeterminazione*, and the numerous rulings on the question of undesired births, of which *infra*, paragraph 4. In doctrine, cfr., for example, C. Martorana, *Considerazioni su informazione del paziente e responsabilità medica*, in «Responsabilità civile e previdenza», 1997, page 389.

378 As an example of non-patrimonial damage, we can take a subject who must face the inconvenience of a non-urgent surgical operation, which involves a long period of convalescence or rehabilitation, and which the patient, if they had been adequately informed about the recovery times and the counter-indications, would have postponed in order to continue certain working activities from which they gained gratification (also in the absence of economic prejudice), or to dedicate themselves to other activities such as caring for their family (R. Omodei Salè, *La responsabilità civile del medico per trattamento sanitario arbitrario*, *op. cit.*, page 805). On the other hand, the damage consisting in the costs of maintenance that a mother must bear when she has given birth to a deformed child, who, if she had been adequately informed, she would have chosen to abort, is considered patrimonial.

379 Cfr. in particular, Italian Court of Cassation joint sections, N. 26972, November 11th 2008, published, amongst others, in «Nuova giurisprudenza civile commentata», I, 2009, pages 10 *et seq.*, with note by E. Bargelli, *Danno non patrimoniale: la messa a punto delle sezioni unite*, and by M. di Marzio, *Danno non patrimoniale: grande è la confusione sotto il cielo, la situazione non è eccellente*, who emphasised that the non-patrimonial damage is not a damage-event (that is damage following the mere infringement of the right, however fundamental, of the person, or in any case constitutionally relevant), but a damage-consequence, which must be alleged and proved by the person harmed, also through recourse to presumptions.

380 Cour de Cassation, N. 380, Bull. Civ I, December 6th 2007; S. Taylor, *The Development of Medical Liability and Accident Compensation in France*, in E. Hondius (ed.), *The Development of Medical Liability*, Cambridge, Cambridge University Press, 2010, vol. III, page 104.

381 Cour de Cassation, N. 128, Bull. Civ I, June 3rd 2010; which states that «*le non-respect du devoir d'information […] cause à celui auquel l'information était légalement due, un préjudice, qu'en vertu du dernier des textes susvisés, le juge ne peut laisser sans réparation.*»

382 That is a "damage-event": cfr. S. Hocquet-Berg, *Devoir d'information*, in «Responsabilité civile et assurance», 2010, N. 222 who states that «*le non-respect du devoir à l'information génère un dommage en soi*».

jurisprudence has been careful to point out – as "damage due to lack of preparation".[383] It is also necessary to emphasise that, although this jurisprudential hiatus, in the part in which the infringement of the right to self-determination in itself and considered apart[384] is considered compensable, is undoubtedly innovative, the doctrine has, however, shown that its practical application risks being somewhat limited, if we consider that the payment of compensation to the patient often amounts to quite modest sums.[385] A similar approach was taken by Spanish jurisprudence, in which the Tribunal Supremo, with a sentence dating from April 2000, sanctioned the compensability of the moral damage deriving the infringement of the rule of informed consent, notwithstanding the verification of damage to health.[386] This solution was welcomed also by part of the doctrine, which, referring to the damage due to infringement of the right to self-determination, stated that "*no hay duda de que la producción de este daño es independiente de que exista o no lesión física y sería indemnizable aun en el caso de ausencia de ésta.*"[387]

This said, and returning to deal with the Italian legislation, it is however important to state that, when the damage-consequence deriving from the infringement of the right to self-determination consists in a non-patrimonial damage, it is necessary, if it is to be compensated, that it translate into a *serious* prejudice and that the damage exceed a certain threshold of harm. In fact, according to the Italian Court of Cassation in the sentences of the joint sections of 2008, on the question of non-patrimonial damage,

[…] the filter of the gravity of the harm and the seriousness of the damage acts as a balance between the principle of solidarity towards the victim, and that of tolerance, with the consequence that the compensation of the non-patrimonial damage is due only in cases where the level of tolerability has been passed and the prejudice is not futile. Harm connoted by futility must be accepted by all persons within the overall social context, in virtue of the duty of tolerance that cohabitation imposes (Article 2, Italian Constitution).[388]

383 G. Viney, *L'indemnisation due en cas de manquement par le médecin à son devoir d'information*, in «La Semaine Juridique Edition Générale», 2014, page 553. On damage due to lack of preparation cfr. R. Omodei Salè, *La responsabilità civile del medico per trattamento sanitario arbitrario*, *op. cit.*, page 807.

384 Under this aspect the approach introduced by the Cour de Cassation, which seems to consider compensable the simple damage-event consisting in the lesion of the right to self-determination, differs from that adopted by the Italian Supreme Court, undoubtedly preferable, according to which the infringement of this right can be restored only when the patient has shown that it led to further harmful consequences (patrimonial or non-patrimonial).

385 M. Bacache, A. Laude and D. Tabuteau (ed.), *La loi du 4 mars 2002 relative aux droits des malades: 10 ans après*, Bruxelles, Bruylant, 2013, pages 1 *et seq.* That the compensation must be of a symbolic nature is, for example, hoped by J.S. Borghetti, *La sanction de la violation par le médecin de son devoir d'information, ou les limites de la réparation intégrale et systématique*, *op. cit.*, pages 1235 *et seq.*, who empahsises that, otherwise, patients would be encouraged to sue their doctors.

386 *Sentencia del Tribunal Supremo*, Sala 4a, April 4th 2000: «*la falta de información supone un daño moral, grave y distinto del daño corporal*».

387 J. Guerrero Zaplana, *El consentimiento informado. Su valoración en la jurisprudencia*, Valladolid, Tirant Derecho, 2004, page 222.

388 Italian Court of Cassation, joint sections, N. 26972, November 11th 2008, *cit*, page 113.

The existence of the damage-consequence, like the causal link between the negligent conduct of the doctor and the damage, which subsists when the patient, had they been adequately informed would have refused the treatment or would have chosen alternative therapeutic methods, must be proven – as already stated for the damage to health – by the actor, while the doctor has the duty to show that they gave the patient the necessary information.

To conclude, it seems opportune to briefly mention the criteria used by the doctrine and the jurisprudence to assess compensation for damage due to infringement of the right to self-determination when this leads to non-patrimonial consequences. On this question, since in order to monetise the damage to a personal right there is no method other than that of equity (Article 1226 Italian Civil Code), it is however, necessary to state that the need was felt to identify rules that can limit the discretion of the judge in effectively determining the amount of this damage. In particular, it was proposed in doctrine to differentiate the amount of the compensation on the basis of the *reason* on which the patient's different decision would have been made, with the consequence that, when the refusal of a given therapy was based on a conviction that could be directly traced to an expression, constitutionally guaranteed, of the personality (such as religious or sexual freedom), the damage should be considered particularly serious, while in cases where the (potential) different decision of the patient derived from a mere personal judgement of opportunity, the harm should be considered less important and therefore, be compensated with a lower sum.[389]

4. *Specific profiles of liability of the gynaecologist for infringement of the rule of informed consent*

Having clarified the types of damages for which the doctor may be called to answer when he or she has not acquired valid consent from the patient, it is now necessary to consider, in more detail, the liability for infringement of the right to self-determination borne by the gynaecologist. This question appears, in fact, to be of particular interest, if we consider that precisely with reference to the problem of the so-called 'wrongful births' following the infringement of the duty to inform borne by the gynaecologist, the jurisprudential approach mentioned in the previous paragraph evolved by tending to admit the compensability of the damage due to "pure" infringement of the duty of informed consent, that is without it being followed also by damage to the patient's right to health.

389 L. Ghidoni, *Il trattamento sanitario tra protezione della personalità e imposizione di valori etici*, in «Famiglia, Persone e Successioni», 2012, page 200.

