



Presidenza del Consiglio dei Ministri

NATIONAL BIOETHICS COMMITTEE

INFORMATION AND CONSENT TO MEDICAL TREATMENT

20th June 1992

CONSIDERATIONS, CONCLUSIONS AND PROPOSALS OF THE NATIONAL BIOETHICS COMMITTEE

The National Bioethics Committee,

- having established that in current medical practice frequent shortcomings are to be found in the obtaining of the patient's 'informed consent' to diagnostic and therapeutic procedures;
- aware that such shortcomings give rise to increasingly unpleasant episodes of litigiousness and consequent interventions by the law;
- reconfirming that the principle that medical practice in its entirety, as in any single medical treatment, must comply with the general regulations set out by the code of conduct and professional deontology, aimed at achieving the wellbeing of the sick person;
- stressing the principle that the first responsibility in the exercising of the right to treatment is the responsibility of each single person, who avails of the work of a freely chosen professional or made available by society through the healthcare system – to be helped to prevent illness or to treat it, or to rehabilitate physical strength and functional capacity;
- aware of the fact that most of the difficulties arising between the doctor and the person defined as 'patient' since they are considered to be in a state of need are due, not only to the objective disparity of technical competences and professional experience between the two parts of the relationship, but also to the precariousness of communication;

considers it fitting to propose the following considerations on the subject:

Under a sociological profile:

1) Informed consent, which can be translated as a wider participation of the patient in decisions concerning him or herself, is increasingly requested in our society; the age of 'medical paternalism' is considered a thing of the past when the doctor considered himself legitimated, by virtue of his position to carry out the practice of his profession, in ignoring the choices and preferences of the patient, and in transgressing them should they be in contrast with clinical practice in the strict sense of the word.

2) The need is therefore recognised to mark the limits of a legalistic exaggeration of the 'principle of autonomy' in medicine, first of all avoiding a bureaucratic definition of the ways in which consent must be expressed and be received.

In the systematic and almost obsessive search for an agreement with all

medical treatment, one can in fact reach an indiscriminate use of ‘forms’ in which to gather ‘written informed consent’: a set of forms of this kind, even if carefully put together, does not cover all the unforeseeable situations of clinical reality and risks bureaucratising the particular nature of the *trust* on which the relationship is founded.

3) According to the NBC the sincere trust that doctor gives even though not giving continuous and detailed information to do as much as is within his means to safeguard the health of the patient, is an essential condition for the serene and efficient conduct of the therapeutic relationship. In apparent contrast with the request for greater information the patients often complain of the degeneration of the relationship with the doctor into an anonymous, and humanly uncommitted, impersonal meeting between the giver and receiver of treatment. The unfortunate lack of a relationship of trust seems to be due to the impossibility of establishing genuine communication, and this impossibility is in turn aggravated by a disheartened and even suspicious attitude. Cold detached information is not enough for interpersonal communication, even though it may be exact from a legal point of view, and on its own does not offer the conditions for a real mutual consent.

Under the legal profile:

I) Informed consent constitutes the legitimation and foundation of medical treatment.

The patient’s consent, which the Anglo-Saxons define as *competent*, that is of a sound mind (of age, of a healthy mind and in a state of conscience) cannot be *delegated* to others just as it cannot be presumed by the doctor. The doctor must therefore refer only to the act of will of the adequately informed subject.

The expression of will by the capable patient cannot therefore be substituted in any way at all; the choices foreseen in common medical practice can only take on importance in the case of unexpected distress or loss of conscience.

Should the patient in possession of sufficient cognitive and volitional capacities not intend to avail of the possibility of knowing and deciding, the doctor is bound to act according to science and conscience to safeguard health and life. In this case decisions and options that may have a negative effect on the action taken by the doctor are not binding and do not relieve from responsibility,

II) If the patient is incapable, legally or physically, the right to information and consent are the responsibility of those having guardianship or having family bonds (or community of life) with the patient that justify the responsibility and the power to know and decide. Such interventions have however a *relative* significance, and when faced with fundamental choices for the health and life of the patient the doctor is not freed from the responsibilities connected to the powers

Under the operational profile:

The NBC considers it opportune to distinguish *the requirements constituting the consent* from the *modalities* of acquisition.

Requirements

The NBC answers the question: “What are *the elements of an authentic informed consent* to medical treatment?”, by referring to four conditions which must be satisfied together.

1 — Offer of information. This undoubtedly represents the central aspect of the whole issue.

In general, the analysis of the case leads the doctor to formulate a proposal, either diagnostic or therapeutic. Therefore the information has to concern a brief description of the methods indicated and the alternative treatment, the aims, the possibility of success, the risks, the side effects. Some *standards* can be mentioned in the healthcare offer.

According to the *professional standard* it is necessary to say what the scientific community considers essential in the present state of knowledge (with the advantage of the scientific correctness of the information, but with the unsuitability of communication that is generally not comprehensible to the man in the street, and considering the neither ascetic nor neutral *or value-free* nature of the decisional *standards* in medicine). The *average standard* makes it necessary to say how much a reasonable person, considered as the average within a community, would want to know and could understand of the medical procedure that will concern them (with the advantage of the popular level of the information, but with the ambiguities linked to the notions of reasonable and average).

Like the *subjective standard* it must say what the single patient wants to and can understand there and then, or what he or she considers most significant (with the advantage of a relational specificity but with the risk of a paternalistic bias of the contents of the information by the doctor in charge). A combination of the second and third standards has even been proposed.

It must be stressed that the information must not be just a transmission of data and facts, but must point out to the patient the possible *alternatives*, therapeutic and non-therapeutic.

In fact, the information is aimed not at filling the inevitable gap in technical knowledge between doctor and patient, but at placing a subject (the patient) in the condition to carry out his or her rights in a correct way and hence to express a will that is in fact his or her own; in other words, to put him or her in the situation to

choose.

Correct information is therefore above all clear in indicating the fundamental stages of the decision making process in one direction or another, and that is, the alternatives that exist: it is up to the doctor to give the reasons for advising one particular treatment rather than another.

2 — *Understanding information.* Obviously the information valid for informed consent must be comprehensible and be really comprehended. Among the limitations of understanding must be mentioned over or under information, the situations or psychological experience linked to the illness (unreasonable delays, consequences of an analgesic, attention deficit).

3 — *Decision making freedom.* For informed consent to be valid, it must be expressed with a free will, as far as is possible.

The freedom with which a sick person agrees to a proposal of therapy can undergo influences and pressure, and sometimes real coercion coming from the social context, from spouses and even from hospitals and medical staff.

4 — *Decision making capacity* (the Anglo-Saxon authors' '*competence*'). Under age patients, mental illness or even physical illness can affect the concrete aptitude to take a certain decision.

A limited capacity can be sufficient to make a decision there and then concerning a certain problem; this however is not equal to the absence of one or any psychiatric illness.

The decision making competence of a subject must therefore be assessed from time to time first of all and with respect to a decision considered significant: this can be present and valid, absent, dubious, changeable.

According to the NBC, the examination of the ways in which the deliberative process takes place is important in order to recognise the capacity of a subject. On the strength of such a criterion it is necessary to ascertain whether the subject is able to communicate with the medical staff, gives external signs of having understood the information and of being ready to decide, understands the alternatives and is aware of the nature (alternatives that must be explained without any influence at all from the doctor's ideological conditioning), answers coherently, and persists in the conclusions expressed.

Modalities of expression

With regard to the modalities for the acquisition of consent, in actual clinical practice, it is necessary to resolve the following problems:

- How and when to inform the patient.
- Within what limits to give information.

— Who must have the responsibility of informing the patient. – What kind of relationship the doctor must have with close family.

– How to be sure that the information has been understood.

The NBC does not recognise the need for the modalities of expression of consent to be regulated by law, besides what is already established in particular cases by the regulations in force; it appears preferable to refer to the national deontological code, also for constant updating.

Furthermore, it considers that it is useful to propose a few guidelines that mirror the various standpoints in Italy.

How and when to inform the patient

In clinical practice the patient usually goes to the doctor who is treating him accompanied by a member of the family (or by a person they can trust) who generally ask for the hard reality not to be communicated (this is obviously in the case of serious illnesses; the problem does not exist or is not as serious in the case of ‘non malignant’ affections and not particularly risky treatment). In this phase not being completely explicit can be justified, but it is necessary to speak to the patient about ‘serious illness’, ‘the seriousness of the situation’, of the need for ‘particular, delicate investigation’, of therapies that may ‘involve risks’.

It is indispensable that the doctor-patient relationship does not end with the first meeting and that it continues over time, establishing a relationship of trust suitable for the fostering of communication. It is rare that the information can be given completely in the first meeting.

The ‘how’ to inform the patient is linked to various factors: general and specific culture, psychology, age of the patient, and other elements that only a more detailed knowledge of the socio-family situation can permit.

Within what limits to give information

With regard to the so-called ‘benign’ pathologies, the information must be complete and given in detail. In the event that the diagnosis is fatal it is necessary to be precise but in such cases to use ‘non traumatising’ terminology (preferring for example terms like ‘neoplasia’ or ‘tumoral pathology’, ‘cell atypia’, rather than ‘cancer’, ‘malignant tumour’ and so on, and to add that the histology may vary, in the case of neoplasia, among forms of greater malignancy and others on the border between benign and malignant). For any examination considered necessary, information must be given in terms of usefulness and possible risks. The aspect relative to the dangers and drawbacks of the treatment is more delicate and above all to its success rate.

It seems essential to speak about the ‘morbidity’ connected to a series of treatment, besides the ‘mortality’; the difficulty of being precise is also linked to the choice between giving numbers taken from general or personal experience or from other sources.

If the doctor in charge is not asked specifically by the patient, certain aspects will be mentioned in the context of the overall talk about the treatment programme, which must take place with the patient in any case.

Who must have the responsibility of informing the patient? This is the job of whoever has the task of carrying out the operation or of deciding on the therapy; in a hospital it is the consultant who can delegate the registrar or an assistant, even though being personally responsible.

Relationship with members of the family. It is unquestionable that an adult patient of a sound mind is the true (and often the only) interlocutor with the doctor. The relationship with the members of the family (or fiduciaries) cannot be disregarded as being helpful in understanding the patient’s psychology and in establishing their position.

It is more difficult to define the doctor’s conduct with regard to the completeness of the information when, as often happens, he has been expressly asked by the family not to give any. The NBC considers that, having clearly explained the need to give information and the advantages (and disadvantages) of this to the family, the doctor should behave with the patient according to the general rules mentioned (exact information without any dramatic tones, characterised by a series of elements that enable the patient to see some hope in the future, the denial of which would not be human).

In the case that the patient expresses the will to the doctor to inform persons outside the family nucleus of the state of his or her health, such will must be respected when formally expressed.

Oral and written informed consent

Informed consent can be oral and written.

The patient is asked for oral consent for any sort of diagnosis or treatment, but the modalities are usually in proportion with the type of intervention.

In the present state of things written consent is to be considered a moral duty on the part of the doctor in all those cases in which the diagnoses and/or treatment by reason of their nature (due to the risk involved, the length of treatment, the personal and family implications, the possibility of alternative options among

which must be included the possibility of choosing another doctor or another hospital) are such as to make an unequivocal and recorded expression of the patient's will opportune.

The document testifying the consent can consist simply in a few statements indicating the type of treatment or in a form that also contains information on the possible risks, given moreover with modalities that bear in mind the possible negative psychological effects on the patient.

In the case of informed consent given by those having guardianship or who, with an incapable patient, are related to the patient or have proven evidence of living together, the consent can be requested by the doctor with modalities that more explicitly point out all the risks possibly involved in the treatment.

The written consent must be attached to the medical record and constitutes an integral part of it. At the same time it is considered opportune that the medical record contains separate notes by the doctor on the reasons for his diagnostic or therapeutic proposals when they are particularly serious.

The preparation of the doctor

Lastly, an aspect must be highlighted that concerns the doctor himself: he must be in possession of sufficient 'qualities' in psychology that allow him to adequately deal with the complexity of the situations.

In fact, in order to recognise the patient's decision making ability, to really understand it, to offer correct information which is followed by a convinced consent, a communicative ability is required which for the doctor identifies with his availability to dialogue, to listen, to the giving of assistance involving real human understanding, besides his professional ability to diagnose and prescribe treatment.

As has recently been expressed in a document on 'Professional Training', the NBC considers that special training programmes are needed for the acquisition and development of this aptitude.

CONCLUSIONS

The NBC considers that informed consent constitutes the legitimation and basis of medical treatment, and at the same time an instrument to realise the search for a 'therapeutic alliance' within the law and the deontological codes and the full

humanisation of the doctor patient relationship, to which today's society aspires.

Therefore, under the ethical profile:

1) In the case of serious illnesses and lengthy diagnoses and treatment the doctor patient relationship cannot be limited to a single brief consultancy.

2) The doctor must have sufficient knowledge of human psychology in order to enable him to understand the patient's personality and their family situation, so as to modify his approach in giving information.

3) This information, if likely to cause the patient worry and particular suffering must be given with great care, using non-traumatising terminology always including elements aimed at conveying to the patient the hope of the possibility of success, even though difficult.

4) The information relative to the series of diagnoses and treatment must be truthful and complete, but limited to those elements that the patient's culture and psychological condition enable them to understand and accept, avoiding exasperated details of data (exact percentages that are also difficult to define – of complications, mortality, failure rate) pertaining to the scientific aspects of the treatment.

In any case the patient must be put into a position to exercise his rights correctly, and therefore to express a will that is really such with respect to the changes and alternatives being proposed.

5) It is the consultant's responsibility to inform the patient in a national healthcare hospital, and in any case lies with whoever has the task of carrying out and coordinating the diagnoses and treatment.

6) The family's request to give the patient untruthful information is not binding. The doctor has the duty to give the patient the necessary information in order to face reality responsibly, at the same time respecting the criteria with regard to the use of careful terminology mentioned above.

7) Written informed consent is a moral duty in all the cases in which owing to the special nature of the diagnoses and treatment, an unequivocal and proven expression of the patient's will is opportune.

8) The request for written informed consent is also the doctor's moral duty, in the case of a legally or physically incapable patient, in the hypotheses referred to in point 7, towards those having guardianship or having family bonds (or community of life) with the patient that justify the responsibility and the power to know and decide, it being understood that such interventions have a relative significance and the doctor, when faced with the fundamental choices for the patient's health and life is not freed from the responsibilities inherent in his powers.

Proposals

Lastly, the NBC considers that an effort must be made to draw closer together (and this is already at an advanced stage) the dispositions regarding informed consent in the deontological codes of the various countries and recommends better regulations on medical records.

REPORT

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I – OUR SOCIETY AND MEDICAL MODELS

With the premise of the obtaining of informed consent for medical treatment coming into normal practice, with the exclusion therefore both of the aspects of healthcare regulated by the regime of compulsory healthcare and the clinical experiments on 'volunteers', the NBC has drafted some observations of a general nature on 'models in medicine' to be taken into consideration.

