INFORMED CONSENT IN THE MEDICAL FIELD

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ABSTRACT

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 and that of Camilla Fin. 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, Chiara Quagliarello 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. Camilla Fin carried out the juridical inquiry examining the state of the doctrine and the jurisprudence (both Italian and European) on the more serious problems relating to consent to medical treatment.

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 – and 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 the 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 and (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.