Therefore, in dealing with this aspect it is necessary first to observe that the birth of a child against the wishes of the parent can occur not only following an unsuccessful operation, aimed at sterilising one of the potential parents,[390] but also due to an error made by the doctor who does not notice malformations of the foetus during an ultrasound scan, or who does not inform the pregnant woman of the findings, thus depriving her of the opportunity to opt for an abortion. Below, as can be expected, we will only consider the second of these events, since it is the only one that specifically concerns the right to self-determination of the patient and on which a lengthy debate has taken place, which also led the joint sections of the Italian Court of Cassation to rule on the question in 2015.

It is known that the purpose of an ultrasound scan is to inform the parents of the state of the foetus in order to allow them, amongst other things, to take an informed decision on whether to interrupt the pregnancy, if there are the conditions foreseen by the law. The lack of a diagnosis of malformation is therefore an infringement of the doctor's obligation to inform the pregnant woman and, excluding at the root the possibility of choosing an abortion, in fact undermines not the right to health, but the right to self-determination of the woman in question.

The jurisprudence – not only Italian, as we shall see – has therefore considered two basic problems, and that is: whether the birth of a child affected by malformations as a consequence of the mother's choice not to terminate the pregnancy, a choice however based on incomplete or erroneous information, can constitute damage to the child itself and whether it can additionally be so for the parents.

We will start by considering the situation of the child. It is necessary to state that a first and minority interpretative position tends to accept the compensatory claims presented by the child against the doctor, on the basis of the consideration that the damage suffered by the person born consists in the handicap that affects them, and that the doctor's non-fulfilment of the informative obligation is the necessary cause of the birth of an unhealthy life.[391]

Nonetheless, the majority thesis, which has recently been confirmed also by the joint sections of the Italian Court of Cassation,[392] excludes that the child born with deformities or disabilities can claim compensation for damages from the doctor.[393] According to this approach, in

390 G. Montanari Vergallo, *Il rapporto medico-paziente*, *op. cit.*, page 314.

391 This thesis is supported above all by the Italian Court of Cassation, N. 16754, October 2nd 2012, in «Contratti», 2013, pages 563 *et seq.*, with note by N. Muccioli, *Diagnosi prenatale inesatta e responsabilità del medico*.

392 Italian Court of Cassation joint sections, N. 25767, December 22nd 2015, in «Corriere giuridico», 2016, pages 41 *et seq.*, with note by G. Bilò, *Nascita e vita indesiderate: i contrasti giurisprudenziali all'esame delle Sezioni Unite*. For a comment on the ruling cfr. also F. Piraino, *«Nomina sunt consequentia rerum» anche nella controversia sul danno al concepito per malformazioni genetiche. Il punto dopo le Sezioni unite, 22 dicembre 2015, n. 25767*, in «Diritto civile contemporaneo», January 6th 2016.

393 Cfr. also Italian Court of Cassation, N. 14488, July 29th 2004, in «Famiglia e diritto», 2004, pages 559 *et seq.,* with note by G. Facci, *«Wrongful life»: a chi spetta il risarcimento del danno?*, in «Nuova giurisprudenza civile commentata», I, 2005, pages 418 *et seq.*, with note by E. Palmerini, *La vita come danno? No… Sì… Dipende*; Italian Court of Cassation, N. 16123, July 14th 2006, in «Corriere giuridico», 2006, pages 1691 *et seq.*, with note by A. Liserre, *Ancora in tema di mancata interruzione della gravidanza e danno da procreazione*; Italian Court of Cassation, N. 10741, May 11th 2009, in «Danno e responsabilità», 2010, pages 144 *et seq.*,

fact, in Italian legislation there is only room for a right to "be born healthy" and that is the right of the foetus to not suffer harm from third parties,[394] while the right "not to be born" or "to be born not healthy" and that is the right of the child not to be born with malformations or disabilities, which would lead to the mother's right to claim compensation when, due to a lack of information from the doctor, she decides to continue the pregnancy, does not exist.

In support of this conclusion it was, in fact observed, that on the one hand the causal link between the doctor's omission and the malformations of a genetic nature affecting the child is lacking. In fact, the malformations are the fruit of a random event and, on the other hand, as can be deduced from Italian Law N. 194/1978, the decision to abort can be exclusively taken by the mother in order to avoid serious and grave danger for *her own* health and cannot be exercised for the purpose of avoiding the birth of a child with disabilities, which otherwise would introduce into our legislation a particular figure of eugenic abortion. Moreover, in order to exclude the legitimation of the child's claim for compensation, Italian jurisprudence has stated that the "right not to be born" would be an *adespota* right until the moment in which the child is born, since it is not possible to recognise the foetus as a legal subject in virtue of the rule set out in Article 1 of the Italian Civil Code (which subordinates the acquisition of this subjectivity to birth), and how, consequently, this right would find an owner only at the moment in which it is infringed.[395] However, the observation that appears truly decisive and which was valorised by the joint sections of the Italian Court of Cassation, and by part of the doctrine, is that centred on the lack itself, beforehand, of a damage, seen as "a loss of utility" by the newborn child, since the alternative to the malformation, which a correct diagnosis could have offered, is represented certainly not by the better physical condition of the child, but by the prevention of their existence, so that no pejorative change to the state of the foetus can be attributed to the doctor.[396]

The conclusion drawn by Italian jurisprudence appears, in effect, to be acceptable not only in consideration of all the arguments set out above, but also of a comparative analysis of the solutions incorporated in other European legislations.[397]

In the **German legislation**, for example, which as in Italy, considered the question of the legitimation of the child born disabled to claim compensation for their malformation from the doctor who, not having informed the mother, prevented her from opting for an abortion, the

with note by F. di Ciommo, *Giurisprudenza-normativa e «diritto a non nascere se non sano». La Corte di Cassazione in vena di «revirement»?*

394 There could be, for example, the liability of the doctor towards the newborn child when it results that the harm to the foetus, if promptly diagnosed and treated in the womb, could have been avoided (M. Nefeli Gribaudi, *Consenso e dissenso informati nella prestazione medica*, Milano, Giuffrè, 2012, page 36).

395 Italian Court of Cassation, N. 14488, July 29th 2004, *cit.,* pages 559 *et seq.*

396 F. Piraino, *«Nomina sunt consequentia rerum» anche nella controversia sul danno al concepito per malformazioni genetiche. Il punto dopo le Sezioni unite, 22 dicembre 2015, n. 25767, op cit.*

397 For a brief panorama cfr. C. von Bar, *The Common European Law of Torts*, Oxford, Oxford University Press, 1998, vol. I, pages 601 *et seq.*

tendency is to deny this possibility. With a well-known ruling dating from the eighties, the *Bundesgerichtshof* (the German Supreme Court) excluded that the child could make an independent claim against the gynaecologist, on the basis of the consideration that the contract between the mother and the doctor did not extend protective effects to the foetus – which therefore could not independently make a claim against the doctor – since the right of the mother to terminate a pregnancy is recognised by German law only in her exclusive interest.[398]

If we consider, instead, the **French legislation**, we can see that in the leading case on the topic of 'wrongful life', that is the *affaire Perruche* decided by the Cour de Cassation in November 2000, which concerned a situation in which the doctor and an analysis laboratory negligently omitted to diagnose German measles (*rubella*) in a pregnant woman, who therefore decided to continue her pregnancy, giving birth to a child with serious physical and neurological disorders,[399] the Court, with a sentence in fact often criticised, in effect accepted the diametrically opposing thesis to that so far presented. In fact, the Court stated – in open contrast with the rulings from previous courts[400] - that the person born with a serious handicap following diagnostic errors made when executing the contract of care stipulated by the mother during the pregnancy, and which prevented her from exercising the choice of whether to terminate the pregnancy, has the right to compensation for damages resulting from the handicap and caused by the negligent behaviour of the doctor.[401]

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398 Bgh, January 18th 1983, Bghz 86, 240. Cfr. on this point G. Müller, *Wrongful life*, in T. Clausen and J. Schroeder-Printzen (ed), *Münchener Anwaltshandbuch Medizinrecht*, München, C.H. Beck, 2013, Rn. 137.