In fact, it is clear that also the expression of the ‘information/consent’ combination has different ways of being realised according to the medical model to which it refers.

The question on the ethicality of the concrete ways in which scientific and medical activity is carried out in our societies has also been extended to the idea itself of doctor and medicine, which was handed down from previous generations.

Bioethics has thus made the critical rethinking of the aims, the obligations and the rights of healthcare staff more explicit and demanding and has set down a more reasoned verification of the type of therapeutic relationship that society will see over the next decades.

Today, for different social and institutional reasons (among which the increase of social mobility and the organisation of healthcare as a public service), medical assistance is delivered more and more by a stranger, with whom the patient does not expect or generally ask for future contacts.

To react to this tendency, which is typical of the treatment based on the ‘hospital’ model, various healthcare systems, in conformity moreover with the recommendations of the World Health Organisation, have created the network of ‘basic medicine’ which should guarantee the continuity of the examination and treatment of the citizen during his whole life under a healthcare profile. However, the trend towards the resorting to high specialisation and the difficult collaboration between basic medicine and specialist medicine networks tend to prevail in wide strata of public opinion.

Moreover, the highly technological dimensions of the medical profession lead to expectations that privilege (in specialist medicine above all) the technical quality of the treatment, to the detriment of the conditions which once fostered a therapeutic relationship that was strongly hinged on trust, consisting in the patient turning to a well-known person, related to him by a certain habit and familiarity. In answer to the new type of social demand, it seems that the notion of medicine as a job is increasingly gaining consensus, defined exclusively by the technical healthcare delivered and not as a profession distinguished by a demanding personal involvement, including an amount of individual risk in the service to the patient and distinguished by specific human qualities in the relationship with the sick person.

In this *technicist model*, the medical treatment would consist in the simple carrying out, competent at the technical-scientific level, of the requests of the patient, except obviously in the case in which such requests were in conflict with the conscience of the doctor. The moral connotation of the profession as such would instead be greatly taken away and in particular the independence of judgement would be weakened with which, according to science and conscience,

the doctor swears to carry out his job to protect life and the protection of health.

In turn the technisist model can take on different forms.

In the more literally 'merchant' version, health is understood as a good, the object of market transactions; the professional is the well-paid technician who supplies the product-service, so that, the greater the availability of resources of the client, the more freely can the range of the doctor's requests be delivered.

This model of relationship can, in a second version, be mitigated by an explicit contract, sanctioned at a social level.

That is, society would watch over the carrying out of a commercial transaction between two partners (one, the doctor, having decision making supremacy in the technical context, the other, the patient, in the context of objectives to be reached), somehow regulating such a relationship and having the right to intervene in difficult situations.

In a more corporative version, the doctor's obligations would not be towards the patient but towards the medical associations. These would stipulate a contract with associations of users and then employ single doctors to actually see to the needs sanctioned as being important in this way.

In contrast with the technical model of the therapeutic relationship is the one which we could call the *model of beneficence*. In this model the moral duty of the single doctor is recognised as unavoidable to act in the interest of the patient, considered in their entirety. This duty would justify the dignity and independence of the profession and therefore would not be negotiable.

This duty would express, in the forms peculiar to medical practice, an attitude of solidarity, belonging to each man as such. What unites doctor and patient would therefore be the need for assistance, which the latter has and which the former must satisfy not only in a technically correct way, but also humanely sensitive, ethically conscious and resisting social pressures or individual requests that could contrast with the objectives of his position.

Even though in a different way from the negotiable-technical one, the beneficiality model also involves the respect for the patient's free choices, in so far as acting in their interest means involving the subjectivity of the patient in the evaluation of the therapeutic strategy most in keeping with his or her position.

In this model too, the protection of personal health (health that does not coincide with the repair of a broken down machine or with the normalisation of a modified biological parameter) demands a significant understanding of the experience, the hopes, the fears of whoever suffers and therefore requires the doctor to have and to cultivate human qualities (the ability to listen and talk, psychological sensitivity, tact) that enable him to do his job.

The doctor that works diligently and with dedication to reach the objectives of his profession establishes the conditions so that the therapeutic relationship may be

based on trust and reciprocal respect. Finally, even though ‘informed consent’ can legally be expressed also for each single diagnosis-treatment in the negotiable-technical hypothesis, it is also true that only in a wider and more authentic relational context can we expect, case by case, to obtain a valid informed consent.

II — ‘INFORMED CONSENT’ UNDER THE **PROFILE OF CLINICAL EXPERIENCE**

In order to identify the most suitable modalities in the offering of information and in the consequent expression of consent, it is fundamental to have a better knowledge of the ‘clinical demands’.

By adhering to precepts of bioethics, it will thus be possible to avoid formulating only theoretical principles, which have no possibility of corroboration in practice.

From a clinical standpoint, it is recognised above all and universally that the patient’s consent to the involvement of his person in diagnoses or treatment presupposes the precise information that the doctor can and must supply, and not only when requested by the person in question.

It must also be remembered that, in theory, the choice of a doctor or of hospital facilities implies in most cases, and at least in those selected, a relationship of trust which alone should guarantee the patient the assumption that the most suitable and least risky treatment has been chosen, according to science and conscience. Nonetheless clinical reality poses situations all the time that require an explicit consent following the giving of precise information on the variety of circumstances in which the basic elements to be considered are represented by the evaluation of the risk and the benefit to be obtained, possible mutilations, alternative therapy, the prognosis etc.

From a clinical point of view, it is considered that it is difficult to limit the subject matter being dealt with to a set of codes, in so much that considerations of an ethical, psychological, humanitarian nature vary significantly from case to case.

Probably for this reason and as will be mentioned more in detail later on with regard to the legal requirements for consent (see Cap. III) the legislator thought fit to use civil and criminal laws that decree, at a general level, the inviolability of the human body without the person’s consent and prohibit, in this absence of this consent, any medical treatment whatsoever. The shortcoming of the doctrine is compensated for by the ample jurisprudence which, for the most part, recognises the doctor who acted outside consent as being guilty, classifying this sometimes under ‘carelessness’ and sometimes under ‘negligence’. These aspects will also be dealt with later on in the analysis.

A more specific contribution has been made by the Medical Associations starting back in 1924, with the promulgation of a 'unified deontological code of medicine', updated in 1948 by the Medical Association of Turin, in 1953 and then in 1989 by the National Federation of Medical Associations. Although without any legal force, the deontological code of medicine represents a precious guide for the doctor to do his job to the best of his ability (see as well as Ch. IV the analysis of the articles of the Italian Deontological code of medicine in a comparative study with the precepts of the corresponding codes in other countries.

However, for the reading of the articles of the deontological code of medicine on informed consent, the regulating nature appears with regard to the information and the ensuing obtaining of consent.

The information: general features

With regard to the ways in which it is given the information must be:

- a) suitable for the single patient in relation to their culture and ability to understand on the one hand and to their psychic state on the other;
- b) exact and complete with regard to the diagnosis, therapy, risk and prognosis.

By analysing these statements more closely it must be recognised that the evaluation of the 'receptiveness' of the patient to the information is entrusted to the sensitivity and experience of the doctor. In some ways the explanation given to an uneducated person, in the general sense of the term, is simpler, as the trust in the doctor is greater, being seen as the only consignee of a technical truth and the requests for details are fewer. On the contrary though this does not authorise an undue simplification of the explanation, at the end of which the doctor could have doubts about not being exhaustive and sufficiently clear enough, and have obtained an unmotivated consent. The relationship with an educated person is usually made easier by a common language; being on the same wavelength however usually results in a request for exasperated details which, even though coming from a legitimate desire to be reassured, can result in obtaining the opposite effect. Some patients of this type ask to establish the relationship between the meaningfulness of a diagnostic investigation and the risk connected with it in terms of mathematical certainty. This often happens with people who do the so-called 'objective jobs': mathematicians, engineers, dealers, entrepreneurs, used to calculating the risk in function of the benefit exactly, trying to apply their mental scheme also in these cases. In many cases the doctor cannot follow this path and answer in numbers and percentages: he makes his own evaluation from the law of the great numbers, filtering it through his own personal experience which leads

him to sometimes diverge.

The doctor's role, therefore, cannot be limited to the simple mathematical listing of advantages and disadvantages. Without having recourse to coercion the doctor must help patients to evaluate the type of choice which he considers the most suitable for their interest, with a different cognisance altogether.

There are cases in which the patient's particular psychic habit makes the giving of information very difficult. Patients who exclude everything that may be the cause of pain in a preconceived way, or fideistically believe in a spontaneous recovery; patients who are psychologically very fragile or obstinately sceptical about the possibilities of medicine make it very difficult to establish the right sort of dialogue with the doctor.

In these cases and in the patients' interest, the doctor can involve to his advantage the expertise of a psychologist, a social worker, and in cases where it may be of help, a priest.

In many situations, if suitably informed according to the modalities and the limits set out further on, the family can collaborate in giving carefully worded explanations to patients, persuading them with affection and solidarity.

Consent in diagnostic procedures

Some diagnostic procedures, by virtue of their non-invasive nature, are accepted by most patients right from the start: for laboratory analyses, scans, cytological tests on organic liquids such as blood and urine, sputum or saliva, conventional x-rays without the use of intravenous contrasts, the informed tacit consent of the patient can reasonably be assumed, even though this should always be discussed with the patient. It is different for invasive methods such as endoscopies, angioradiology, scintigraphy, or the pricking of the cavity, biopsies by excision or needle, for which an incidence of complications, even though negligible, is foreseen. In these cases patients cannot not be informed, obviously not in an alarming or misleading way but however in a fitting way as to enable them to express their conscious explicit acceptance of the procedure. This is particularly important when the therapeutic phase is associated with the diagnostic one at the same time, as in the case of the angioradiological intervention (angioplastic, trans-luminal, embolisations etc.) or the operative endoscope. Similarly, there may be the immediate need to proceed to treatment during diagnosis, as in the case of a miocardiac heart attack during a coronagraph or the perforation of the colon during illnesses such as ulcerous rectocolitis, which make

this eventuality quite probable during a colonoscopy. Many more examples could be given, but it is sufficient to remember the case of the pregnant woman who is dutifully informed of the even though moderate foetal risk of the amniocentesis, the corial biopsy, the funicolocentesis and other procedures that affect the foetus through the mother's body.

A particular case of informed consent for diagnostic investigation concerns the determining of sierological positivity for HIV, responsible for AIDS. In this case patients must express their prior consent to the test, having being duly informed of the clinical meaning of sieropositivity.

Information on prognosis and consent to emergency treatment

If the validity of informed consent is indisputable with regard to diagnostic procedure, it is even more so in the case of any proposal of treatment. It is however useful to differentiate between what happens in *emergencies* from what takes place by *choice*.

In the first case clinical experience shows that the seriousness of the pathology and the frequent imminent risk to life oblige doctors to make quick decisions on treatment. They cannot however skip the phase of assent, unless the patient is in an obvious state of unconsciousness, in which case it is common practice to inform the relative having authority, if present.

In the chapter regarding the legal requirements for consent the aspects of the 'dutifulness' or not of this practice will be investigated in more detail.

If patients are in a critical condition but in full possession of their faculties, they can accept or refuse the proposal of treatment, once they have been carefully and clearly informed of the state of gravity, the benefits to be hoped for, the possibilities of alternatives and the risks of the type of therapy compared with the risks of refusing it.

Is it licit to minimize the real state of health to patients whose life is in imminent danger? In line of principle, if they seem to be collaborative and accept the proposed treatment, a risk to life can be admitted when giving information in such a way as to allow patients to prepare their mind and will accordingly, without giving room for hope. This is in fact a doctor's duty and at the same time the mechanism which leads patients to giving their consent. In most cases it is given,

even when the therapeutic procedure alone is the cause of inevitable mutilation or disablement. It suffices to think of patients with occlusion who almost always give the authorisation for a preternatural anus, or the case of a person who accepts the mutilation of a limb, the eyes, the voice, obeying the strongest of instincts, that of conservation. In these cases the doctor must explain what the foreseeable mutilation will be.

A particular case is represented by patients who are seriously anaemic as a result of haemorrhage or haematological disease who, even though in danger of dying, refuse blood transfusions. This mainly happens in the observation of a particular religious belief, as in the case of the Jehovah Witnesses. Despite the suffering of the doctor who sees patients die without being able to give treatment that would probably save them, he must base his own behaviour on art. 40 of the code of medical deontology (1990) which states 'the doctor must refrain from any diagnostic or therapeutic procedure as no medical treatment against the will of the patient is allowed'. The case is different in which the refusal of transfusion regards a minor and is expressed by the parent having parental authority; in this case, in accordance with art. 41, the doctor must take the consideration as valid that nobody can be deprived of life by their own parents and can therefore ask immediately for the ordinance of the mayor or the magistrate to authorise the transfusion.

In the past, medical literature and non-medical literature has been full of episodes in which the expectant mother finds herself with the choice of saving herself or her unborn child. In reality the now common practice of the Caesarean section in difficult cases has made this possibility quite an exception. Despite the maximum effort by the obstetrician to save both lives, in the distressful and absolutely exceptional case of the choice that mainly concerns the period of foetal development, the doctor must consider the mother's will and agree on the best action with her.

Moreover the NBC proposes a more in depth analysis of the ethical-judicial relationship of the 'maternal-foetal symbiosis', so as to identify the possible duty to give treatment exclusively in the interest of the unborn child.

Information on prognosis and consent to therapy in elective practice

When explaining the therapeutic proposal to patients in elective practice, the doctor or surgeon must make sure that the patient has fully understood what the treatment consists of, what the risks and advantages are in terms of quantity (presumable length) and quality of life; in practice he informs the patient not only of the alternatives of treatment but also the corresponding prognosis.

In Anglo-Saxon countries the exchange between doctor and patient is equally

clear whether the prognosis is good or not. It is considered in fact that each individual has the right to know what his or her fate is, even in the case in which death is inevitable and close.

In Latin countries this concept is considered differently, to such a degree that art. 39 of the professional code of deontology foresees that ‘the doctor can evaluate, especially in relation to the responsiveness of the patient, the case of not revealing or of mitigating a serious or fatal prognosis, in which case it must be given to the relatives’.

Ample discretionary power is therefore given to the doctor, who approaching the patient in the right way at a professional and human level, can understand whether each single patient would despair, or on the contrary, having full knowledge of their illness would be more motivated to face and fight it.

In every case it must be recognised that the opportunity to give the patient a diagnosis or a serious or fatal prognosis, and the ways in which this should be done, represent one of the most debated issues on the question being dealt with.

In these situations, in fact, the doctor finds himself before two contrasting needs: on the one hand, the legal and moral duty to inform patients, who have the right to know anything concerning their health in their interest; on the other hand, the fundamental deontological duty of his profession, which is that of not harming the patient (*primum non nocere*), as the task of the doctor is to defend the physical and psychic integrity of man (art. 5 the Italian Code of Deontology). In fact, there is no doubt that giving a fatal prognosis to patients can have negative effects on them, and it is exactly with this motivation that, for example, the Brazilian Code of Deontology and the Patient’s Charter justify the need to violate the patients’ right to information on their own clinical state, elsewhere explicitly stated. The Italian Code of Deontology also states that in communicating the diagnosis to patients, it is necessary to bear in mind the ‘patient’s responsiveness’, by this evidently referring to the possibly serious consequences for the psychophysical equilibrium involved in the awareness of having an illness with a fatal prognosis.

On the other hand, the lack of information poses a serious problem in the event that, as often happens, patients have to undergo risky diagnostic-therapeutic procedures (radical surgery, antineoplastic or radiation therapy etc.). Such procedures would be difficult to justify to the patient owing to the seriousness of their condition. It is in such cases that patients need most to be able to decide whether to face such risks in view of a possible increase in the probability of their survival or this may contrast with their expectations regarding the period of survival remaining. For example, it suffices to think of patients with cerebral neoplasia who are offered risky surgery which could involve an increase in their chances of

survival but probably jeopardise their mental faculties. Psychic integrity or the possibility of providing for a family economically can be more important to patients than the length or probability of survival or the reduction or suppression of pain too, which nonetheless seem just and ethically correct objectives to the doctor in charge.

It is therefore necessary to ask what would be right for patients, but also what patients would consider right for themselves, which may be quite different from what the doctor expects. It must be remembered that in the document recently approved at the International Conference of Medical Associations it is stated that 'the doctor cannot impose his conception of life on that of the patient's'.

With regard to the appropriateness to generally conceal a fatal prognosis from the patient, it must be remembered that studies have shown how a considerable number of patients with fatal illnesses are in various measure aware of their diagnosis even when this is not revealed to relatives and medical staff, and how instead these patients are generally willing to discuss the serious problems connected to their illness with the doctor, on condition that it is explained correctly, that is to say leaving the initiative to the patient. The problem of the difficult acceptance of the diagnosis by these patients should not be resolved, as is sometimes done, with complete negation, but rather with a gradual approach that case by case takes into consideration what patients really want to know, or that is, how much of the truth they are able to bear, keeping an attitude that is as frank and correct as possible.

The possibility of not revealing the diagnosis is set out by the Italian Code of Deontology also in the case of a 'serious' prognosis, distinct therefore from a fatal prognosis but not specified in any better way. Such a measure with regard to serious or invalidating illnesses, but with a non-fatal prognosis at least short term, does not appear justified in subjects with a normal responsiveness for the above reasons.

In concluding this report and by way of a summary, it appears evident that we find ourselves before two different standpoints.

According to a number of oncologists, the truth should not be revealed to some patients: for example, the case of the person who comes for a diagnosis with widespread plurivisceral neoplastic diffusion for which any treatment is at the most palliative: in these cases the information would be really hopeless and the doctor must only tell close relatives the truth. It must be stressed however that in most neoplastic patients the diagnosis is not so late and there are many possibilities of therapy, from surgery to radiotherapy to chemotherapy to immunotherapy. To

know the truth is useful for some of these patients. the stronger ones with greater self-control, used to taking responsibility and facing adversities, but those who unconsciously or unwittingly ask others for truth and prefer that it is not revealed or revealed in part are certainly more numerous. It is surprising for the doctor to hear refusals of what is obvious every day, the accepting of benevolent explanations to keep a sentence without appeal at a distance.

In these cases many oncologists think that the truth should be given to the relatives, giving patients just sufficient information to convince them to start treatment. In practice they consider that it is not necessary to tell an anxious frail woman that she has breast cancer so that she accepts the idea of a mastectomy: it is sufficient to refer to a lesion at risk which in the even near future could degenerate.

Instead, other oncologists including some Italians follow the principle of informing the neoplastic patient. At the basis of this standpoint is the concern that patients having to undergo chemotherapy evaluate the treatment negatively owing to its side-effects and, if unaware of their own illness, soon refuse it.

It is probable however that a process of patiently persuading the sick person can in many cases be crowned with success and, only when this fails is it right to reconsider the hypothesis of telling patients that the withdrawal of treatment implies a real danger for their life.

Particular aspects of 'consent' in surgery

One condition in which the doctor cannot ask for the patient's prior consent is when in exceptional cases the surgeon finds himself before an unforeseen situation during an operation. A correct diagnosis, the giving of general information to the patient that other organs next to those being treated could be involved in the operation, reduce this possibility but do not eliminate it completely. In these cases, which can take on a precise medical-legal angle (for example the sacrificing of all or part of the reproduction apparatus of a fertile woman). *In emergency cases* the surgeon has the duty to operate in the patients' interest excluding the possibility, even when technically possible, of delaying this to an operation at a later date, if this should constitute serious harm to patients, and if they had not explicitly refused that operation (see also Ch. III). To what extent is the opinion of the relatives to be taken into consideration if present? As well as the indisputable legitimacy of a close relative interpreting what the patient's decision would have been, the state of agitation must also be considered as it could clearly impair any serene judgment.

A frequent subject of medical-legal controversy is offered by surgery for merely aesthetic purposes. At first glance it would seem that the 'non-essential'

nature of an operation for aesthetic purposes would imply the patients' consent. It is however important that the doctor explains clearly what the risks of the treatment are and how it is not mathematically certain that the best results may necessarily be achieved. Only then can it be considered that an informed consent has been expressed.

The sector of organ transplants for therapeutic purposes is the starting point for some particular considerations. The first concerns the recipients who must be informed of the seriousness of the illness; similarly they must be informed of the surgical and immunological risks and of the not necessarily immediate and the delayed success of the treatment. In particular, where there are possibilities of alternative treatment to the transplant, like in the case of the kidney, clear information on the advantages and disadvantages of the two methods must be given to patients so that they can choose rationally.

As far as concerns the living donors of a double organ they are anyway subject to surgery, even though not ill. The generosity and spontaneity of the donation, as foreseen by the law, would imply consent in itself. Also in this case, however, it is right to carefully explain to the person involved not only the risk of the operation but also the possible risks arising from the taking away of a double organ. They shall receive the same information from the magistrate in charge at a later date.

With regard to dead donors, the relative act of 1975 and the following regulation of 1977 clearly set out the conditions for consent which, should it not have been expressed by the person while alive, it is in fact (in some circumstances) or by right (in others) transferred to the relatives having authority.

The NBC recently drafted a document on the 'donation of organs' that tends to review this formulation.

III – LEGAL REQUIREMENTS FOR CONSENT

In order to fully understand the meaning of 'informed consent', it is necessary to widen the discussion to the juridical principle regulating medical practice.

Considering that according to the commonly accepted notion, 'healthcare' is all the diagnostic and therapeutic activity carried out to protect health, and therefore to prevent and treat the state of illness, it is evident that this involves measures by which that the individual is required to make his/her own body available for the giving of specific healthcare. These interventions involve moreover the most intimate and private sphere of the subject, regarding values protected by the Constitution: the right to life and health, the right to personal integrity, just as personal freedom, religious freedom and freedom of thought.

The protection of health in the Constitution

The fundamental constitutional reference to this question is given in art. 32 Const. according to which ‘the Republic protects the health as a fundamental right of the individual and interest of the community, and guarantees free healthcare to the indigent. Nobody can be forced into certain healthcare if not by provision of the law. In no case at all can the law violate the limits imposed by the respect of the human person’. This is an article which not only contains the principle of the protection of health, but also sets down quite a detailed branch of healthcare. A first and more general problem facing the interpreter of the provision under examination, concerns the form of a duty of the individual to health next to the individual right to health. The problem becomes particularly important in relation to the interest of the community with regard to health protection, which art. 32 Const. declares to be worthy of protection, and therefore in relation to the legislative provision of obligatory healthcare.

A different solution has been given in juridical doctrine and jurisprudence to the *de quo* problem.

According to a first standpoint, there exists a generalised duty to health, a duty which becomes specifically an obligation when the state of illness of the single person can jeopardise the health of others or the community. This assumption is founded, (referring also to the preparatory work of the text of the Constitution) both on the consideration of art. 32 Const. (that entails a specific obligation to seek medical assistance in the case of jeopardising the health of others), and on the consideration of the provisions of other articles of the Constitution and by the general personalist framework of the Constitution itself.

In particular it must be noted that the provision of a series of constitutional duties, like those foreseen by art. 4, second para., Const. (‘Each citizen has the duty to carry out (...) an activity or a function that contributes to the material or spiritual progress of the society’), or by art. 52, first para., Const. (‘The defence of the fatherland is the sacrosanct duty of citizens’), involves as a consequence a duty to health which is instrumental to these. With regard to the personalist principle that characterises the Constitution, the limit imposed by ‘the respect of the human person’ to obligatory healthcare is mentioned, as in art. 32/2nd para. Const., to infer that the subjective situation originating from the constitutional protection of the right to health would emerge as a right-duty. In the sense that all people have the duty of respect towards themselves, of protection of their own physical-psychic integrity in order to realise their own full development also in

consideration of the ‘naturalness’ of the goods of life and health and of the state of ‘dignity’ of the person that results being unavailable.

Stances in this sense are to be found in recent legislative developments: in particular some provisions of Act 25 of June 1990, No. 162 must be considered on ‘The subject of drugs and psychotropic substances, prevention, cure and rehabilitation of the relative states of addiction’, as well as Act 5 of June 1990, No. 135, containing ‘Programmes for urgent interventions for the prevention and fight against AIDS’.

On the contrary, a different standpoint considers that a duty to health cannot be inferred from art. 32 of the Constitution. This is above all due to the consideration that there is no textual reference to the concept of duty in this article, which instead appears in numerous other constitutional dispositions. In other words the silence of the constitutional legislator (*‘ubi voluit, dixit’*) would be a clear sign of the will not to make the subjective juridical position deriving from the constitutional protection of the right to health appear as a right-duty.

Moreover, it must be added that in a personalist, defender of civil rights Constitution, like the Italian one, other duties besides those explicitly foreseen are not admissible.

With more direct bearing to what is decreed by art. 32 Const. it is then pointed out that in the absence of explicit legislative provision, there exists a real right to refuse medical treatment, with the obvious consequence that there would exist the principle of the availability of the right to health in the Constitution, at least within certain limits.

With regard to the above mentioned limit of the ‘respect of the human person’, this should be understood subjectively, in the sense that with this formula the Constitution would be referring to the single individual, in the entirety of his/her person, including the range of ethical, scientific, religious etc. convictions that motivate his/her volitional decisions. Hence derives the principle of consent to medical treatment (when this is not laid down by the law) and consequently the non-emergence of a duty to health.

This second stance appears to be preferable. In short, considering the existence of the right to health and a certain degree of dutifulness to keep it, obtainable from the set of constitutional dispositions, the faculty – or rather, the lawfulness or the mere actual freedom - would however exist to sacrifice such right, or more precisely the health that is the content of such right.

Furthermore, the existence of a duty is understood to be when the state of health of the single person may harm the health of others, but within the limits in which this is foreseen by the precept in art. 32/2nd para. Const.

The subjective juridical position outlined by art. 32 Const. can be defined as a subjective right (right to health), as a right to freedom (legitimizing the claim of abstention from any illegitimate interference of self-determination of the subject),

as a social right (source of positive claims towards the State, instrumentally oriented also towards the satisfying of collective interests).

This is a fundamental right and as such, inalienable, indefeasible, non-transferable, non-disposable.

It is worth having a brief look at the nature of non-disposability.

Self-determination and its limits

According to the prevailing doctrine, this comes down to the prohibition of the contractual disposition of the right to health in inter-subjective relations, but does not forbid the non-contractual disposition of the good that is the object of protection, with reference that is to the acts that exhaust their effects in the personal sphere of the subject agent. This can be inferred from art. 32 Const., which guarantees the subject's self-determination with regard to his/her own health. Such freedom would furthermore be ascribable also to the more general provision as in art. 13, first para., Const.. according to which 'personal freedom is inviolable'. This disposition certainly has a minimal meaning, given the possibility of disposing of one's own body in an exclusive way, even if within the limits set down by the legal system.

From the provisions of the constitutional norms just mentioned, the principle can be inferred therefore by which it is left exclusively to the person in question to decide on the carrying out of extraneous operations on his/her body, except in the case of a minor, about which more will be said later on.

This principle finds corroboration moreover in ordinary provisions. It suffices to think of indictability as 'private violence' (art. 610 penal code) or as a 'state of incapacity brought on through violence' (art. 613 penal code), of the medical treatment carried out without or against the consent of the person in question; vice-versa one must also think of the exemption from responsibility of the doctor who for scientific or healthcare reasons carries out treatment on a person with their consent, which suppresses their conscience or will, even if this jeopardises the safety of that very person (art. 728 penal code).

Even art. 5 of the civil code, prohibiting acts of disposing of one's own body 'when they cause a permanent decrease of the physical integrity, or when they are otherwise against the law, public order or immoral', does not seem to be in contrast with the constitutional principle of consent of the recipient of healthcare, at the same time an expression of the right to personal freedom and the right to health. This in fact would forbid only 'contractual' acts of disposability; and on the other

hand, the protection given concerns only the ‘physical integrity’ of the person, while art. 32 Const. protects the more general and complex good of ‘health’. It follows that acts (non-contractual) of disposing of one’s body are lawful when aimed at protecting or recovering health, even when they involve permanent harm to the physical integrity of the subject.

It should also be noted that consent to medical treatment is not identified with the consent of the person having right as in art. 50 of the penal code, having as object the activity directed at the prevention or treatment of illnesses, but not the renunciation of the protection of the juridical good that makes the lesion of a disposable right not punishable (thus it has been commented that the doctor who treats a conscious person does not violate their freedom but puts it into effect).

In conclusion it can be seen that from the provisions of articles 13 and 32 Const., and more generally from the personalist principle prompting all the fundamental Charter (art. 2 Const.), it follows that the principle of consent is to be found at the centre of medical-surgical activity, and expresses a choice of value in the way of conceiving the doctor patient relationship, in the sense that said relationship seems founded rather on the patient’s rights than on the doctor’s duties. Medical treatment without consent is to be considered illegitimate, as a ‘duty to treat oneself’ does not exist if not within certain limits as in art 32, para. 2 Const.

It must be stressed however that even the principle of consent comes across limitations, as notwithstanding the consent, the intervention is unlawful when it goes beyond the safeguarding of life, health, physical integrity, as well as human dignity.

With regard to the specific problem of the limits of the principle of consent to medical treatment in relation to the demands of experimentation, the National Bioethics Committee will come back to this with a more detailed explanation in another specific document.