399 Cour de Cassation., a.p., November 17th 2000, published in Italy in «Nuova giurisprudenza civile commentata», I, 2001, pages 209 *et seq.*, with note by E. Palmerini, *Il diritto a nascere sani e il rovescio della medaglia: esiste un diritto a non nascere affatto?*; in «Danno e responsabilità», 2001, pages 475 *et seq.*, with note by M. Gorgoni, *Nascere sani o non nascere affatto: verso un nuovo capitolo della storia della «naissance d'enfants sains non désirés»*.

400 The jurisdictional procedure was extremely complex. The first degree ruling of the Court of Evry (1992) was followed by the decisions of the Appeals Court in Paris (1993); of the Cour de Cassation (1996) and of the Appeals Court of Orléans where the judge, with what is known as *arrêt de rebellion* (1999), departed from the principle of law affirmed by the Cour de Cassation, to re-propose the solution adopted in the previous sentence. Finally, the ruling of the *Assemblée plénière* of the Cour de Cassation confirmed, with the sentence in question, the principle of law already set out in its first ruling.

401 The ruling states: «*La Cour, Vu les articles 1165 et 1382 du Code civil; Attendu qu'un arrêt rendu le 17 décembre 1993 par la Cour d'appel de Paris a jugé, de première part, que M. Y, médecin, et le Laboratoire de biologie médicale d'Yerres aux droits duquel est M. A, avaient commis des fautes contractuelles à l'occasion de recherches d'anticorps de la rubéole chez Mme X alors qu'elle était enceinte, de deuxième part, que le préjudice de cette dernière, dont l'enfant avait développé de graves séquelles consécutives à une atteinte in utero par la rubéole, devait être réparé dès lors qu'elle avait décidé de recourir à une interruption volontaire de grossesse en cas d'atteinte rubéolique et que les fautes commises lui avaient fait croire à tort qu'elle était immunisée contre cette maladie, de troisième part, que le préjudice de l'enfant n'était pas en relation de causalité avec ces fautes; que cet arrêt ayant été cassé en sa seule disposition relative au préjudice de l'enfant, l'arrêt attaqué de la cour de renvoi dit que "l'enfant N. X ne subit pas un préjudice indemnisable en relation de causalité avec les fautes commises" par des motifs tirés de la circonstance que les séquelles dont il était atteint avaient pour seule cause la rubéole transmise par sa mère et non ces fautes et qu'il ne pouvait se prévaloir de la décision de ses parents quant à une interruption de grossesse; Attendu, cependant, que dès lors que les fautes commises par le médecin et le laboratoire dans l'exécution des contrats formés avec Mme X avaient empêché celle-ci d'exercer son choix d'interrompre sa grossesse afin d'éviter la naissance d'un enfant atteint d'un handicap, ce dernier peut demander la réparation du préjudice résultant de ce handicap et causé par les fautes retenues; Par ces motifs, et sans qu'il soit nécessaire de statuer sur les autres griefs de l'un et l'autre des pourvois: Casse et annule, en son entier, l'arrêt rendu le 5 février 1999, entre les parties, par la Cour d'appel d'Orléans; remet, en conséquence, la cause et les parties dans l'état où elles se trouvaient avant ledit arrêt et, pour être fait droit, les renvoie devant la Cour d'appel de Paris, autrement composée que lors de l'audience du 17 décembre 1993*». The *Conseil d'Etat*, which, in France, has jurisdiction with reference to the controversies between patients and public health structures, or doctors employed by them, has instead always stated that the damage caused by 'wrongful life' does not give the right to compensation. (S. Taylor, *The Development of Medical Liability and Accident Compensation in France*, *op. cit.*, page 105).

Nonetheless, the effects that this jurisprudence risked setting off – not least, a shameful increase in the premiums announced by the insurance companies[402] – led the French legislator to approve Law N. 303/2002 (the so-called *Loi Kouchner*), which in Article 1 (now incorporated in Article 5 Law 114 of the *Code de l'action sociale et des familles*) forsees, in paragraph 1, that «*Nul ne peut se prévaloir d'un préjudice du seul fait de sa naissance*» e, al comma 2, che «*La personne née avec un handicap dû à une faute médicale peut obtenir la réparation de son préjudice lorsque l'acte fautif a provoqué directement le handicap ou l'a aggravé, ou n'a pas permis de prendre les mesures susceptibles de l'atténuer*». It is clear that the law, which rejects the idea that birth in itself can constitute a prejudice and guarantees for the subject born with a handicap the possibility of obtaining compensation from the doctor only when the negligence of the latter has materially caused or aggravated the handicap, or has not consented the adoption of opportune measures to limit it, openly and definitively contradicts the position adopted by the Cour de Cassation in the *Perruche* case,[403] excluding the compensability of the damage allegedly suffered by the child born with malformations.

The **British legislation** also seems to have settled on solutions that substantially conform to those of the aforementioned systems of *civil law*. This in fact includes a law the *Congenital Disabilities Act* of 1976, which would seem to exclude the admissibility of claims of *wrongful life* for anyone born after 1976.[404] In particular, in the light of the interpretation given by the Court of Appeal,[405] the child could present a claim for compensation against the doctor only when, in the absence of the doctor's negligible conduct, he or she would otherwise have been born healthy and not also if he or she had not been born at all. Furthermore, of particular interest, since they substantially correspond to those adopted also by the Italian Court of Cassation, are the arguments used by the Court of Appeal to consider the action for *wrongful life* inadmissible. They are substantially based on two aspects. The first refers to the absence of a *duty of care* of the doctor towards the foetus, since the right to choose whether to carry forward or to terminate the pregnancy is recognised only for the mother, otherwise it would be necessary to admit that the doctor has a duty to the foetus to allow the mother to kill it. The second consists in the impossibility of

402 S. Cacace, *«Loi Kouchner»: problemi di «underdeterrence» e «undercompensation»*, in «Danno e responsabilità», 2003, page 436.

403 In doctrine, on this manner, known as «*La loi a donc brisé la jurisprudence Perruche*» (P. Jourdain, *Loi anti-Perruche: une loi démagogique*, in «Dalloz», 11, 2002, page 891).

404 In fact it forsees that «1) If a child is born disabled as the result of such an occurrence before its birth as is mentioned in subsection 2) below, and a person (other than the child's own mother) is under this section answerable to the child in respect of the occurrence, the child's disabilities are to be regarded as damage resulting from the wrongful act of that person and actionable accordingly at the suit of the child. (2) An occurrence to which this section applies is one which *a*) affected either parent of the child in his or her ability to have a normal, healthy child; or *b*) affected the mother during her pregnancy, or affected her or the child in the course of its birth, so that the child is born with disabilities which would not otherwise have been present».

405 In *obiter* in the case *McKay v. Essex Area Health Authority*, 2 All E R 771, (CA) (1982), which concerned a child born before the *Congenital Disabilities Act* (cfr. the considerations of D'Angelo, *«Wrongful birth» e «wrongful life» negli ordinamenti inglese e australiano*, in Id. (ed.), *Un bambino non voluto è un danno risarcibile?*, Milano, Giuffrè, 1999, page 172). For a comment on the case cfr. A. N C Liu, *Wrongful Life: Some of the Problems*, in «Journal of Medical Ethics», 13, 1987, pages 69 *et seq.*

identifying the harmful event, since this would result from the comparison between a life with illness or disability and a non-life, of which it is difficult to assess the value.[406]

Having concluded this (necessarily brief) comparative analysis, if we move on to consider the second interrogative, that is the one concerning the legitimation of the parents to obtain compensation for the damage for the birth of a child affected by malformations or disabilities, it is possible to substantially observe that the jurisprudence admits the existence of a responsibility of the doctor for harm suffered first of all by the mother, as a result of the infringement of her right to self-determination and the right to a free and informed procreation.