Juridical requirements for consent

The question has been asked whether the principle of consent requires a manifestation of will expressed with regard to the medical treatment understood in its entirety – with the consequence of considering the consent to all procedures that may become necessary during therapy implicit, or whether it needs a renewed

consent for every single act. The standpoint is that with reference to the Constitution (which in art. 32 speaks about 'medical treatment' and not single medical therapies) the obligation for the relevant consent for every single intervention cannot be inferred, unless the doctor works in accordance with a contract stipulated with the patient, since in this case the lines of action are defined by the contract.

In order to be valid, the consent of the person in question must be personal, specific and conscious. In particular they must know what treatment their body is going to be subjected to, the risks involved, the possible alternatives. The doctor's obligation to inform corresponds with this.

In this case, if there are no dangers or risks of serious harm to the patient's life, the respect of the principle of explicit consent involves the need to wait for the person concerned to be once again able to express their own will. In the presence however of the above mentioned dangers and risks, when medical treatment cannot be delayed, the reasonably founded juridical principle of the presumed consent of the person in a state of unconsciousness, besides the juridical duty to give immediate assistance, would undoubtedly legitimise the doctor in deciding the necessary medical assistance.

Cases in point do occur in which it is not possible to obtain valid consent at the moment of need.

The first is when the subject is incapable of consenting, due to a state of unconsciousness that existed before the need for specific medical care. In this case, if there are no dangers or risks of serious harm to the patient's life, the primacy of the principle of explicit consent involves the need to wait for the person concerned to be once again able to express their own consent. In the presence however of the above mentioned dangers and risks, whereby the medical treatment could not be delayed, by reason of the state of need and the duty to deliver assistance the treatment in question must be given, with the consequent responsibility of the doctor not duly delivering it (see also Ch. II, page 27).

Under a juridical profile, it is debated whether or not the patient's consent could be substituted by that of relatives in a case of need.

Because of the above mentioned responsibility of the doctor that does not intervene in a state of need to give assistance, it seems that the consent that might be given by relatives must be considered irrelevant, even though jurisprudence, including the Court of Cassation, has often opted for the valorisation of the consent of close relatives.

It is certainly correct from the deontological point of view that the doctor informs the relatives or the people who are close to the patient. Such information however cannot be considered juridically obligatory, nor can the opinion expressed by them be considered binding. It must be noted that sometimes the relatives, or those who are close to the patient, often have interests that are in

conflict with those of the sick person.

The case could be different should the patient have previously had the possibility to entrust the protection of their person concerning healthcare to a third party, in a juridically valid and inderogable way.

A second case in point is that of the patient who goes into a state of unconsciousness before needing medical treatment. There is the example of the patient who, having validly expressed his/her opposition to a certain diagnostic-therapeutic procedure, goes into the terminal phase of the illness that often precedes death.

In this case there exist various dissenting opinions. According to some, the will that was previously and validly manifested must hold, as the state of unconsciousness cannot on its own create a presumption regarding the reversal of the previously formulated dissent with respect to the *de quo* medical treatment. Others, instead, consider that even in this case there appears a state of need, so not only is the doctor legitimated in intervening, but even has an obligation to do so.

It seems opportune to always make a clear distinction between the will expressed in an abstract way by the sick person and the will expressed concretely about a certain diagnosis and treatment, when the former is evidently not juridically able to stop medical treatment. In the same way it is necessary to refer to the problem of the prospective difference between the real intentions of the patient and the reality of the situation in which they find themselves, as such a difference can legitimate treatment that does not come into the intentional sphere of the subject.

It is certain that, considering the doctor's juridical obligation to take action should there be need to give assistance, by reason of the principle of the non-disposability of life, any type of persistent therapy or persistent diagnosis must be avoided, according to the guidelines already indicated by the National Bioethics Committee in the document on euthanasia even though provisional, and on the treatment of the terminally ill following the declaration of the Committee for the protection of the environment, public health and consumer protection of the European Parliament (6 September 1991).

With regard to such cases, a useful instrument to guarantee the constitutional principle of consent could be found in the so called 'living wills': the fact remains that – for many the contents of the dispositions of the subject cannot be in contrast with the principle of the non-disposability of life and the doubt is overcome of the validity of a dissent expressed about a certain treatment before the subject finds himself/herself actually in that phase of the illness.

Another case in point regards subjects without the capacity to act, in so far as they are minors. This subject will be dealt with in detail in Ch. V but it is worth stressing how in this case too there are two different standpoints from a juridical

point of view. According to some, by virtue of the principle stated in art. 2 of the civil code, consent to medical treatment on a minor must be given by whoever has parental authority, by reason of the power of attorney but above all of the duty to provide for the minor. According to others it is necessary to distinguish the so called 'mature minors' within the general category of minors, that is, those children who because of their 'natural capacity' would be able to give a valid consent to medical treatment.

This hypothesis is not without ethical meaning, nor juridical arguments supporting it. Both the legislator and jurisprudence have in various cases referred to the category of 'mature minors' to legitimate their direct exercise of rights, especially in cases of public rights. Furthermore, the criteria by which to assess the acquisition of this capacity appear to be controversial. For some in fact, an objective criterion must be used, that of being of a certain age (e.g. the age of 14, with which the acquisition of natural capacity is usually associated) or being in a certain class at school; for others, a subjective criterion must be used, in the sense that it is necessary to assess the maturity of the subject each time (as in the case of the marriage of minors over the age of sixteen, as in art. 84 of the civil code).

It must however be stressed that the Italian legal system in force contains various norms that also expressly limit the capacity of the 'mature minors' to express a juridically valid consent to medical treatment (for example, the law on giving blood or kidney explants).

For the minor under the age of sixteen however, the principle established by art. 316 of the civil code remains imperative, for which reason parental authority is exercised by common agreement by both parents, with the possibility of each one going informally to the judge in the case of disagreement on questions of particular importance. In the case of any immediate danger to the health of the child, it is possible for the father to take urgent and undeferable measures.

In the case of minors the doctor can appeal to the judge (see articles 330, 333, 336 e 384 of the civil code), should the parent having parental authority refuse medical treatment which is considered necessary to safeguard the basic interests of the minor, such as those of life and health.

IV – CONSENT IN SOME CODES OF DEONTOLOGY

The NBC though it fitting to examine the problem of informed consent also from a comparative point of view. In this chapter various deontological codes and in particular the European ones will be examined with reference to how consent is foreseen.

The 'European guide to ethical medicine', today 'Principles of European ethical

medicine'

In making this analysis it is first of all necessary to study the contents of the European Guide to Biomedical Ethics (Paris, 1982, revised in 1987 in 'Principles of European biomedical ethics'), as this represents the main document from which all the codes of deontology in the European Community have drawn inspiration.

This document, which will be referred to as the Guide hereafter, puts consent, explicitly defined as 'informed' on the front line (the emphasis is immediately placed on what will be the main point of the problem), discussing it in art. 4 (informed consent) and maintaining that 'except in emergencies, the doctor will explain the foreseen effects and consequences of the therapy to the patient', and only after this 'will get the patient's consent, especially when the treatment proposed involves serious risks'.

In the second paragraph the Guide stresses that 'the doctor cannot substitute his own conception of quality of life with that of the patient, a specification that could seem out of place in this context, but which instead touches on the problem that most of all concerns the person of the doctor at the moment in which the patient denies consent to treatment that in his opinion is necessary, or gives consent to treatment that he considers excessively risky or useless.

Therefore, dealing with these issues right from the first article, the Guide puts the emphasis on the absolute need to give suitable information before getting the patient's consent. This information must concern both the 'foreseeable' effects and consequences of the treatment and, that is, the doctor must make clear to the patient with as much certainty as possible not only what the outcome of the proposed treatment will be, but also how 'foreseeably' he should infer it. The doctor is required to give exhaustive, ample information, which covers both the certain effects and the potential ones. The Guide does not go into details concerning the psychological side of the act of informing a patient of a medical treatment, but this is not to say that the problem has not been tackled in various European countries which have examined it in their codes of deontology.

Art. 4 emphasises how consent must be requested especially when 'the treatment proposed involves a serious risk'. This corresponds exactly with the common opinion whereby medical assistance is based on a contract of trust between the patient and the doctor; any decision that the doctor takes will be accepted by the patient without reserve, but only as long as this concerns normal diagnostic-therapeutic practice. At the moment in which the medical prescription involves what could be defined as a 'general serious risk' to the patient, the information must be given in any case.

The problem of the quality of life is an element that appears for the first time

in some European codes of deontology and seems to have arisen from the cultural evolution that has been taking place over the last decades and which has brought to the forefront the right of the human being to have a life of 'quality'. Despite the various attempts of objectification of the concept, it is however left to the single person and to him/her only to decide what it means to have a life of quality. It is for this reason that the Guide deemed it necessary to highlight something that is only apparently obvious, that is, that each patient has the right to decide whether one type of diagnostic investigation or therapeutic treatment corresponds with what he/she considers 'worthy of being lived', and the doctor must never condition him/her in any way whatsoever, putting his idea of 'quality of life' before that of the patient.

The problem of how to ask for the patient's consent is developed in more detail when the Guide speaks about human experimentation; in fact, art. 20 lays down that 'the free and informed consent of the subject destined to experimentation is acquired after having suitably informed them of the objectives, methods and benefits foreseen, and likewise of the risks and potential disorders'.

Unfortunately it is not specified what is meant by 'suitably', which would have undoubtedly been useful as a guideline. However, as mentioned above, some codes have gone into this point in more depth. Logically the information regarding experimentation requires the doctor to make it clear to the patient that they have 'the right to not participate in the experimentation and to withdraw at any time'.

The NBC intends to further investigate these problems in the section reserved for this.

Lastly, the issue is touched upon indirectly when dealing with organ transplants. In fact, in art. 15 of the Guide it is ruled that 'the doctors taking organs shall ensure with every means possible that the donor has never expressed an opinion to the contrary, neither in writing nor to relatives'. In this way, the importance of the lack of consent is emphasised in the case of organ transplants, an issue on which the Bioethics Committee has dwelt upon in great detail.

A last point to be considered is that the Guide does not give directives on how to get consent expressed. Only art. 15 considers the possibility of consent or dissent given in writing by the person concerned, while otherwise nothing is said on the subject. It will be seen how some codes have, on the other hand, considered it right to specify the cases in which consent must be given in writing.

The NBC does not consider it necessary to dwell on the case of urgency which, as in art. 4, dispenses with asking for the patient's consent, since this is well acknowledged by the legislation in force in various countries. The interpretative problems of this question will be dealt with later on at the end of this chapter.

Comparison of various European Codes of Deontology

Firstly, it must be said that the Greek code of deontology has not been dealt with in the review, as it dates back to the 50s and cannot therefore be compared with the other codes.

Before reaching a final summary, it is useful to have an idea of the lines of thought that issue from each of the codes examined. Therefore they will be briefly summarised one by one, referring to the various articles published as attachments.

The Belgian Code (1983)

A great number of articles refer either directly or indirectly to consent; nonetheless there is no article that speaks about it explicitly or that clarifies its features.

First of all, the information is given to the patient, which must be given in any case (art. 29) leaving the right to decide however to the doctor, according to science and conscience, when the patient is incapable and when it is impossible or even 'inopportune' to get the consent from a legal representative (art. 30). This article seems to give ample room for decision making to the doctor.

Explicit consent, in writing, is required for sterilisation (art. 54) and artificial fertilisation (art. 88) (by the patient or the partner and it is not clear why the partner's consent is sufficient), the removal of organs and autopsies (arts. 53 and 133 that require implicit or explicit consent).

Lastly, the consent of the person concerned is required for abortions (art. 86), human experimentation (art. 90 for a healthy subject, art. 91 for an ill subject – strangely enough written consent is not required for these cases), in the transmission of data between preventive medicine services (art. 109) and blood samples for alcoholometry (art. 131).

The Spanish Code (1979)

The Spanish code is, generally speaking, along the same lines as the Belgian one; in fact, it requires the doctor to inform the patient of every therapeutic or diagnostic measure and can end the relationship if the patient refuses (arts. 21 and 22). Also in Spain, should the patient be unable to give his/her consent and 'it is impossible and inopportune' (the same considerations as before) to get the consent

of relatives or someone with power of attorney, the doctor can act according to science and conscience.

The Spanish code, however, considers the psychological element implicit in the need for consent. In fact, it maintains that 'in line of principle the diagnosis must be given to the patient; however, it can be legitimate not to inform the patient of a serious or fatal prognosis' (art. 25).

The doctor is required to act with great care, sensitivity, attention and sense of responsibility (art. 25).

Lastly, the Spanish code adds: 'It is the doctor's duty to always tell the truth to the family of the patient, unless he/she has forbidden the giving of such information beforehand or given the names of other persons to inform' (art. 25). This partly relieves the doctor of his responsibilities but creates a new problem: are the relatives able to bear the burden of such information and behave in the right way towards their nearest and dearest? The fact of having allowed the patient to decide differently and indicate the person that he/she thinks is more suitable to 'know' the truth is interesting.

The articles concerning human experimentation (1.07 and 108) are in line with the world declarations on the subject and also with the European Guide to Ethics. It must be stressed that this is the only case in which consent is required in writing.

Articles 38 and 39 require the patient's consent for the transferring of clinical data to another colleague; this obviously appears more or less in all the codes.

The Code of Luxembourg (1991)

In line with the European Guide, this code requires consent, except in urgent cases and the prior informing of the patient about the effects and consequences of the proposed examinations and treatment, especially when presenting serious risks (art. 9). In the case of impossibility, the relatives will be informed (art. 8).

Consent is required in particular for abortion (art. 22), mutilations, except in urgent cases (art. 23), for maltreatment or torture (art. 24). This last point is interesting as moreover it is foreseen only by this code in an explicit way, also because should the patient be a minor or incapable, it is possible to disregard the consent of anyone.

As regards experimentation, art. 28 can be superimposed onto art. 20 of the European Guide; both, in fact, do not require written consent.

The doctor who reveals the confidential information with the person's consent

is not liable according to the Code of Luxembourg (art. 36).

The Portuguese Code (1985)

Also in this case information is given prior to obtaining consent (arts. 1 and 3) specifying though that should the patient be a minor or incapable, the doctor must 'respect the patient's options as far as possible in agreement with the capacity to discern that he/she understands them, always behaving according to conscience to defend the interests of the sick person' (art. 2). This appears quite innovative, as the possibility that minors or the incapable too are able to give consent that can be considered valid is not contemplated by many deontological codes. Obviously at this point there arises the problem whether the doctor is able to 'understand' the patient's capacity or not; even so, the article seems to be in line with the tendency to give the incapable the right to decide for themselves as far as it is possible.

The need to ask for consent in writing appears when the treatment involves risks (art. 39).

It is interesting to note how prohibited treatment or treatment with a proviso (art. 45) are applicable should the patient (or his/her representatives) have given formal consent 'preferably' in writing, after having been informed of the possible risks and 'always in the interest of the patient for the purpose of restoring his/her health'. This article leaves plenty of room to the imagination, considering that it allows the carrying out of prohibited treatment or treatment with a proviso that by definition should be excluded from medical practice. It is furthermore specified that the patient is exposed to risks. It could be asked what 'for the purpose of restoring health' means, when 'rash experimentation' is mentioned and 'use of diagnostic or therapeutic procedures that may cause a modification of the conscience with a decrease in free determination or responsibility or that may cause morbid states'.

Another innovative element is given by the contents of art. 47 which does not consider euthanasia the abstention from treatment that has not been started, if this has been freely and consciously refused by the patient or their legal representative. In this sense, it is more similar to our code (art. 44) which, however, does not take into consideration the possible will of a third party, but only of the person concerned leaving the last word to the doctor in the event of unconsciousness.

Consent is required, in particular, for treatment involving the risk of abortion (art. 48), for the removal of organs from a living person (art. 52), sterilisation (should the situation really justify it) (art. 54), experimentation on healthy and ill people (arts. 59, 60 and 61, in this case written consent is required), the

transmission of confidential information (art. 68) and for the exclusion of the giving of confidential information (art. 70).

The French Code (1980)

The French express themselves using few words; in fact, they maintain that the patient's will must be respected in every way possible, and, if he/she is incapable, that of the relatives, except obviously in emergencies (art. 7, art. 43). Explicit reference is made to consent for cases of mutilation. The only interesting point lies in the fact that 'if the incapable person is able to express an opinion, the doctor must bear this in mind as far as is possible' (art. 43). This appears to be in line with the Portuguese code, in so far as it takes into consideration also the possibility that an incapable person can anyway give valid consent.

Guide to Irish ethical conduct and behaviour (1989)

This guide is not structured in articles but in conversational indications, often presenting the information in an interlocutory way.

In fact, when speaking about consent, it recognises the difficulty of being able to say when a person is or is not sufficiently informed and free to consent to a medical investigation or treatment; it therefore recommends that all possible efforts be made to understand whether the patient has understood the nature and intentions implicit in the medical treatment, in particular if they are minors or incapable.

To date these considerations seem to be those closest to reality, in so far as they really recognise the difficulty of informing well; hence the need to check that the information has been understood, but at the same time there is the difficulty that the patient, as such, can in any case be free to decide and not instead be conditioned by their position of inferiority before the doctor, owing to their illness and the possibility of being treated by the doctor. All this appears to be even more obvious in the case of human experimentation.

Moreover, according to the Irish, the relatives should be informed as much as possible about the patient's health, as long as he/she allows this. Lastly, unlike other codes, the problem of AIDS is tackled quite openly when the doctor is asked to convince the patient to inform the relatives and partner of his/her condition in every way possible. In the event that they do not give their consent to this, and the doctor warns the medical and nursing staff that, by virtue of the treatment, they and the patient's partner are at risk, his behaviour will not be considered unethical.

The Dutch regulations on doctor-patient relationships (1984)

It is very interesting that the doctor is required to give, if requested also in writing, all the information about the nature, extension and reason for a medical examination or treatment that he considers necessary, the possible risks and effects, the possible alternatives of investigation and treatment, the state and the prospects with regard to the scientific knowledge of the pathology at the time (art. 4.1), as well as about the procedures that will be carried out during the investigations or treatment (art. 4.2).

The point that differentiates these articles from the others so far examined is that, for the first time, there is the possibility to ask the doctor to leave something in writing; furthermore, the information required is clearly listed so as to give the doctor a guideline to follow.

Also this Guide considers that the patient must indicate the persons to be informed of his/her state (art. 4.3).

Article 5 summarizes the contents in the previous article asking that an 'informed consent' always be given by the patient before carrying out any investigation or beginning any treatment (point 1); if required by the parties, this consent shall be given in writing (point 2), unless the patient is incapable or it comes under a field subject to different legislation (point 3).

Further clarifications are given in art. 6, which specifies that informed consent must be asked for if the actions or results are not of a drastic type, even if it does not specify how one should behave in these cases, that is, if written consent is required or whether medical treatment must anyway be started.

Holland goes beyond Portugal and Ireland when it maintains that, should the minor be considered capable of reasonably seeing to his/her own interests, he/she will be given the same rights as a major by the doctor (art. 17).

Lastly, consent is required for the transmission of data (art. 24.2) when the patient is entrusted to another doctor (art. 35) and for the breakdown of the doctor-patient relationship (art. 40).

Ethical rules adopted by the Danish Medical Association - DMA (1989)

Article 4 confirms, as in all the other codes, the patient's right to complete information in order to make a decision concerning treatment. What is remarkable is the accuracy with which the second paragraph explains how this information must be given and how consent is obtained: 'The doctor must always, to the best of his ability, identify, bearing in mind the patient's overall psychological, social and somatic situation, and accurately consider the spirit with which the

information must be given. Therefore, the doctor must not force information onto the patient that he/she clearly does not want to know'. Furthermore, for the first time the case is considered in which it is the patient himself that DOES NOT WANT to be informed. This paragraph so far seems to be the one that best clarifies the problem of the request for consent, even if it highlights two fundamental points: that of the doctor's personal ability, which in part goes beyond his medical profession, and the patient's will to become aware of his/her state, a will that greatly depends on his/her psychological equilibrium and contingent personal situation.

The obligations to confidentiality without the patient's consent are reiterated in art. 5. As far as experimentation is concerned, also in this case informed consent is absolutely necessary, and which must be given only after having had sufficient time to reflect.

Article 14 sets down that x-ray documents can be used for teaching purposes only with the patient's consent. In this sense the norm seems to be more restrictive than in Italy and other countries where it is sufficient for the patient not to be identified. In the second paragraph is considered the possibility of the medical staff refusing to take part in experiments.

Regulations on the relationships among Danish doctors (1989)

It stresses the need to get the patient's consent, in the case that the doctor in charge deems it necessary to entrust the patient to another colleague to continue the treatment and for the subsequent transmission of data.

The Italian Code (1989)

In the Italian code (arts. 13 and 16) the confidential nature of the information given by the patient's consent is stressed too.

The Italian code expresses a particular sensitivity and attention in the description of how the information should be given to the patient, and consequently, of the modalities needed to obtain their consent. In fact, art. 39 asks the doctor to bear in mind the patient's level of culture and capability to understand at the moment in which the information is delivered, defined as 'serene' (here the subject of the doctor's own sensitivity is touched on indirectly), 'in the awareness of the limits of medical knowledge, respecting the person's rights, and lastly with the aim of getting the best possible consensus to treatment alternatives'.

Moreover, the doctor has the responsibility to evaluate the possibility of not revealing or of mitigating a serious prognosis, ‘particularly in relation to the patient’s responsiveness’, giving it rather to the relatives.

Article 40 takes up again what is to be found in the European Guide, asking for conscious and explicit consent should the treatment involve risks.

In the case of an incapable person, consent must be expressed by those having authority, except in emergencies (art. 42).

Written consent is required for experimentation (art. 49), while any possible consent given by healthy subjects for experiments has no validity at all (art. 51).

Lastly, art. 56 deals with the dissent of the prisoner to feed himself to the extent that this is valid.

The German Code (1988)

It must first of all be said how Germany is still going ahead with the formulation of guidelines for informing the patient, which will be published separately from the Code of Deontology.

The Code of Deontology confines itself ([art. 1a](#)) to maintaining that to start treatment the doctor needs the patient’s consent who prior to this has been informed during a consultancy.

It also emphasises the need for consent for the transmission of data and the entrusting of the patient to another colleague.

Conclusions and synthesis

From the synthesis of the various articles of the European Codes of Deontology regarding the problem of consent either directly or indirectly, the following conclusions can be drawn: as a rule the different codes are in line with what is laid down by the European Guide to Ethical Medicine or rather, in most cases the various points discussed have been dealt with in greater detail.

It must be noted how the European Guide to Ethics emphasises the importance of consent ‘especially’ when the treatment involves serious risks; in turn, the various countries have considered it opportune to ask for consent for ‘any’ medical treatment, while whatever the risks may be, this must be given in writing.

It appears evident that local legislations have given greater importance to the

presence of consent always and in all cases.

What all the codes examined have in common is the heartfelt need to give information to the patient who is able to give consent, which must always and anyhow precede the requirement of consent prior to treatment. Nonetheless, according to Denmark, this giving of information must not be 'forced', should the doctor understand that the patient does not desire to receive it.

It must be highlighted however how only some codes give detailed directives about what the information must contain and on how it must be given. In particular, Holland, Denmark, Spain and Italy have dealt with this in detail: the doctor is asked to act with great care, sensitivity, attention and sense of responsibility (Spain), and must, to the best of his ability, bearing in mind the overall psychological, social and somatic situation of the patient, accurately consider the spirit with which the information must be given (Denmark), and also bearing in mind the patient's cultural level and ability to understand (Italy). The information, given as serenely as possible (Italy), must contain the nature, the extent and the reason for the treatment, the explanation of the procedure to be followed, the other possible methods of investigation and treatment, the present state of medical knowledge on the treatment (Holland), the therapeutic prospects and the consequences in the awareness of the limitations of medical knowledge (Italy).

However this does not resolve the problem of when a person is, or is not, sufficiently informed and free to give their consent to a medical examination or treatment (Ireland).

The European Guide requires consent above all when the proposed treatment involves serious risks. Nonetheless, the member states agree in asking for consent in any case at all, even though this is considered implicit in the most banal of cases (Italy).

This must be given in writing in cases at risk (Portugal, Italy), prohibited treatment or treatment with a proviso (Portugal), experimentation (Portugal, Spain, Italy), the various codes generally being limited to asking for explicit consent, not necessarily written, for particular cases.

It must be highlighted how Holland foresees a written report for the doctor should the patient request it and written consent in all the cases in which both parties request it.

It goes without saying that all the codes require the patient's consent for the transmission of data and the handing over of patients to another colleague, and that the patients' consent relieves the doctor of the obligation of professional secrecy.

A very interesting point is represented by the possibility that Portugal, France and Holland give to minors and the incapable, if they are deemed able to express valid consent in so much that they are sufficiently able to understand and therefore

able to agree or disagree with treatment in first person.

Some cases in point considered by various codes deserve special mention: in Italy experimentation cannot be carried out on healthy subjects, in Denmark it can be refused even by medical staff, while in Portugal prohibited treatment and treatment with a proviso (unfortunately not specified in detail) can be carried out with the consent of the person concerned; in Denmark the use of data and x-rays for teaching purposes needs the consent of the persons concerned, as it is not sufficient that they cannot be identified; in France, Holland and Spain the patient can decide who can be informed; Ireland tackles the problem of AIDS maintaining that, even with the patient's dissent, the medical and nursing staff and the partner must be informed; Belgium and Spain consider the possibility that it may be thought 'inopportune' on the part of the doctor to inform the family when the person concerned cannot give valid consent; Luxembourg requires the reporting of cases of maltreatment with the patient's consent, or, in the case of a minor, even without the consent of the relatives; lastly, with regard to a prisoner on hunger strike, Italy considers consent valid up to the point of the person going into a state of unconsciousness.

Situations in which it is impossible to give consent or derogation

In the examination of the codes of deontology of the various European countries, the NBC deemed it important to pay particular attention to the conditions in which a derogation to consent or the request for consent is foreseen (or supposed) from a person *different from the patient, being unable to express it.*

In the following paragraph are examined the four situations that deserve mention:

- 1 — Short or medium term risk of death in a patient not able to express consent;
- 2 — Short or medium term risk of death in non-consenting patients;
- 3 — Risk of death of a minor or incapable;
- 4 — Informed consent in a patient with pathologies with fatal prognosis.

1 — Short or medium term risk of death in a patient not able to express consent;

In the Italian code the subject is dealt with in the second paragraph of art 42 in which basically it is confirmed that the doctor's action disregards the patient's consent if three conditions exist: 1) serious intellectual confusion implicitly means the incapacity of patients to express their consent; 2) the need for medical assistance which in the doctor's opinion cannot be avoided; 3) urgency and

therefore the non-deferral of the operation.

In such conditions, as the consent of the person concerned is lacking, which as mentioned in other articles of the code (arts. 40 and 41), constitutes an indispensable condition for the carrying out of any diagnostic-therapeutic activity, the doctor must behave according to science and conscience in the interests of the patient, or according to the ethical principles set down in arts. 5 and 7 of the code.

However, no mention is made of the need to inform the family or relatives of the patient in such circumstances and the possibility of asking for their consent, which, instead, is foreseen explicitly by the *French Code of Deontology* (art. 7). The *Canadian Code of Deontology* also foresees (art. 14) that the doctor must give appropriate therapy on his own initiative when the dual condition exists of it being impossible for the patient to express their own consent and the absence of another person with the authority to do so, that is a figure who must obviously be recognised as a relative, a legal representative or another subject whose consent is considered valid by the law for this purpose.

2 — *Short or medium term risk of death in non-consenting patients;*

As already mentioned in the treatment of the subject under a clinical profile (see Ch. II), the refusal of consent to diagnostic and therapeutic treatment by patients whose clinical conditions are so serious as to jeopardise their lives in a short or medium term is not exceptional and can be due to various reasons: excessive fear about the treatment itself; self-harming intentions (for example, suicidal intention of the person refusing medical assistance); but, above all, motivations of a religious kind (for example, refusal to have a blood transfusion by Jehovah's witnesses).

In the case of the explicit refusal of therapy by a patient able to express valid consent, the *Italian Code of Deontology* instructs the doctor to abandon any diagnostic or therapeutic treatment (art. 40) and does not mention possible exceptions that may involve serious consequences, including the death of the patient. The Code of Deontology prohibits the doctor from carrying out, upon the patient's request, treatment that harms their physical and psychic integrity or that shortens their life (art. 43), but requires the doctor to respect the patient's will even though asking for neglectful conduct that indirectly harms the patient himself/herself.

It must be noted that the patient's refusal to medical treatment that is compulsory by law, which harms above all the interests of the community, calls for the immediate ordinance of the mayor (art. 42 para. 3).

Even authoritative foreign codes of deontology do not foresee the conscious refusal of treatment by the patient; such is the case of the *French Code of Deontology*, which states though that ‘... the patient’s will must always be respected in every possible way’ (art.7), which implies the respect of any dissent by the patient, as long as it is validly expressed, independently of the gravity or urgency of the case. A similar concept is expressed by the *Canadian Code of Deontology* in art. 5, in which the right of the dissenting patient to go to another doctor for a consultation is hinted at.

In the *Belgian Code of Deontology*, in the event of the patient’s refusal to undergo the prescribed diagnostic-therapeutic treatment, the possibility is foreseen for the doctor to end his assistance, without making reference to specific conditions of urgency (art. 29).

Some peculiar aspects, and partly contradictory ones, appear in the *Islamic Code of Medical Deontology* which would be worth a mention, considering that Italy has become a multiethnic country.