Nonetheless, the obligation of the gynaecologist to compensate the damage of an undesired birth does not *automatically* follow the non-fulfilment of the duty to inform about the malformations of the foetus, but presupposes that the pregnant woman demonstrate a series of elements, such as the subsistence of the conditions foreseen by Italian Law N. 194/1978 to choose voluntary abortion,[407] the existence of a causal link between the lack of information given by the doctor and the choice of the woman to continue with the pregnancy and, finally, the damage (patrimonial and non-patrimonial) that resulted as a consequence of the infringement of the right to self-determination.

In relation to these conditions, an important juridical question that emerged amongst the interpreters is the one that relates to the way in which the causal link between the omission and the infringement of the right to self-determination can be proven.

On this point, a first jurisprudential approach considered that from the simple fact that the pregnant woman had decided to undergo prenatal analysis it was possible to deduce that she, if informed of malformations of the foetus, would have terminated the pregnancy, since there would undoubtedly have been a danger for her (psychological) health which, pursuant to Article 6 of Italian Law N.194/1978, legitimates the exercise of the right to an abortion.[408]

A different approach considered that the proof of causal link could be considered to have been proven only in the presence of an *unequivocal* wish of the pregnant woman to terminate the pregnancy in the case of serious malformation of the foetus (for example, when she had previously

406 On this matter the Court was asked: «But how can a court of law evaluate that second condition and so measure the loss to the child? Even if a court were competent to decide between the conflicting views of theologians and philosophers and to assume an "after life" or non-existence as the basis for the comparison, how can a judge put a value on the one or the other, compare either alternative with the injured child's life in this world and determine that child has lost anything, without the means of knowing what, if anything, is gained?».

407 As is known, Italian Law N. 194/1978 foresees that the exercise of the right to terminate a pregnancy depends on certain conditions, which become even more rigorous by reason of the gestational age of the foetus. During the first ninety days, to practice an abortion it is sufficient for there to be "serious danger" for the physical or psychological health of the mother (Article 4). After the ninetieth day of pregnancy the woman can exercise her right to an abortion only if *a)* the pregnancy or the birth present serious risks for the life of the woman; *b)* pathological processes are ascertained, including those relating to important anomalies or malformations of the foetus, which determine a serious risk for the physical or psychological health of the woman and *c)* there is no possibility of autonomous life for the foetus (Articles 6 and 7).

408 Italian Court of Cassation, N.6735, May 1^{0th} 2002, in «Nuova giurisprudenza civile commentata», I, 2003, pages 619 *et seq.*, with note by R. de Matteis, *La responsabilità medica per omessa diagnosi prenatale: interessi protetti e danni risarcibili*.

made an express declaration in this sense), since otherwise it would not be possible to deduce this intention merely from a simple request for diagnostic tests.[409]

The joint sections of the Italian Court of Cassation ruled on this debate, with the sentence previously mentioned, establishing that, in order to obtain some sort of compensation from the doctor, the woman must prove – as on the other hand the previous sentences had already established – the following elements: the important anomaly of the newborn child, the omission of information by the doctor, the serious damage to her psychological and physical health and, finally, the abortive decision that she would have taken, at the same time stating that the proof of the latter two elements can be given also through *presumptions*, taken, for example, from having previously declared that she had consulted the doctor precisely in order to understand the state of health of the foetus, of the precarious psychological and physical condition of the pregnant woman or from the previous manifestations of opinion.[410]

Where all these elements are demonstrated, the mother can obtain compensation from the doctor for the damage-consequence deriving from the infringement of the fundamental right of self-determination, compensation that is normally identified in prejudices of a patrimonial nature, generally consisting of the greater expenses that it will be necessary to sustain for a child affected by serious pathologies, compared with those for a healthy child,[411] and of a non-patrimonial nature, linked to the disruption of the family lifestyle deriving from the need to assist an invalid child.

Finally, it is necessary to observe how in the past it was generally discussed whether there was an active legitimation to claim compensation for this type of patrimonial and non-patrimonial damage also for the *father* of a child born with malformations. In particular, in favour of a negative solution the consideration was invoked that, since Italian Law N. 194/1978 attributed only to the mother the right to opt for the termination of the pregnancy, it would be particularly arduous to ascertain the causal link between the doctor's omission and the damage suffered by the father, since these two elements are subject to an act of will that appertains to a third part (the mother).[412] Nonetheless, today the jurisprudence pacifically considers this legitimation possible – extending it in some rulings also to the siblings[413] - applying the category of the contract with protective effects also for third parties. According to this theory, in fact, the non-fulfilment of the doctor of the pregnant woman's rights brings into the orbit of the contractual safeguards also those damages that derive from the infringement of fundamental rights and which are suffered by subjects, who

409 Italian Court of Cassation, N. 7269, March 22nd 2013, in «Nuova giurisprudenza civile commentata», I, 2013, pages 1082 *et seq.*, with note by R. Pucella, *Legittimazione all'interruzione di gravidanza, nascita «indesiderata» e prova del danno (alcune considerazioni in merito a Cass., 22 marzo 2013, n. 7269).*

410 Italian Court of Cassation, N. 25767, December 22nd 2015, *cit.*, pages 41 *et seq.*

411 M. Nefeli Gribaudi, *Consenso e dissenso informati nella prestazione medica*, *op. cit.*, page 36.

412 R.F. Iannone, *Responsabilità medica per omessa o tardiva diagnosi di malformazioni fetali*, in «Giustizia civile», 2013, pages 711 *et seq.*

413 Italian Court of Cassation, N. 16754, October 2nd 2012, *cit*,, page 563.

although extraneous to the contractual relationship, find themselves in a relationship of qualified proximity to the performance of the contract.[414]

5. *Specific profiles of liability of the cosmetic surgeon for infringement of the rule of informed consent*

The sector of cosmetic surgery deserves to be examined separately because it also presents singularities with respect to the general system of medical liability, which are manifested with reference to two different profiles. In the first place – as already mentioned when it is a question of the requisites of consent to treatment – there is, in this sector, compared with others, a diversification of the informative obligation ascribable to the doctor; in the second place, the criteria used by the jurisprudence to ascertain the causal link between the infringement of the informative obligation and the damage to the patient's health are different.

With reference to the first of these aspects, it is sufficient here to recall what was said in the chapter on the requisites for consent to medical treatment, which is that, since the purpose of cosmetic surgery is to improve the patient's physical appearance, the information that the doctor must give the patient is more extensive than that which must be given prior to therapeutic surgery.[415] In the first of these situations, in fact, the information must concern not only the prevention, the diagnosis, the prognosis, the possible existence of a number of alternative therapeutic treatments and the advantages and risks of each therapy, but also the effective possibility of attaining the aesthetic improvement and, above all, the *most remote risks* that could prevent this improvement.[416] This approach can easily be understood if we consider that, since these are elective operations, and that is not dictated by therapeutic needs, it is fundamental for the patient to have all the information necessary to decide whether to undergo an operation that is often not necessary and whether to accept the risk of a possible worsening of their physical appearance.[417]

The further profile that it is important to consider is, then, the one relating to the ways in which the jurisprudence usually ascertains the liability of the doctor in this sector of medicine. In fact, we have seen that generally speaking, it is the patient who must demonstrate the causal link between the doctor's omission and the damage to their health. That is to say, had the patient been

414 Italian Court of Cassation, N. 13, January 4th 2010, in «Responsabilità civile», 2010, pages 582 *et seq.*, with note by R. Partisani, *Il danno esistenziale del padre da nascita indesiderata.*

415 Italian Court of Cassation, N. 4394, August 8th 1985, in «Giurisprudenza italiana», I, 1, 1987, c. 1136.

416 M. Nefeli Gribaudi, Consenso e dissenso informati nella prestazione medica, *cit.*, page 31.

417 Italian Court of Cassation, N. 12830, June 6th 2014, in «Danno e responsabilità», 2015, pages 246 *et seq.*, with note by L. Mattina, *Chirurgia estetica: la Cassazione tra consenso informato e «dissenso presunto» del paziente.*

correctly informed of the risks linked to the operation, he or she would undoubtedly have refused it.[418]

In the hypothesis now taken into consideration, on the other hand, the jurisprudence – given the purpose of the operation – generally *presumes* that the consent would not have been given if the information on the possible negative results of the operation had been offered in an adequate manner, with the further consequence that the ascertainment of the choices the patient would have made if they had been informed of the possible risks, is in effect, considered superfluous.[419] This reconstruction has been, moreover, criticised in doctrine by those who have pointed out that the reasoning of the Italian Court of Cassation tends to attribute importance to a sort of "presumed dissent" of the patient and to give space, in Italian legislation, to placing liability of an almost objective nature on the shoulders of the cosmetic surgeon, since he or she, in the presence of defective information, would *always* be liable, even when the patient had agreed to run the risk, undergoing in the operation in any case.[420]

6. *Exceptions to the obligation of prior acquisition of informed consent from the patient: a) mandatory medical treatment*

In concluding this chapter, it appears opportune to analyse the exceptions to the rule of informed consent and that is the cases in which the intervention of the doctor must be considered lawful despite the fact that the informed consent of the patient was not acquired prior to treatment, and/or despite their explicit dissent.