Having highlighted the patient’s implicit consent to treatment at the moment of choosing the doctor, it recommends putting the consent to surgery into writing, along with any possible refusal to follow the treatment prescribed. However, should the doctor deem that such refusal is the consequence of the patient’s fear of medical treatment, he is bound to use diplomacy and authority to convince the patient to start the treatment, and, if necessary, to administer drugs (for example, sedatives) which ‘... might help the patient to take a decision’. Further on it states explicitly that in emergencies the doctor ‘... must take the necessary decisions alone’ to save the patient’s life (art. 8). In art. 7, furthermore, even though recognising the patient’s right to know what illness she/he has, the possibility is foreseen of avoiding the use of certain terms or coining names or new expressions to describe the patient’s clinical situation. In our opinion these statements, even though expressed in the patient’s interest, and professedly referring back to the ethical principles of the Islamic doctrine, lend themselves to arbitrary interpretations which could seriously harm the patient’s rights (it suffices to think of the possibility of giving drugs to influence the patient’s decision) and in several points are in contrast with the principles of truly free informed consent.

In our opinion, the need for complete and correct information on the state and evolution of the clinical situation is of fundamental importance when patients are not willing to give their consent to diagnostic-therapeutic procedures. Therefore, time permitting, ample space must be given to a direct dialogue between the patient

and doctor and with other specialists too. It could also be useful for patients to be able to speak to the family doctor or another doctor who they know well and who is better acquainted with their personality and convictions.

When there is a risk of death it would be opportune that patients' relatives were present when speaking with the doctor, except for when patients are against this, so that they too are participant in receiving the news and during the decision making; moreover, if the illness should take an unexpected turn, the doctor would have the relatives to refer to.

3 — Risk of death of a minor or of someone under authority

Owing to its peculiarity the subject is dealt with more widely from a juridical aspect in Ch. III. In this section we are reminded that in the case of patients who are minors or incapable, art. 38 of the *Italian Code of Deontology*, which deals with their protection, states that, if their legal representatives are against the 'necessary treatment' the doctor must appeal to the competent legal authority. However, this statement is placed in a general context and does not make explicit reference to the emergencies and special need mentioned above. Furthermore, the appeal to the legal authority takes time and modalities which are not always compatible with real emergencies, and in line of principle does not authorise the doctor to disregard the consent of the patient's legal representatives.

The *French Code of Deontology* does not explicitly foresee the above described case, even though stating that in an emergency, *or* if the relatives cannot be found, the doctor must give the necessary medical assistance. The emergency is therefore kept distinct from the absence of the patient's legal representatives, which could imply that in the first case the doctor should act anyway, independently of the consent of those having authority. The passage deserves to be formulated more clearly however.

According to the Belgian Code of Deontology, in the case of an under age or incapable patient, the doctor '... sees to the delivery of the necessary medical assistance' should it be impossible to get the consent of the legal representative *or* 'inopportune' without further specifying what this term refers to exactly (art. 30).

4 — Informed consent in patients with pathologies with a fatal prognosis.

This rather delicate and complex issue is not even hinted at in some of the codes

here presented. In others, as in the *French Code of Deontology* (art.42), the possibility is foreseen of not communicating a very serious diagnosis or prognosis to the patient, but the doctor is not obliged to inform the relatives, who can instead be kept in the dark should a conscious patient request it.

The Italian Code of Deontology (art. 39, para. 3) on the other hand foresees this obligation, and distinguishes between two possible lines of conduct by the doctor: *denying* information that the patient has a right to or limiting himself to *mitigating* it. The subject is dealt with in a similar way in the *Belgian Code* (art. 33) and the *Brazilian Code* (art. 31); in the latter the possibility is foreseen of informing the patient's legal representative instead of the family.

The debate under the clinical profile has already been presented in Ch. II.

Other considerations from a purely ethical point of view will be resumed in Ch. 7.

V – INFORMED CONSENT IN PAEDIATRICS

The NBC considers it useful to spend some time looking into this problem in more detail.

In fact, to speak about informed consent in paediatrics does not correspond with what is usually carried out in adult medical practice. It is the children and adolescents that are involved in the decisions through their parents and also directly. The manner of informing, the waiting for answers, the adapting of words and gestures to answers and the decisions are different for the doctor. It can be said that even the way of considering informed consent is different in paediatrics, owing to the undoubted impressions it receives from the knowledge and perception of the reality of children and adolescents, of their development in the environment, their way of belonging to the world, of the way in which it is the parents that belong to them, and from grasping their verbal and analogical communications, expectations, requests and proposals. It is possible therefore that paediatric culture can give a contribution to that of informed consent, to the culture of those who study it and use it professionally.

References to the bioethical aspects of consent

In order to fully understand the question, it seems opportune to resume and develop some of the concepts that have already been introduced in Ch. I of this report.

Today informed consent is a principle that bioethics diffuses and asks to be

used as a model in the delivering of medical treatment. In reality these have always been the fundamental principles and virtues, as they represent the very bases of medicine. The way of considering them is the way to be doctors, and it does not appear mistaken to believe that often they are considered midway between compassion and hypocrisy. Between the compassion that means to sympathise with, suffer with, participate in the nagging problems, in the distress of decision making and facing problems, in the suffering that they can cause; and the hypocrisy originating from the obligation to accept the principle without conviction and to disguise the bother that comes from giving up the dominion over others, which the principle requires.

It does not even seem wrong to believe that there are three types of doctor that consider them. The first is willing to accept the principle but does not consider it sufficiently and in the search for the necessary virtues needs to be helped, seeks a guide to apply it, experiences it almost as though it were a new medical procedure. The second is the doctor who moreover sees the medical-legal aspects and worries about the legal consequences of his decisions. The third type of doctor has a deeper understanding along with the rationality and sentiment of compassion, and is committed to working out his own personal behaviour, assuming responsibility with the tolerance of the uncertainties and anxieties.

It is in the cultural context of informed consent that more than ever the basic question is asked about what it is like, could be or should be to be a doctor today with all the medical techniques and interaction with patients, about what the system is like in which he is trained and updated, on how much schools are able to enrich the medical culture of the body and make the needs of the people who 'have and are a body' understood.

The characteristics of consent in paediatrics

The question takes on special importance for the doctor of children and adolescents that present a particular condition. There is another type of relation in suffering, as minors possess a sensitivity and a finer and quicker perception of hypocrisy. They can sense the stereotypes and the lack of genuineness, they recoil from suspicions, are immediate in giving their trust, refuse and understand duplicity more than adults and, pretending not to notice it, are more indifferent to that of others. If they end up accepting situations that are not genuine, it is because they are led into acquiescence and therefore abused. In dealing with children and adolescents and their families the doctor has less possibility of being guided, unless with the general references to the complexity, variability, changeability and unpredictability of their thoughts and behaviour and relations. The doctor's task is one of 'child advocacy', taking stances that are not always those of the parents, the families, sometimes deciding in contrast

with their choices, manifest or implicit. The responsibilities the doctor finds himself having to bear are special and can be great, moral, human and legal. It must be said that the 'disembodied' medical-legal suggestions are not sufficient to him. In reflecting on informed consent it is educational not to have only one idea of the information to give and the consent to be obtained. One can run the ethical risk of directing the first towards the second too much, even without really noticing it. It is educational also to reflect on the distinction between consent and assent. Much of the hypocrisy that sometimes surrounds the acceptance of the principle of informed consent arises from a concept of misunderstood information. Information that is not just the cold conveying of knowledge and facts but a commitment to the fostering of its assimilation requires sharp intuition and perception, reflexivity, and a sincere will to compassion. Only with committed information-giving of this type is it possible to be sufficiently convinced of the validity of the consent obtained. Otherwise the consent can only be an assent, the accepting of a consent of which the reality of the experience is not really known. With patients at the age of development, with cognitive competences, thoughts and feelings evolving, the ethical risk of directing the information towards the obtaining of consent and of mistaking assent for consent is much higher.

Children and adolescents are defined by society as 'minors' and adults as 'of a mature age'. Minor age and maturity are 'attributable values' and belong to two populationist categories, not always corresponding to the real values of the single persons. Communication, the quality of which is based on informed consent, is established with single individuals. It can be 'symmetrical', 'complementary' and 'reciprocal'.

The communication is symmetrical when the individuals are equally strong in the interaction. It is healthy productive communication if it does not cause splits, the so-called schismogenesis. Communication is complementary if one is stronger, or in a 'one-up' or dominant position, and one is weaker in a 'one-down' dominated position. Both can be satisfied, but the one-down position can feel unease, even amounting to suffering. The communication is reciprocal when the one-up and one-down positions alternate, in mutual respect, in the recognition of the respective autonomies and dignity. This is the healthiest, the most productive and gratifying kind of communication. The most convinced and convincing consent originates in reciprocity, but can be reached also by means of communicative symmetry. In complementarity whoever is one-up can believe, or elude themselves more or less in good faith, that they have obtained a convinced consent, which is instead only an acquiescing assent.

These considerations, which refer back to Bateson's systemic school, are extremely useful in the reflection on informed consent in general, and even more so in paediatrics. It is not easy to have a clear idea of the type of communication that is established with children and adolescents. The tendency of the adult, doctor, teacher, parent is to be complementary one-up and not notice how productive the reciprocities or healthy stimulating symmetries can be. The type of communication is inspired also by the equilibrium that has been established in single individuals between the 'elements that make up consent' and the 'elements on which the competence is constructed' to give it. The elements of consent are considered 'information', 'understanding', 'voluntariness', 'decision making'. It is the data and knowledge that are respectively transmitted and which are reasonably considered to influence the will to participate in decisions, the capacity to weigh the effects of the information and its utilisation in taking decisions, the freedom to participate and refuse, the awareness of the nature of the decisions taken and the ability to express it clearly. Elements of competence are the 'ability to decide', the 'reasoning' over decisions, 'the 'forecast' of the results of such decisions. The balance among these elements is progressively established at development age. It is quite a widespread tendency among adults to attribute equilibriums to children and adolescents that they do not have, to make them into adults, or to deny equilibriums that they have instead reached, to infantilise them, when not exploiting them. Wearing communicative symmetries, one-up/one-down complementarity ignoring the unease and suffering that can be caused, attributions of equilibriums that are not real, certainly not making for informed consent, verge on forms of abuse. Also the parents can be abused with distorted or at least little convincing information, or by not recognising the equilibriums that they are able to sustain. The matter of informed consent in paediatrics is empty if no careful consideration is given to the doctor's attitudes and competences to understand the parents' decision-making competences, to the doctor and parents to understand the decision-making competences of children and adolescents. The doctor also has the task of understanding the family relationship, with its differences that are always present, explicit, hidden or masked of thoughts, feelings, and even values, between minors and mature adults, not only when the minors become adolescents but even before that. Without the appreciation, respect and defence of these differences, the genuineness of the consent received is dubious. Flexibility is essential in understanding the competences, which are variable and changeable over time, in people of mature age and even more so in minors and in minors of equal age. It is necessary to cancel the idea of reliable standards: information and consent have to be adapted from case to case in every different situation and it is dutiful only to know a 'minimum standard' of competence so as not to commit abuses.

In order to speak about informed consent in paediatrics, knowledge of cognitive development is essential and a reference to the Piagetian concept of the evolution of thought is useful, from the pre-operational one, to the concrete-operational and formal-operational ones. Up until the age of 6 decisions are guided by a thought limited to personal operative experiences which is inventive and magical. The behaviour and experiences of others have meaning only through the perceptions and the personal experience of the child. After the age of 7 the child manages to have an idea of the point of view of others, to integrate them into his own reasoning, to make use of them for his own decisions. He explores his own motivations and compares them with what others say and do. At 10-12 the hypothetical, critical, abstract thought begins on things as they are or on how they could be presented for the first time, on future events, on contingent and probable events, on the relations of cause and effect and the consequences of events. From this conception it seems logical to deduce the impossibility of an autonomous consent before the age of 6-7. Consent is to some extent conceivable between 7 to 10, but still not completely autonomous and to be considered together with the parents'. Only at the beginning of adolescence can it be considered that consent becomes progressively autonomous. The reference to the flexibility with which this Piagetian concept is applied, case by case and situation by situation, is of no use. This is corroborated by the suggestion of the Royal College of Physicians of London to the ethics committees for research in paediatrics. After the age of 7 the consent of the child and parents must be sought, and after the age of 14 the adolescent's consent has priority. In line with this suggestion are the results of a recent American survey on the 'legal risk' for the doctor who takes therapeutic decisions with just the consent of the adolescent. The risk is not 'significant' if the doctor knows the laws allowing the adolescent to give his/her own consent, 'trains himself' to understand the exceptions relative to the maturity of each single adolescent, adopts these as criteria to decide the age over 14, has proof that the adolescent showed confident decision making abilities in previous situations, also non medical, and if the intervention in question is not a major one and nobody else benefits from it. The age limit whereby to propose the possibility of obtaining real informed consent would therefore be 14.

For some it would be 'reasonable' that an adolescent of 14 or over were also involved in the decision to withdraw terminal treatment. There is a logic in these suggestions and similar opinions, but the logic of the prognostic uncertainty and prudence must certainly not be forgotten. It is essential not to be inclined to make rules out of suggestions and opinions, even though authoritative; not to forget that informed consent is subject more to exhaustive thoughts and in-depth feelings than to rules, as some would like to maintain.

Aspects of consent in neonatology

One aspect of informed consent in paediatrics has a scientific and ethical importance that can be considered unique. Owing to its complexity it is one of the most indicative examples of the contribution that paediatric culture can give to the culture of informed consent. It regards the intensive and sophisticated care for newborn infants in high risk conditions, even incompatible with survival. This includes mechanical ventilation, artificial feeding, high level technical surgery, already being carried out on foetuses, along with organ transplants nowadays, for example in the case of the heart of a newborn with congenital hypoplasia of the left ventricle. The decisions are taken together with the parents. Some maintain that only they must decide on the beginning or withdrawing of treatment, while others maintain that it is inhuman to involve them in such dramatic decisions. The outcome of such decisions is always uncertain and the long term results are the cause of extreme anguish. The parents live an extremely critical moment of their existence, that is, the phase called extension of the family life cycle, of 'bonding', or the consolidation of the bonds of affection with the baby. If the infant dies, the death is not experienced like that of a child definitively included in the family's relational system. The parents have a sense of guilt for what they experience as a procreative failure, reacting to the event with anger, refusing it, unable to accept the reality, torn by contradictory feelings and overcome by scruples, frequently ones of euthanasia. The suffering penetrates into the life of the couple and the family relationship. The crisis is difficult to overcome and not always do the couple and family find their equilibrium once more.

All this has been demonstrated and is scientifically based knowledge, like the therapeutic, medical and surgical techniques. The neonatologists must be acquainted with this and participate in scientific progress thanks to which many newborn infants survive. Nonetheless the doctors who experience situations in which newborns are kept alive by ventilator in the uncertainty of their survival and the long term outcome of the therapies, do not know what the baby's quality of life will be like, cannot know how the event is really experienced within the family, how the life of a possibly disabled person will be lived, to what extent the disability will be tolerated by the family. The expert surgeon must place himself on the frontier of great progress in surgery, but he does not yet know to what extent the immediate successes of prestigious cutting-edge operations will be maintained over time. Offering operations that are in the forefront leads to needs which the doctor does not know to what extent are truly felt, and which raise hopes which he does not know how much and with how much resignation were given up as lost nor, when they are disappointed, cause suffering once more. These are unique reflections, particularly complex and difficult, which along with others

on the phase of the extension of the life cycle of the family and the development of the child in the environment from birth to adolescence, form that paediatric culture which can undoubtedly give its contributions to the general culture of informed consent.

With regard to the rather complex aspects of ‘transplant surgery on children’ the NBC will deal with this in a specific document.

In conclusion, behind every reflection on informed consent, particularly with regard to paediatrics, there is the big fundamental question as to what the doctor’s culture is like and should be like and how the system is in which this is shaped. It is by reflecting on informed consent that one can better understand that it must be the culture of life, ‘scientific’ for life, even experimental with the risks that it involves, but also the culture of death, that is, to help people to accept it and to fight against the natural fear of dying.

VI – THE LACK OF CONSENT IN NORMATIVE PROVISIONS AND JURISPRUDENTIAL EVALUATION

The NBC considers it necessary to stress the juridical consequences arising from the lack of consent.

It must first of all be stated that medical conduct that disregards the ethical-deontological preconditions of informed consent, besides being foreign to the precepts of a correct expression of relations in the complex delivery of voluntary medical treatment, is liable to sanctions in a legal system framework that pays increasingly more attention to the protection of the rights of the person whose hierarchy in terms of prevalence is not given to others to establish but to the subject having that right (except of course in the case of a precise and specific provision of the law).

In the now consolidated confirmation of consent as an unavoidable premise to all medical treatment, there is an ever pressing need for an appropriate synthesis of the provisions on the subject in force, for a fitting completion of the issues and problems relative to the informing of the patient and his/her assent to healthcare decisions. Furthermore there is increasing awareness that such principles are for the most part evolutively subject to their progressive adaptation to the changed and definitively matured social sensitivity, by means of a jurisprudence directed towards the overall protection of the citizen, driven also by far-reaching significant comparative doctrinarian suggestions.

The question of medical treatment 'without consent' on a 'competent' person.

It must above all be considered how medical treatment without the consent of a 'competent' person (term of North American origin that summarises both the full legal capacity and psychic suitability that is not disturbed by pathological conditions) even the more so if elective and not conditioned by emergency situations, but all the more reason if invasive and risky, can incur censure and sanctions, even if not resulting in harmful consequences prejudicial to the psycho-physical integrity of other individual rights. It is some time now that the jurisprudence of the *common law* countries has set out the concept of *battery*, under which every diagnostic-therapeutic or merely experimental procedure goes, if not corroborated by explicit and documented consent. Or even if consented, it has been insufficiently understood by a passive subject who is not completely free to express their will or who is partly unaware of the probable or possible unforeseen events due to inadequate, reticent or even cunning information. This is a condition of unlawful behaviour in itself even if not made concrete by negative effects. This is not explored to any great extent by Italian jurisprudence as it is not yet put under any pressure in that direction by case histories and the tendency to claim for the *damage* rather than for the *unlawful*, where *violence* is more and more frequently invoked as an expression of unfair behaviour but only in the perseverance of consequences such as to represent *personal harm or manslaughter*, which in criminal law combine the two possible alternatives of damage to the person, which in a civil law context is given patrimonial value as damage to health and/or damage by death. The judicial possibility is not however excluded and avoidable in the Italian legal system that medical treatment that is not explicitly consented by the passive subject, even though not causing harmful consequences either temporarily or permanently, and perhaps accompanied only by a simple painful reaction, but not necessarily mortifying the person: the situation is referred to by the criminal hypothesis of *coercion* as in art. 610 of the penal code. This highlights moral influence in such terms that the condition of suffering and anguish in hospital or during clinical tests in a judicial context in cases like for example sexual crimes cannot avoid being associated with.

It must be noted how in civil law the ascertainment of a medical error is considered of prejudicial significance with respect to the question concerning any possible violation of the patient's freedom to make a decision. In the ruling of 18 June 1975, the civil Court of Cassation states that the reference to *neglectio voluntatis* of the patient can constitute at the most an element of further seriousness in a verdict of guilt that implies proving, in any case, the doctor's negligence, malpractice or carelessness. Only in the presence of a technical error by the doctor does the violation of a duty of *humanisme médical* seem to be noticed (the Court of

Cassation deems that the ascertainment of this is superfluous in the ruling of 29 March 1976, No. 1132).

The main condition in which the legal provision and the jurisprudential evaluation are increasingly topical is represented by the *damage to the person* arising from medical actions or omissions, or from healthcare in general, not preceded or not entirely supported by consent offered in the real awareness of the risks that are not just reasonably possible but also highly probable. To give substance to medical choices correct information must be given, according to a line of conduct that found a first faint jurisprudential formulation in the Court of Appeal ruling in Milan of 21 March 1939, relative to a diagnostic operation of contrastography prior to lumbar puncture, carried out without adequately informing the patient and followed by very serious complications. Today it is stated much more clearly that the holder of the right must 'given valid and definitive consent' (Criminal Court of Monza 15 October 1989).

In criminal law therefore, it has now been shown how a lack of consent can be used by the injured party and the prosecution as a psychological element of wilful crime and therefore different and alternative with respect to guilt through negligence, malpractice or carelessness. This is a nevertheless exceptional hypothesis, even though already covered with absolutely devastating consequences with regard to the consolidated medical-legal principles for which reason behavioural anomaly seemed unimaginable and irrelevant to the 'honest' limits of the technical error. And yet, the overcoming of the classical, and in a certain sense gratifying conception, of the relationship of trust between doctor and patient, solidly founded on the prevailing significance of the therapeutic goals with respect to the choices of the person, has established important consequences on the assessment of anomalies in behaviour, strongly eroding the sphere of medical authority not so much of the preliminary choice but of the actual carrying out of procedures, means and modalities of diagnosis and treatment, to the point that conscious neglect of the person's options, before they can be illustrated or even in contempt of the real terms of the proposition made, is liable to being connoted as a wilfully committed crime. From this to ascribing the damage as the wilful crime of an active subject, that is, of the doctor that has consciously violated the principles of consent (which remains the only condition capable of legitimating a harmful impact on psycho-physical integrity even for the purposes of the protection of health when no ineluctable reasons for need exist) there seemed to be an unbridgeable gap (even if the intent could be considered only 'possible' or dangerous that represents a non-majority doctrine).

But the recent ruling of the Court of Appeal of Florence (see also the ruling of the Court of Assizes of first instance of 18.11.1990) has overruled such supposed limit, holding the surgeon responsible for the death of a patient who had undergone radical surgery for which consent had been explicitly denied, as guilty of *manslaughter*, as a further criminal consequence of conduct involving wilful bodily harm. And yet, apart from any considerations on the crude realism of such exasperated reasoning, the fact remains of the cautionary meaning of a ruling that dramatically takes its place in the most advanced stances of the doctrine of informed consent.

The question of the 'illegitimacy' of consent

The rather dark area of the illegitimacy of consent must not be omitted, even though consciously expressed, when the medical-surgical activity not related to reasons of health *strictiori sensu*, involves functions and organs the integrity of which is not liable to damage with impunity, not even if authorised by the subject. This is a hypothesis regarding the area of civil law and the sphere of contractual responsibility which is increasingly used in the jurisprudential assessment of the practice of medical activities that are not strictly connected with diagnosis and the treatment of pathologies considered with the classical nosological parameter, as happens for example in the experimentation of new drugs on healthy subjects. The indisposability of physical integrity is established moreover as seen in art. 5 of the civil code and therefore comes out of the context of private law. Such a prohibition also has a non-secondary effect in criminal law, so much so that the consent to treatment not justified by a condition of real illness, like for example the explant of the kidney from a living and obviously conscious person, is legitimated only on the basis of legislative provisions. This has been frequent practice for the taking and transplant of kidneys between living people, in accordance with Act No. 458 of 26 June 1967 authorising this in explicit derogation to art. 5 of the civil code and for the surgical correction of transsexualism, juridically possible according to Act No. 164 of 14 April 1984, only in cases in which the pathological experience of apparent organic normality is proven (in terms of serious personality disorder to the point of the non-acknowledgement of one's sexual naturalness).

On the other hand, with regard to voluntary sterilisation, consent to the temporary or permanent suppression of a completely whole function and feared for this reason, is always considered from a strictly juridical point of view and without going into evaluations of a moral nature on the legitimating and discriminating condition of the relative medical, pharmacological or surgical treatment, when the latter is aimed at restoring a psychological equilibrium that is threatened or

disturbed, as reasoned by the Criminal Court of Cassation in ruling No. 438 of 1987.

Informed consent and tort liability

Informed consent, also defined as ‘illuminated’ in the decision of the Civil Court of Cassation of 9 March 1965, has an even deeper meaning in the field of tort liability, drawing substance from illicit medical treatment or from a contractual violation by default (by the doctor himself) of the obligations of the actual treatment. In the first case, the damage (ex art. 2043 of the civil code) refers to the doctor’s conduct in the case that this is vitiated by the supposition of guilt, as a proven relationship of material fortuitousness exists between the event and the action or omission of the agent; this also applies if it is carried out in contrast with the principles of informed consent, as clearly emerges from the decisions of the civil Court of Cassation, section III of 14 January 1976 on the issue of pain-surgery and section II of 15 December 1980, on hand surgery.

The typically contractual connotations of medical practice not related to pathologies in the true sense of the word, which become more and more necessary in the sometimes unclear catalogue of medical authority, such as aesthetic surgery and dental technology with its progress in implants, do not lie outside the rule of the unavailability of informed consent. While the old debate on the nature of the obligations of the treatment contract is in fact waning in the jurisprudential panorama, which for the type of activity given as example were defined too drastically by some as obligations of result rather than of means or of conduct (differently from what is required for ‘normal’ medical practice), there is an increasing need, also for the purposes of contractual legitimacy, for clear precise information by the passive subject who also sets out the risks, (especially in plastic surgery) of possible complications and also failures of a mere aesthetic nature. In this sense, after the first injunctions of 25 July 1967, No. 1950 concerning ‘aims of an aesthetic nature’, the Court of Cassation (civil section III, 3 February 1982) ruled that the removal of a lipoma from the right thigh leaving serious scarring without adequate information about the risks was illegitimate and (civil section II, 21 January 1985) and similarly the plastic surgery carried out on the breast of a striptease artist not sufficiently informed of the possible scarring that often remains. In these cases ‘the information’ must in fact include every explanation of the real extent of the operation, its seriousness, the effect attainable and the inevitable difficulties and complications in the foreseeable risks that could involve a fatal outcome (Civ. Cass. 12 June 1982, No. 3604).

Conclusions: deontology, ethics and right before consent

The medical-legal substance of *informed consent* is expressed therefore in an increasingly more coherent and at the same time disquieting way, to the point of conferring to the deontological and ethical profiles typical of such a significant and essential moment of the relationship between doctor and patient a rigour of characteristics that may seem excessively drastic and harsh, moreover touching on such a slippery area as authority and individual rights. It is furthermore sterile and arbitrary to express attitudes of refusal or detachment on this, if it is true that the provision and sanction arising keep to a climate of relations that is ethically far more valid than in the past. And not vice versa.

The deontological regulations, the infringement of which pertains to the obsolete disciplinary context of the professional association, confirms the need for conscious and explicit consent (art. 40 of the Code of Medical Deontology) by the competent patient ‘when the medical treatment involves the risk of temporary or permanent decrease of physical integrity’; but even in the more recent version this formulation is not yet without ambiguity if one considers the continued involvement of *implicit consent*, also in an authoritative doctrinarian context at the basis of the relationship of trust in common diagnostic-therapeutic *routine*. The thoughtlessness of such a statement can no longer be tolerated today – it lies not so much in its concrete importance, as in the ‘*mens*’ inspiring it, not completely free of the ‘vices’ of paternalism even nowadays. On the other hand, the problem of the particular variants of consent, from implicit consent to delegated and presumed consent and lastly prior consent, have been critically examined from a jurisprudential viewpoint (Court of Assizes of Florence), concluding in a series of essential points: consent is never implicit when there exists a relationship of competent collaboration between doctor and patient; consent can never be delegated except for the hypothesis of ‘incompetence’ already thoroughly examined in this opinion, and lastly, the value of dissent is dubious when expressed on medical treatment well before the subject gets to that stage of the illness as to need it and is not able to confirm the previous option or back down from it. Elsewhere there is a tendency (in the CRUZAN case for example) to give an increasingly substantial value to prior free expressions of will from a juridical point of view, but in the Italian legal system it still seems paramount and therefore opportune for the doctor to keep to the thesis, according to which in a state of need he is not only legitimated to intervene but even has the legal obligation to do so.

In conditions, increasingly more frequent in the scientific dimension of medicine that is progressively defined by new dynamic frontiers, where decisions have to be made urgently and at the same time it is impossible to know the patient’s ‘present’ will, the doctor’s authority is foremost as he is the one and

only protagonist in making emergency decisions, which can be alternatively such as to overcome the risk barrier or be directed towards abandonment and convinced renouncement. It is illusory and foolish to think instead that the regulations can always be of assistance in so far as being endowed with and endowing an exhaustive range of hypotheses. This is the grey area of all deontology that can be made clearer only by means of sufficient ethical sensitivity on the part of the doctor, to be reached by the arcane and irreplaceable call to science and conscience.

Continuing with the medical-legal evaluation being discussed in this chapter, it is nonetheless certain that the solitude and individual responsibility of the doctor cannot, in circumstances of this kind, be mitigated by resorting to the opinion of relatives or to whoever is closest to the patient. Just as prevailing doctrine and an insistent jurisprudence have excluded the libertarian meaning of the refusal of blood transfusions of the minor whose parents are Jehovah's Witnesses, and likewise other strong currents of thought tend to refuse the interference of others in the options of the doctor in charge of the treatment of the 'incompetent' or so presumed patient, which with regard to the mentally ill Act 180 of 1978 has done full justice. The stances with regard to Italian jurisprudence are rather cautious, granting that in exceptional cases the doctor can inform the relatives and proceed legitimately according to their assent (Court of Appeal of Milan, 31 March 1939, 11 October 1964) without having to specify the nature of the problem. These are old juridical interventions that cannot be conciliated with the respect of the principle of autonomy, and absolutely opposed by the more recent juridical doctrine as well as the 'historic' decision by the court of Florence.