The first exception to the rule of informed consent is constituted by mandatory medical treatment foreseen by law, pursuant to Article 32, paragraph 2 of the Italian Constitution, according to which "No one may be obliged to undergo any health treatment except under the provisions of the law."

Although, therefore, the legislator can configure certain treatments as compulsory, the Italian Constitutional Court, with the sentence N. 307/1990,[421] identified a series of limits to the prevision of said treatments, establishing first of all, that the treatment must be directed not only at improving the state of health of the person in question, but must also preserve the health of others, since only the safeguarding of health in its collective dimension can justify the suppression of the right to self-determination in relation to the healthcare due to all; moreover, that the treatment can be imposed

418 Cfr. *supra*, paragraph 2.
419 Critical on this point is I. Pizzimenti, *Responsabilità civile del medico per violazione del dovere d'informazione: il crinale della necessità dell'intervento*, in «Nuova giurisprudenza civile commentata», I, 2014, page 1179.
420 L. Mattina, *Chirurgia estetica: la Cassazione tra consenso informato e «dissenso presunto» del paziente*, in «Danno e responsabilità», 2015, page 256.
421 Italian Constitutional Court, N. 307, June 22nd 1990, in «www.giurcost.org».

only in the prevision that it does not negatively affect the state of health of the person who is subject to it; and finally, that the law which foresees treatments of this kind must also recognise a protection in favour of the passive subject in the form of fair compensation for the damage suffered due to the treatment itself, which shall be borne by the collectivity.

This said, at the level of ordinary legislation it was Italian Law N.833/1978 (which established the Italian national health service) that identified – with rulings of an exceptional nature, and therefore not analogically applicable, since they are in derogation of the principle of self-determination of the individual in relation to their health – the premises and the procedures on which mandatory medical treatment must be based.

In particular, mandatory treatment during hospitalisation can be ordered by a ruling of a mayor in their role as health authority, on the basis of a motivated proposal from the doctor, when the following cumulative conditions subsist: *a)* the person must be in a state of alteration such that urgent therapeutic intervention is required; *b)* the interventions proposed are refused by the patient; *c)* it is not possible to adopt prompt measures outside the hospital environment. The existence of these premises must be certified by a first doctor (also a GP or a free-lance physician) and subsequently confirmed by a doctor employed by a public structure. Once the medical certificates have been presented, the mayor has forty-eight hours in which to order mandatory medical treatment and have the person accompanied by the municipal police to a psychiatric diagnostic and treatment ward. The mayor then has a duty to communicate the order for mandatory medical treatment to the competent tutelary judge, within the forty-eight hours following hospitalisation, for the necessary ratification. The tutelary judge, having verified the information, ratifies the procedure within the following forty-eight hours. In the case of non-ratification, it is once again the mayor who declares the cessation of the efficacy of the mandatory medical treatment order.[422]

Although the mandatory medical treatment order is normally carried out despite the dissent of the patient, it may be considered unlawful if it is ordered in violation of the conditions set out above and, in these cases, represents a damage for the patient themselves, which may be of a patrimonial nature (for example, income lost by the subject during hospitalisation *contra legem*) or of a non-patrimonial nature, consequent to damage to the personal dignity of the patient.[423]

7. *(Continued) b) The state of necessity*

422 Cfr. on this point M. Quaragnolo, *Trattamento sanitario obbligatorio illegittimo e danno non patrimoniale*, in «Responsabilità civile», 2005, page 244.

423 Court of Venezia, December 19th 2005, in «Responsabilità civile», 2005, pages 237 *et seq.*

The second exception to the rule of consent that must be referred to is represented by the *state of necessity*, on the basis of which, where the medical treatment is necessary to save the patient from imminent danger of serious harm to their person and it is impossible to obtain or wait for their consent, the doctor, who carried out the treatment without previously acquiring the valid consent of the patient will be exonerated from liability, since his or her conduct was not illegal but, rather, necessary.[424]

Although this statement can be said to be substantially shared by the interpreters, nonetheless, the *juridical basis of the lawfulness* of the doctor's behaviour appears controversial. In fact, while a first approach identifies this foundation in the exonerating circumstances codified by the state of necessity, according to which "He who acts in order save himself or others from imminent danger of personal injury, danger that was not voluntarily caused, nor avoidable, as long as the action is proportional to the danger is not punishable for his or her actions" (see: Article 54 Italian Criminal Code of Criminal Procedure and Article 2045 Italian Civil Code),[425] part of the doctrine, vice versa, does not consider this solution feasible, since it presumes that the urgent medical treatment carried out on a patient who cannot express their consent must be considered an *unlawful act* with respect to which there is a cause for exclusion of the illegality, when instead, it is necessary to start from the concept according to which the medical activity is in itself a *legal* activity.[426] It has further been observed that the application of the institute of the state of necessity is unsatisfactory also because the civil law that regulates it imposes the person who causes harm to pay the person harmed an indemnity, the amount to be decided by the judge (Article 2045 Italian Civil Code), when on the other hand "no one has ever stated that the medical treatment carried out in order to save the patient from immediate danger of serious harm to their person prefigures the liability of the doctor for a harmful legal act pursuant to Article 2045 Italian Civil Code."[427] Finally, it has reasonably been observed that the reference to the state of necessity regulated by Article 54 Italian Code of Criminal Procedure and 2045 Italian Civil Code carries the serious drawback of making the doctor's intervention legal even when it has been *legitimately refused* by the patient,[428] while we will see that the informed refusal of treatment must be taken into due consideration by the doctor, even when the treatment itself appears necessary to safeguard the health or the life of the patient.

Precisely in the light of all these observations, part of the doctrine and of the jurisprudence – both civil and criminal – prefers to identify the foundation of lawfulness of the doctor's activity in

424 M. Graziadei, *Il consenso informato e i suoi limiti*, in L. Lenti, E. Palermo Fabris and P. Zatti (ed.), *I diritti in medicina*, in *Trattato di biodiritto*, directed by S. Rodotà and P. Zatti, Milano, Giuffrè, 2011, page 259.
425 F. Ambrosetti, M. Piccinelli and R. Piccinelli, *La responsabilità nel lavoro medico d'équipe*, Torino, Utet, 2003, page 136.
426 G. Montanari Vergallo, *Il rapporto medico-paziente*, *op. cit.*, page 43.
427 M. Graziadei, *Il consenso informato e i suoi limiti*, *op. cit.*, page 261.
428 G. Montanari Vergallo, *Il rapporto medico-paziente*, *op. cit.*, page 44.

the so-called state of medical necessity.[429] This institution is characterised, with respect to the state of necessity governed by the law, above all by the fact that it presupposes a *current* impossibility to acquire the consent of the patient and, on the other hand, that it is not possible "(alone) to exclude the juridical relevance of *anticipated directives* expressed in view of emergencies such as the one that has produced the state of medical necessity in question."[430] In other terms, in the light of this category, the doctor would always be required to respect the wishes of the patent expressed prior to the medical treatment, even when this translates into a refusal of treatment, otherwise the patient would be deprived of the right to refuse non-mandatory medical treatment foreseen by Article 32 of the Italian Constitution.

This said, at this point it is necessary to point out that the jurisprudence, although recognising in abstract the right of the patient to refuse treatment, has often considered null and void the dissent expressed by the same before an emergency occurred and therefore only considered legitimate, since it was justified by the state of necessity, the decision of the doctor to carry out the treatment even though it was contrary to the wishes previously expressed by the patient.

This, in particular, occurred – as mentioned in the previous chapter – in the case of Jehovah's Witness patients who, being unconscious, manifested their refusal of life-saving blood transfusions by means of a 'no blood card'. It is, in fact, necessary, from this standpoint to remember that, although an increasing part of the interpreters considers that the dissent expressed by the patient must always prevail over the doctor's duty to heal,[431] the jurisprudence considers generally lawful, since it is exonerated by the state of necessity, the blood transfusion carried out in contrast with the previous wishes expressed by the patient, where there is a situation of serious and irreparable danger for the physical integrity of the latter, given the lack of the requisite of current dissent expressed by the patient.[432]

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429 G. Vassalli, *Alcune considerazioni sul consenso del paziente e lo stato di necessità nel trattamento medico-chirurgico*, in «Archivio penale», 1973, pages 81 *et seq*; F. Ramacci, *Statuto giuridico del medico e garanzie del malato*, in E. Dolcini and C.E. Paliero (ed.), *Studi in onore di G. Marinucci*, Milano, Giuffrè, 2006, vol. II, page 1714; Caet seq, N. 52829 May 2002, in «Studium Juris», 2003, page 511, according to whom the therapeutic activity is "exonerated by an ontologically intrinsic 'state of necessity', without it being necessary to refer to the codified causes of justification."

430 F. Ramacci, *Statuto giuridico del medico e garanzie del malato*, *op. cit.*, page 1714.

431 For this opinion cfr. G. Facci, *I medici, i Testimoni di Geova e le trasfusioni di sangue*, in «Responsabilità civile», 2006, pages 938 *et seq.*

432 Cfr., for example, Italian Court of Cassation N. 4211, February 23rd 2007, in «Danno e responsabilità», 2008, pages 27 *et seq.*, with note by G. Guerra, *Il dissenso alla trasfusione di sangue per motivi religiosi*, and Italian Court of Cassation N. 23676, September 15th 2008, in «Nuova giurisprudenza civile commentata», I, 2009, pages 170 *et seq.*, with note by G. Cricenti, *Il cosiddetto dissenso informato.*

Conclusions

The divergences between the principles that should guide the gathering of informed consent and the practical dimension of this procedure are clearly illustrated by the factors analysed in this volume.

The first area in which this incongruence emerges relates to the *content of the information* that must be transmitted prior to the start of treatment. In reality, on the legal plane, we see a progressive extension of the doctors' obligation to inform, since they – in view of the recent jurisprudential rulings – are obliged to inform the patients not only with regard to the characteristics of the treatments proposed, the risks linked to them and the possible alternatives, but even, for example, of the inadequacies of the hospital in which the patient is being treated and the possibility of being treated at a more specialised medical structure.

Nonetheless, on the abstract plane, a similar dilation of the quantity of information to be supplied to the patient does not correspond, in practice, to their effective acquisition of greater awareness of the characteristics of the treatments they are to undergo.

In fact, if we analyse the medical practices, far from finding that the doctors spend more time on the information process, given the amount of information to be transmitted to the patient, in effect, we find that the information is often limited by a series of factors within or beyond the doctor's control.

The adequacy of the information given to the patients clashes above all with the way in which the hospital work is organised. As shown in the analyses proposed in this volume, the hospital schedules often limit the opportunities for organising doctor-patient dialogue. The comparison between the various hospital departments made it possible to show how, in the majority of cases, the conditions for gathering informed consent and supplying information to the patients are lacking. The doctors' lack of time, the absence of spaces specifically destined for conversation with the patients, the increasing number of patients to be cared for each day, the difficulties in guaranteeing continuity of the dialogue with the patients due to hospital shifts, and the problem of linguistic barriers in the case of foreign patients, are some examples of the *structural limits* that the staff encounter in building healthcare directed at informing the patients.

Apart from these systemic problems, which do not depend on the will of the individual member of the medical staff, the difficulties that the personnel encounter when responding to the criteria for gathering informed consent appear to be linked to other factors. The question of *to what extent* it is possible and right to inform the patient is one of these. In fact, the content of the information to be given to the patients often poses ethical and bioethical choices for the professionals. As described for the various sectors of hospital medicine – such as, for example, the oncological sector or end-of-life treatments – the tendency *not to tell the whole truth* is linked to the system of values promoted by the medical staff. According to the operators interviewed, in the majority of cases it is a conscious choice that aims to defend the patients' overall well-being. The same is true for the lack of information regarding the risks linked to diagnostic examinations and surgical operations considered necessary for the improvement of the patient's state of health. What might appear at first to be omissions, or ways of going against the law, in fact represent decisions linked to a therapeutic purpose and dictated by positive intentions. On the other hand, the analysis of the literature shows that the same attitude can be found amongst professionals in other hospitals in Italy and throughout Europe, unlike the situation found in clinics in the United States. This situation emphasises the extent to which the methods of informing the patients and the way in which the informed consent is gathered is not equal in all countries, but varies from one context to another. Thus, the same procedure in international law is enacted in different ways *in practice*, according to the medical culture shared at local level: what is impossible elsewhere turns out to be

the norm in Italy, where the decision to tell the patients the whole truth is considered counterproductive for their health.

Another question that revealed interesting aspects for consideration, if analysed in parallel with the medical practice and the juridical principles of the doctrine and the jurisprudence, is precisely *who* should be informed.

The dogma of the therapeutic alliance between the doctor and the patient, long enshrined in the Italian legislation, in effect presupposes that the latter is a legally capable subject, who can fully understand the extent of their decisions. Precisely for this reason, and in consideration of the fact that the patients are the first addressees of both the treatments and the informative processes, the principle of informed consent is difficult to apply when the clinical conditions of the patients do not allow the staff to inform them (the case of medical emergencies, informing incapable or disabled patients, informing psychiatric patients, or even informing patients affected by senile dementia, to give just a few examples).

From this point of view, if we consider the situations in which the patient – who in principle should receive the information and be the one to give their consent – is interdicted or assisted by a court-appointed guardian, it is interesting to note that an advantageous process of adapting the doctrinal and jurisprudential guidelines to their needs (based on daily procedures in the hospitals) has been undertaken, with the aim of safeguarding the patient's decisional autonomy and taking into account – where possible – their expressions of will. Also, the traditional tendency, rigidly formalistic, according to which the decisions regarding the medical treatment must be manifested in the place of and on behalf of the patient, by their legal representative, is now being replaced by the theory that, vice versa, when the patient has even limited natural capacity, they should be allowed to decided which treatments to undergo. This is undoubtedly a step forward in the adaptation of juridical procedures to the practical dimension in which the doctors operate; at times dealing with patients who are partly or wholly incapable and for whom they prefer to individually ascertain the residual capacity for decision-making, in order to determine how far to involve them in the choices to be made.

Furthermore, the results of the research carried out show the substantial absence of a juridical response also in the case of geriatric patients, who often depend on assistance from their children and who, in consideration of their limitations, prefer to entrust the dialogue with the doctors to their family, rather than undertaking it themselves. In this case, the rigid application of juridical rules on the capacity to act should, in theory, lead to the non-validity of the consent given by the patient's family, since the only subject with a legitimate right to express their wishes

regarding treatment remains the geriatric patient themselves, unless a declaration of legal incapacity has been issued.

Hence, the abstract nature of this juridical solution and its substantial inadequacy to guarantee the best safeguards for the weak subject could be overcome if Italian legislation were to adopt (like the French model) the theory that attributes importance to the so-called 'natural protectors', that is the persons close to the patient, who would thus in effect be in a position to guarantee for the patient. Such legislation would attribute to them not only the duty to protect the incapable person, but also to take decisions regarding the care of that person.