Returning to the deontological aspect, it seems that the Code of the Federation of Associations has once and for all recently given informed consent a more intelligible structure, coherent with the jurisprudential standpoint even though some grey areas still exist (for example relative to the presumed decision making role of the parents) still delayed by a standpoint on organ transplants, unfortunately also present in the law of 1975 and in that of 1967 on the explant of a kidney from a living person.

Lastly, the examination of the Italian juridical system also in the light of criminal and civil jurisprudence proposes connotations of unlawfulness with regard to medical treatment without consent, except naturally for the cases foreseen by the law or imposed by the contingent non accomplishment of the specific appeal of the patient, in the increasingly clear overall respect of the principle of '*informed consent*' now prevailing in all modern social systems.

VII – OLD AND NEW AREAS IN WHICH CONSENT IS REQUIRED

In this chapter that concludes the evaluation of ‘informed consent’ from its various perspectives, the NBC deemed it opportune to propose a more homogeneous treatment of the *ethical profile* of the subject, developing ideas and considerations that have just been touched upon in the different chapters of this report.

1. *Beneficiality and freedom*

Under an ethical profile, the problem of informed consent is to be found between two extreme cases. One is constituted by normal medical practice, in which the information to be given is moderate and does not pose serious problems of consent. The other is the case of the serious operation on a person that is not able to decide or fully appreciate the information and needs someone else to decide for him or her. In the *first case* the information that can be given is the maximum, but there is no room for a significant choice. Also in the *second case* the information is maximum, and this time the choices are significant but are not taken by the patient. In these cases it could be said that the maximum information tends to exclude the patient’s consent.

As has already been mentioned above (see Ch. I), usually it is considered that the traditional relationship between doctor and patient is of a paternalistic type, with the latter entrusting all decisions to the former. This solution seems to be based on the very fact that the maximum information can coexist with the maximum possibility of choice only when the choice is not taken by the patient: the doctor in fact has all the information at his disposal and by definition this does not coincide with the patient. In traditional medical culture, the patient-client decision concerns only the choice and revocation of the doctor, who must have the patient’s trust, that is, he must not betray his/her interests by jeopardising his/her health. He thus receives a kind of authorisation to decide, even though since ancient times it has been recognised that, when there is social and cultural equality between doctor and patient and the patient is able to understand and choose, the doctor can discuss the illness and treatment with him/her, establishing a friendly relationship in which the authorisation takes second place. The traditional function of the doctor has been placed under the model of the ethic of beneficiality. The doctor sets out to realise the *well-being of the patient* and in the name of this objective structures the information to convince the patient, and possibly even to force him/her, ‘to do his own good’, even when this involves sacrifices which at that moment the patient is not willing to face.

The ethic of freedom contrasts with the moral one, which gives preference to the *patient’s autonomous determination*. Medical treatment becomes positive not so much because it realises the good of the patient as because it is a result of his/her free choice. In the simplest cases the two criteria can give the same result. The

difference arises in the difficult cases when the doctor could find himself before what he considers is not 'for the good of the patient', with the prospect of having to suspend his own evaluations or of doing what he does not consider fit or of ending his relationship with the patient. In order to avoid exaggerated conflict between the assessment of the doctor and the patient's, it has been suggested that the doctor could make use of the criterion of *average behaviour*, which objectively speaking a sensible person would have. The doctor could give the patient the information needed to choose between different prospects, but all comprehensible according to shared criteria of reason (see Ch. II).

But this model too works in not particularly difficult cases, when it is easy to bring the possible treatment down to a few alternatives. It has in fact been seen that by using criteria of reason, the doctor could impose his own choices on the patient, with the aggravating circumstance of not recognising them even as his own and with the claim of justifying them with relatively objective criteria. To refer to objective models can become a way of confirming widespread social practices and of hindering new emerging practices. The only way that the doctor would then have at his disposal of respecting the patient's freedom as much as possible would consist in adopting a *subjective model*, that is, in bearing in mind not what it is reasonable to do in the patient's conditions but of what that patient wants to do in that moment for that illness. Some are of the opinion however that this could seriously threaten the autonomy, the responsibility and the professional conscience of the doctor.

2. *The doctor's antagonists*

The refusal of the paternalistic interpretation of medicine and the praise of individual rights tends to make the doctor and patient antagonists. This way of defining things originates partly from the interpretation of liberal societies as societies founded on individual rights rather than on the protection of general common interests. In a liberal society, which is not modelled primarily on an ethic of beneficence, everyone must be able to assert their rights, even in conflict with the rights of others, and the position of the patient before the doctor can be interpreted in these terms.

In the countries in which this interpretation of liberalism has been most successful, like in the United States, at the moment in which doctor and patient tend to appear as two antagonists, the patient seeks the protection of a third element, which is the *insuring* one. This is above all economic protection. In traditional society illness is always presented as an economic threat and the doctor, despite his paternalistic function, or perhaps for this very reason, has often been seen as a social antagonist not only of the poor. Generally speaking, any healthcare protection system

interferes with the link between information and consent, since it tends to get between the doctor and the patient. The private insurance system, even though interfering above all with the economic relationship of the patient with the doctor, has consequences however on the patient's choices, because the insurance company has interests which it defends by asserting the exclusion clauses of the compensation: information is important for the application of these clauses. In order to protect themselves from the insurance companies, patient and doctor can go to legal representatives who defend the parties to the case in the protection of their own interests. In the private system the respect for the autonomy of the patient thus introduces a series of figures who are interposed between the doctor and patient and who generate a series of institutional steps, by means of which the connection between information and consent is set out.

The main unrest introduced by this system consists in the persistent nature of the information of which patients can be victim. Finding themselves before the doctor as their antagonist and the insurance company as their economic guarantor, patients risk demanding or receiving information not to help them to decide how to behave with regard to their illness, but to draw up safe insurance policies, just as the doctor risks giving an enormous quantity of information in order to protect himself from any possible legal consequences of his interventions. The maximum elevation of the patients' individual rights can create a situation in which the most important thing is not the free choice of the patients themselves.

The countries in which liberalism has recognised the problems posed by the socialist political culture and which have adopted techniques suggested by the economy of wellbeing, healthcare protection has been entrusted to the public system. In this solution the composition of interests and the pursuit of a common interest works considerably more than the reference to individual rights, or better the principle of beneficence more than that of freedom. For this reason the autonomy of the individual does not enjoy maximum protection. But also in this case a new figure comes between the doctor and patient. This time it is the national health service in which the traditional figure of the doctor tends to recede, while the organisational machinery, guaranteeing widespread protection, tends to tighten healthcare assistance *in a bureaucratic way*. The collective objectives of the system will be considered as prevailing over the projects of the single individuals.

3. The doctor's return

Important changes have taken place not only in the external organisation of medicine but also in the conceptual consideration of illness and the approach to it. The traditional doctor was supposed to lead patients to recovery or do everything

possible to avoid their death, trusting in his own knowledge and experience, and the forecast that he could make almost never presented important alternatives for the patients themselves. An important change takes place when the illness is also considered like a statistical fact, and to give patients a diagnosis means to give a forecast of what they must expect. The evaluations depend only to a certain extent on the doctor's personal experience just as they do not only concern one particular patient. The doctor places patients in a class of cases and puts possible outcomes before them.

Another change is represented by the fact that the medical treatment itself can present alternatives. Therapeutic interventions can be more than one and can be assessed bearing in mind the results and the costs involved in terms of physical or psychological suffering. In certain cases however it is not a case of reaching recovery in different ways or of countering death, but of choosing the most acceptable state of coexistence with the illness. In these cases the role of the patients is decisive and they can only choose by having the necessary information at their disposal. The doctor's function becomes important once again, but no longer because he has to choose in the patients' place, but because he must give patients the information needed to make a decision.

By means of the giving of information the return of the doctor's role comes into being as a decisive element for the patient's behaviour. And another aspect of medical tradition already hinted at also returns: the importance of the patient's cultural level. To be able to understand the information that the doctor can give requires a cultural level that not all patients necessarily have. Furthermore, patients must often take decisions in difficult psychological conditions, for the very reason that they themselves are involved, and in these cases not even the cultural level and the capacity to appreciate scientific knowledge can suffice to use the information in the making of appropriate choices. If all the information available is given to patients, they can be blocked in their ability to choose, because they can be led into assuming attitudes of defence towards those that seem to be the most unpleasant prospects, or they can be led into manifesting and living symptoms or illnesses generated only by knowing that they are possible. In the administration of information the doctor objectively has ample room for intervention. Even when it can be supposed that an objective system of relevant information exists, to which the doctor could refer, cutting out for example the statistically insignificant possibilities, there still remains the task of adapting the available knowledge to the subjective conditions of the patient; and in a case like this the doctor should make conjectures and estimates on the case history and will of the patient. Obviously, this becomes more complicated when it is a case of choosing from among different ways of dealing with very serious situations, incurable in the true sense of the

word. In this case the doctor should even propose the possible alternatives and give information in such a way that patients can choose the one that is most suited.

The reassessment of the figure of the doctor has come about in many ways, even though sometimes surreptitious, since due to the development of medical knowledge and the technical possibilities of intervention, consent is presented not only as the acceptance of the costs of the therapy and the consequences of the illness, but also as a real possibility of choice of alternatives, and because the national or private healthcare systems risk deforming the use of information as an essential instrument to choose from the alternatives. It is the doctor who, in order to make up for the dangers represented by the healthcare systems, should try to establish real communication with patients, bearing in mind their objectives, psychological case-history, expectations and fears, and also their structural and immediate capacity to understand the information given. In this way the doctor risks regaining similar power towards the patient to what he had in the paternalistic conception of medicine, if not greater. In fact, he becomes a sort of *global interpreter* of the patient's personality, who can exercise his influence by modulating the medical information which has become a prevailing instrument of the decisions. Particularly if the ascertainment of the patients' will becomes one of the fundamental duties of the doctor, he could be led into giving patients all the available information, without even taking time to organise it or even select it, for fear of influencing the patients' self-determination from the outside. All this leads to oppressing patients with information and basically to influencing them, or even more, their choices.

4. New problems and approaches to analysis

It is easy to give a stylised image of traditional society and the paternalistic interpretation given to the doctor's role. It is probable that the medical profession was quite stratified in that society too and that the doctor, besides having the patient's authorisation for medical matters, was the source of real models of behaviour not only concerning illness. This explains why the doctor could take important decisions concerning his patients. It is difficult to substitute that mechanism with another procedure consisting in the deep direct knowledge of patients. This would require investments at least in time, freedom of action which no longer exists in the modern public facilities or with examinations for legal and insurance purposes. Furthermore, it cannot be said that we have a reliable interpretation at our disposal of what the patient's decision may be even in emergencies and complex illnesses.

Before the complexity of the ethical aspects, the NBC considers it fitting to offer some further reflections and in-depth examination at the end of this analysis.

In the situations described the appeal to ethics has sometimes acted as an

instrument of simplification. Ethics can be appealed to in order to eliminate the possibility of a certain conduct by the patient when faced with life and death, relieving the doctor of the need to bear it in mind and making the doctor the trustee of the patient's true needs: that is, it can be supposed that some notion of good dominates the doctor's decisions and the patient's choices. But even when it is considered that the doctor must bear in mind only the patient's will a simple recommendation is given as the solution, since we do not have at our disposal reliable knowledge on behaviour in emergency situations and the interaction between information and medical choices. It is probable that it is right to urge the healthcare workers to consider the patients' projects, to weigh the information carefully, to avoid persistent information but also to help patients to understand their own situation. All this reintroduces the so-called medical paternalism even through information and there is nothing wrong with this. However, something that is more than simple prohibitions in the name of a hypothetical common good or absolute trust in the doctor's psychological capabilities could be sought. Perhaps the doctor himself would be helped by the study of *typifications* which make it possible to render the problem a little more definite.

In the opinion of some of the members of the NBC, ethics is not a science because it does not have even a modest nucleus of easily shareable objective knowledge, but above all because many of its scholars think that it has certainties that are superior to any proof.

Many are convinced that ethics suffers from a lack of knowledge that perhaps could be sought and 'commissioned'.

For example, psychologists and sociologists could be asked to suggest surveys on the behaviour of patients in situations generated by the cognitive and technical possibilities of contemporary medicine and their reaction to the giving of information. A typification could result in predictable behaviour in relation to difficult but classifiable cases, and it could be possible to give doctors significant indications on the levels of information that can be given and on the possible behaviour profiles in difficult situations.

The jurists could be asked to make an in-depth study of *healthcare delegation* for the drawing up of regulations suitable for the relationship between patient, the delegate and doctor with regard to the control of the information flow and the decisions to be taken. In fact, the important information could go through a delegate appointed by the patient, who could also make sure that the therapeutic decisions come into the patient's plans. The introduction of the delegate would make it possible to institute a mediator between doctor and patient that is not a party concerned, like the insurance company, and that is not depersonalised like the national healthcare service. The doctor could furthermore have a guarantee and witness in the delegate as to his conduct and make reference to a person with whom to discuss the quantity

and the type of information to give the patient. The delegate could compensate for the roles that the family does not always and not necessarily have. That is not to say that the family is better informed of the patient's will and moreover not always today is the family, at least the legal one, the community in which the individual really lives. Instead, the family could be the origin and place of psychological conflict with the patient and see his/her health in ways not coinciding with their own.

According to some lines of thought, between the utopia of the doctor-father and the individual that decides for himself/herself at all moments, there could be intermediate forms. In fact, the setting up of the healthcare delegate could be defined in *conventional programmes of healthcare conduct*, which should not have to have public approval, but which could be made known and which one could indicatively accept in time before a real emergency makes it difficult to choose, if there is no possibility of revocation or correction. Plans for healthcare conduct administered by volunteer associations over which some public bodies could act as watchdog could also be foreseen.

There are *difficulties* however also *for the delegation*. An adequate juridical discipline is lacking which protects the ill from the possible abuses by the person delegated. Not only would it be necessary to foresee the conflicts of interests between the patient and delegatee but also to establish *the type of control that the patient can exercise over the delegatee*. In regulating the flow of information the delegatee could be spurred on by the desire not to upset the choices that the patient had expressed before the state of emergency and to hinder the changes in the 'healthcare plan' by the patient.

Again according to some lines of thought, there is a need to foster the possibility of proposing the drawing up of *varied 'healthcare behaviour plans'*, giving citizens the possibility to assert differentiated psychological needs and to follow different systems of values, but there is also a need to defend individuals against the possible degeneration of volunteer associations created around healthcare conduct plans, which should not use exasperated forms of propaganda and exercise undue types of authority over their associates. They should carry out their role of delivering assistance like that offered by the volunteers who help cancer sufferers.

The extreme delicacy of the issues considered seems evident, the mere 'recording' of which appears to be appropriate at the moment, aside from any hurried conclusion.