This problem is to some extent similar to that of minors. On this question there are doubts as to how far they should be involved in the medical decision-making process, particularly when they fall within the category of 'juveniles', that is the subjects who are at least partially capable of understanding the effects of their choices.

In the face of the rigidity of some juridical solutions, which recognise the legitimation to express consent only for the parents or the court-appointed guardian, as the representatives of the minor, in practice we have seen, in recent years, a series of initiatives aimed at encouraging the spread of forms of ludic communication for the younger patients (those aged less than ten years old), which represents the efforts made in the paediatric sector to inform the children.

Nonetheless, the problem of informing minors remains an open question for the hospital professionals. The absence of specific indications at a normative level translates into the tendency to decide case by case whether to inform these patients in the presence, or absence, of the parents. At the same time, the evaluation of how far to go in giving explanations and to what extent the patient's personal opinions should be taken into consideration changes from time to time, according to the 'maturity' shown by the patients in conversing with the doctors.

Together with the difficulties encountered by the professionals in informing the patients, the analyses presented in this volume highlight the need to deconstruct a series of fundamental concepts underlying the practice of informed consent. Starting from the assumption that the gathering of consent does not correspond exclusively to the moment in which the forms are signed but represents the result of an exchange with the medical personnel, the first notion on which to reflect critically is precisely that of the *relationship* or the *doctor-patient alliance*. As repeatedly mentioned in this volume, rather than what is supposed to occur in the abstract, the doctor-patient relationship is almost never a relationship that involves only two players. The protagonists of the informative process leading to consent are generally numerous. Amongst the hospital figures who play an important role alongside the doctors we find: the nurses (and the obstetricians) to whom the doctors delegate part of the information to be given to the patients; the psychologists to whom the

'management' of bad news that could traumatise the patient is delegated; the various specialists who take part in the gathering of 'multiple consents'; the social workers and the linguistic-cultural mediators, respectively charged with the management of the so-called 'social cases' and informing foreign patients. Except for multiple consents in which, as suggested by the term itself, the responsibility to inform the patients is formally distributed amongst a number of professionals, in the other cases the figures mentioned do not officially appear amongst those who sign the consent together with the doctor. From here, the tendency to identify only the doctors as responsible for informing the patients, without considering the complementary work of other members of the hospital staff. The presence of other players in the doctor-patient relationship is also valid for some patients, who, except in rare cases, are always accompanied by one or more family member. To these we must add the series of 'invisible' players, such as persons consulted by the patients online (Internet forums) and offline (at the hospital), who equally participate in the process of informing the patients.

The second notion on which it is necessary to reflect critically is that of *autonomous decision-making*. In continuity with what has been said so far, the image of the patient in which they have the right to decide autonomously how to deal with their own body and their own health, can be described as an abstract figure. The representation of the patient as the owner of their choices in fact clashes with the importance assumed by the immersion of the patients in a network of interpersonal relationships that influence the construction of their choices. The impossibility of considering the patients as individual subjects or separate and separable actors from the remainder of the group emphasises the relative value of the concept of self-determination of one's choices. On the one hand, the opinions of one's family play an important role. On the other hand, the direction of one's choices depends on the information received from the doctors.

Although each patient is a separate case for whom the information offered by the doctors necessarily passes through a process of personalisation of the content at a clinical level, the social profile of the patients – factors linked to age, education, social class, or even Italian or foreign origin – contributes equally to the way in which the explanations offered by the medical personnel are received. Therefore, in similar clinical situations, the information to the patients does not seem to be equally distributed. The consideration that it is worth spending time in a lengthy discussion of the pathology, the risks and the possible treatments only with certain patients and not others, emphasises the point to which the *social inequalities* influence the information process. Hence, it is necessary to reflect in a critical manner on the forms assumed nowadays by the so-called *healthcare democracy*. The weakness of this category emerged on two levels. On the one hand, the fact that the detail of the explanations changed according to the social profile of the patients could testify to the

absence of a democratic attitude amongst the hospital staff. On the other hand, the attempt to go beyond the objective data – that is, the fact that the patients do not all have the same cultural capital – trying to inform them all in the same way or 'imposing' healthcare democracy on them appears to be a process undertaken merely for its own sake. In fact, the result is neither an increase in the level of information nor the overcoming of the asymmetries linked to the cultural gap of which the patients seem to be wholly aware. Except for very few cases, the lack of perception of a discriminatory attitude towards the *quality* and the *quantity* of information received from the doctors – which is *in reality* not equally distributed – is emblematic in this case.

The varying identity of the patients therefore influences the expectations and the manner in which they experience their relationship with the medical staff. Despite this, there are shared tendencies, which seem to suggest the need to ponder the complexity of another of the basic concepts of informed consent, that is, the notion of *joint medicine* as against the model of medical paternalism. Although nowadays, except in cases where it is possible to appeal to a state of necessity, the doctors can no longer act on the body of the patients without asking for their prior consent, or for that of the parents in the case of a minor, the prevalent attitude amongst the patients (or the members of their families) remains that of trusting in the treatments suggested by the doctors. Remitting one's choices to the advice and the indications of the doctors, to whom the role of 'guide' is attributed, goes hand in hand with the tendency to only rarely make use of the new possibilities offered to the patients, such as the opportunity to go against the doctor's opinion, refusing the proposed treatments, abandoning the treatments or withdrawing one's consent. With regard to the way in which the patients experience informed consent, in the majority of cases they do not appreciate its worth nor do they criticise it, considering it merely an administrative formality, or something secondary to their relationship with the medical staff. At the same time, despite the difficulties encountered by the professionals in offering complete and exhaustive information, the problems emphasised by the patients in the complaints lodged against the medical personnel are above all of a different nature. The idea that the principle duty of the professional is to better serve the patients still subordinates the limits of the informative process to the imperfections of the treatment. Consequently, only in very rare cases do the patients identify the presence of a damage to their person if the professional's failings involve *only* the informative process.

For their part, the doctors, excluding those who try to promote 'humanist medicine' based on the development of all the elements that compose the relationship with the patients tend to associate informed consent with a bureaucratic process imposed by the jurists. In the vision proposed by some of them, this procedure 'is added' to other commitments to be completed every day, obliging the professionals to produce excellent documentary proof in order to avoid any medical-legal

problems. The principal use associated with informed consent is, in other terms, for defensive purposes, as witnessed for example by the efforts paradoxically made by certain doctors in producing complementary reports in addition to the consent forms, in which they emphasise the amount of information given to the patients, even when, for various reasons, the treatment has not taken place. The commitment of the doctors in appearing impeccable with respect to the way in which the patients should be informed, like the patient's lack of consideration of themselves as holders of *new rights*, bear witness to the deficient interpretation of the informed consent process by both parties. As emphasised in this volume, we can conclude that this leads to the insufficient implementation of the true function of informed consent, that is, the development of the relational dimension in the healthcare association. It is for this reason that the practice of informed consent has often been described by the players involved as a 'façade' behind which they can see no effective change in the doctor-patient relationship.

Appendix

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Table 1. *Summary of field research*

Hospitals	Total number of wards	Clinics and wards analysed	Interviews with medical personnel	Interviews with patients (PZ) And members of patients' families (FPZ)	Duration of the observation
Molinette	95	13 (INT, RAD*, ONC, PSI-ONC*, EMA, CAR*, CHE*, CHT, GAS,	39	21 PZ, 11 FPZ	5 months

		TER, RIA, PSI, DIA*)			
Sant'Anna	37	7 (CEDP, CPMA, ONC1, ONC2, OEG1, OEG2, OEG3, RIA-NEO**)	23	19 PZ, 10 FPZ	4 months
Regina Margherita	49	10 (INT, RAD*, ONC, CAR, CHE*, CHT, GAS, TER, RIA, PSI)	25	8 PZ, 17 FPZ	3 months
CTO	36	3 (PS1, PS2, RAD)	11	3 PZ, 5 FPZ	1 month
Total	217	33	98	51 PZ, 43 FPZ	13 months

Key to departments Molinette
INT: Internal medicine ward
RAD: Radiology ward
ONC: Oncology clinic and ward
PSI-ONC: Psycho-oncology clinic and ward
EMA: Haematology clinic and ward
CAR: Cardiac surgery ward
CHE: Elective surgery wards
CHT: Transplant surgery clinic and ward
GAS: Gastroenterology clinic and ward
TER: Intensive care ward
RIA: Reanimation ward
PSI: Psychiatric ward
DIA: Diagnostic centre

Key to departments Sant'Anna
CEDP: Centre for ultrasound scans and prenatal diagnosis
CPMA: Clinics and ward for breast cancer (Breast Unit)
ONC2: Clinics and ward for gynaecological oncology
OEG1: Clinics and ward for obstetrics and gynaecology (obstetrics and gynaecology (low risk pregnancies)
OEG2: Clinics and ward for obstetrics and gynaecology (medium risk pregnancies)
OEG3: Clinics and ward for obstetrics and gynaecology (high risk pregnancies)
RIA-NEO: Neonatal reanimation ward (ward referring also to Regina Margherita Hospital)

Key to departments Regina Margherita
INT: Internal medicine ward
RAD: Radiology ward
ONC: Onco-haematology clinic and ward
CAR: Cardiac surgery ward
CHE: Elective surgery wards
CHT: Transplant surgery clinic and ward
GAS: Gastroenterology clinic and ward
TER: Intensive care ward
RIA: Paediatric reanimation ward

PSI: Psychiatric ward

Key to departments CTO
PS1: Accident and Emergency minor traumas
PS2: Accident and Emergency major traumas
RAD: Radiology clinic and ward

- All the wards marked '*' are temporary wards, that is wards where my presence was limited to the presence of the patients treated for a short time on one of the wards covered by the research; the sign '**' indicates wards belonging to more than one hospital.
- The opportunity to analyse more than one ward in a short time was due to the fact that the number of paediatric patients is lower than that on the adult wards.

Table 2. *Summary of interviews held at the Molinette hospital complex*

Clinics and wards	Interviews with personnel	Interviews with patients	Interviews with members of patients' families
Internal medicine	3 MED/3 SPE/2 INF/1 CAP/1 ASS	5	2
Oncology	1 PRIM/3 MED/1 CAP/1 MEC	5	2
Haematology	3 MED/1 SPE		3
Transplant surgery	2 MED/2 PSI	4	1
Gastroenterology	1 PRIM/1 MED/2 INF		2
Intensive care	2 MED		3
Reanimation	1 PRIM/2 MED		3
Psychiatry	1 PRIM/2 MED/3 INF		2
Total	39	21	11

Key
PRIM = Consultants
MED = doctors (internists, oncologists, haematologists, gastroenterologists, cardiologists, surgeons, anaesthetists, psychiatrists)
SPE = trainee doctors
INF = nursing staff
CAP = head nurses
RAD = radiologists
ECO = sonographers
ASS = social workers
PSI = psychologists
MEC = cultural mediators

Table 3. *Summary of interviews held Sant'Anna*

Clinics and wards	Interviews with personnel	Interviews with patients	Interviews with members of patients' families
Ultrasound scan and prenatal diagnosis	1 PRIM/2 MED/ 2 INF/1 ASS/1 PSI/ 1 MEC	4	2
Medically assisted procreation centre	1 BIO	1	1
Breast Unit	1 MED		1

Gynaecological oncology	1 MED		1	
Gynaecology and oncology 1	1 MED/3 OST/1 MED		4	
Gynaecology and oncology 2	1 MED/3 OST/1 MED		4	
Obstetrics and gynaecology 2	1 MED/2 OST/1 PSI	4		2
Obstetrics and gynaecology 3	1 MED	4		2
Neonatal reanimation	2 MED		3	
Total	23	19		10

Key
PRIM = consultants
GIN = gynaecologists
MED = doctors (sonographers, oncologists, cardiologists, surgeons, anaesthetists)
BIO = biologists
OST= obstetricians
INF = nurses
CAP = head nurses
ASS = social workers
PSI = psychologists
MEC = cultural mediators

Table 4. *Summary of interviews held Regina Margherita*

Clinics and wards	Interviews with personnel	Interviews with patients	Interviews with members of patients' families
Internal medicine	2 PED/1 SPE/ 1 INF/1 MEC	2	3
Radiology*	2 RAD		
Onco-haematology	2 MED/1 PED/1 INF	1	3
Cardiac surgery	2 MED/1 ASS	2	2
Transplant surgery	1 MED		2
Gastroenterology	1 MED/1 INF	1	2
Intensive care	2 MED/1 PED		2
Paediatric reanimation	1 PRIM/1 MED		3
Psychiatry	1 MED/2 SPE		2
Total	25	8	17

Key
PRIM = Consultants
PED = Paediatricians
MED = doctors (oncologists, haematologists, cardiologists, surgeons, anaesthetists, psychiatrists)
SPE = trainee doctors
INF = paediatric nurses
RAD = radiologists
ASS = social workers
MEC = cultural mediators

- All the wards marked '*' are temporary wards, that is wards where my presence was limited to the presence of the patients treated for a short time on one of the wards covered by the research; the sign '**' indicates wards belonging to more than one hospital.

Table 5. *Summary of interviews held CTO/Maria Adelaide*

Clinics and wards	Interviews with personnel	Interviews with patients	Interviews with members of patients' families
A&E 1	3 MED/2 INF	2	2
A&E 2	3 MED/2 INF		3
Radiology	1 RAD		1
Total	11	3	5

Key
MED = doctors (surgeons, anaesthetists, orthopaedic specialists)
INF = nurses
RAD = radiologists

Table 6. *Summary of interviews with patients Italian/foreign)*

Hospitals	Italian	Foreign	Total
Molinette	16	5	21
Sant'Anna	12	6	19
Regina Margherita	7	1	8
CTO	3	–	3

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Fig. 1. Frequency of corporate reports

Booking system 1%
Relational aspects 18%
Waiting times 30%
Technical-professional aspects - healthcare 15%
Technical-professional aspects - administration 20%
Logistics 3%
Accommodation 4%
Humanisation 1%
Information 3%
Other 5%

Source: Annual complaints report 2013, Public Relations Office (Molinette, CTO-Maria Adelaide, OIRM S. Anna).

Fig. 2. Complaints by topic

Relational aspects 18.4%
Waiting times 42.8%
Technical-professional aspects - healthcare 14.2%
Logistics 2.5%
Humanisation 0.9%
Booking system 1.3%
Other 3.1%
Accommodation 4.4%
Information 4.2%
Technical-professional aspects - administration 8.2%

Source: Annual Complaints Report 2014, Public Relations Office (Molinette, CTO-Maria Adelaide, OIRM S. Anna).

Relational aspects 11.7%
Waiting times 45.2%
Technical-professional aspects - healthcare 10.4%
Technical-professional aspects - administration 9.7%
Logistics 1.8%
Accommodation 6.9%
Humanisation 0.5%
Information 4.6%
Other 9.3%

Fig. 3. Corporate complaints by topic

Relational aspects 11.7%
Waiting times 45.2%
Technical-professional aspects - healthcare 10.4%
Technical-professional aspects - administration 9.7%
Logistics 1.8%
Accommodation 6.9%
Humanisation 0.5%
Information 4.6%
Other 9.3%

Altro = other

Aspetti tecnico-prof. sanitari = technical-professional aspects – healthcare

Aspetti tecnico-prof amministrativi =

Struttura logistica = logistics

Aspetti alberghieri comfort = accommodation

Tempi di attesa = waiting times

Umanizzazione = humanisation

Informazioni = information

Aspetti relazionali = relational aspects

Fig. 4. Distribution of the reasons (percentage of total number of complaints).
Source: Annual Complaints Report 2015, Public Relations Office (Molinette, CTO-Maria Adelaide, OIRM S. Anna).