CRISTINA AGENO, Brief observations regarding medical responsibility due to inadequate information.

An essential requirement for the validity of consensus to medical treatment is the observance by the medical practitioner to provide adequate and exhaustive information to the patient, in conformity with the development of the doctor-patient relationship and to the increasing importance of dialogue and the so-called therapeutic alliance.

With regard to the informative obligations, both the doctrine and jurisprudence are not in unanimous agreement, and at times, the source of such an obligation can be individualised in the general clause of contractual good faith, and the principal constitution for the protection of freedom and human dignity in which the following has been observed:

> Independently from the preferred theory, the common denominator for the indicated legal orientations may, however, be individualised in the primary role assumed by the informative obligations to define medial responsibility. Indeed, if on one side the violation of the obligations in question, derives from the application of an autonomous title of responsibility amongst the sanitary operators, on the other hand, if we reason in a diametrically opposed manner, the precise observance of the same may imply the exemption of responsibility for the execution of medical activities, in accordance with the aforementioned terms.
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> However, informed consensus profoundly affects medical performance, obliging the health sector to make an increased commitment to the fulfilment of their obligations towards the patient, and in some circumstances, influences the very nature of such activities. An area which benefits is surgery, which we must remember is traditionally connected to the obligations of the means. In some cases, jurisprudence has come to acknowledge even the criminal responsibility of medical staff precisely on the basis of the scarce information provided to the patient.
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> (Lalanne - Landi (Ruffolo) 2004, 257).

Information represents a fundamental element in the process that leads the patient to validly express their consent and merits great attention, in the light of the particular delicacy of the theme, with specific regard to content, modality, duration, consequences, effects, alternatives etc.

Firstly, the information must regard every element of the relationship and therefore: diagnosis, prognosis and the diagnostic-therapeutic programme.

It must be clear, complete and thorough, or rather, it must be specific, as well as covering every single phase of the treatment - that is in relation to the personal/objective clinical subjectivity of each single case - offered by the same practitioner who is called upon to provide their professional services. It must also include the importance of the intervention, any inevitable difficulties, consequent effects, eventual risks, possible alternatives and the conduct of the patient after such an intervention etc.

With regard to a number of formal requirements, it is underlined that as the patient is not generally an expert in medical science, the information must be simple and provided in an appropriate language; or rather customised, in relation to the cultural level of the patient and their ability to understand; it must be thorough, or rather, provided in such a way as to satisfy the request of the patient; truthful, but serene and emotionally balanced; and in the eventof an illness with an unfortunate prognosis must give hope.

The Deontological Code of Medicine also dedicates its entire IV charter to information and consent, with particular reference to Article 30 as follows:

> The medical practitioner must provide the patient with the most suitable information with regard to diagnosis, prognosis, future prospects, any eventual diagnostic and therapeutic alternatives, and the foreseeable consequences of

the chosen intervention. In providing this information, the medical practitioner must bear in mind the patients ability to understand with the aim of promoting the full adhesion of the patient to the diagnostic or therapeutic methods proposed.

All further requests for information on behalf of the patient must be duly satisfied.

The medical practitioner must also respond to the citizen with regard to information requests on the theme of prevention.

Information provided with regard to a grave or unfortunate prognosis, must be made in such a way as to not incur worry or suffering to the patient, and must be provided with care, using terminology of a non-traumatizing nature and without excluding an element of hope.

The documented patients decision to not be informed, or to divulge such information to other subjects must be respected.

(Art. 30, The Deontological Code of Medicine).

As well as individualising and specifying the content of obligatory information that the medical practitioner must provide, the above mentioned article also foresees the patients decision to not be informed in first person, but to delegate this role to another subject, and therefore, the consideration of a right to not be informed.

The acknowledgment of such a right is not however without its problems, especially when we consider the basic principles on which the health service is founded with regard to informed consent. The following has been observed:

At this stage it is necessary to implement an <alternative system of legitimation>, because in the absence of the same it would be impossible to arrive at a result, with obvious repercussions for the sick person (Cendon 2003, 123). Above all, the patient, even though they have refused their right to be informed, can personally delegate a subject, or subjects, of their choice (family, friends, social services, family practitioner or other), to whom the health services will be authorised to provide information regarding the illness (Cendon 2003, 124). Consequently, this point poses the problem not only of the limitations of the indicated suubject, but also the resort to representative civil models, when opportune and recommendable, in such a delicate field as as medicine (...)

It is also important to remember that any decision made by the patient, with regard to the refusal to be informed and the choice of the subject(s) delegated to receive such information, must be noted in the medical records, not only to avoid any eventual equivocations or unpleasant misunderstandings, but also to allow the health practitioners who proceed with the treatment of the patient, to be informed of such a decision.

(Ravera - Palermo (Cendon) 2005, 45).

Indeed, it has also been highlighted that in some cases, one must avoid that the patients right to be informed does not transform itself into an excess of information, or even, therapeutic obstinacy.

Article 31 of the same Deontological Code, foresees the admissibility of information to third parties, because the same has been explicitly requested by the patient.

Information provided to third parties is admissible only with the explicit consent of the patient, except in the events foreseen in Article 9, when the health or life of other subjects is in grave danger.

In the event a patient is admitted to hospital, the medical practitioner must gather the names of the subject(s), duly indicated by the patient, who will be authorised to receive the communication of sensitive data.

(Art. 31, The Deontological Code of Medicine).

With regard to the above in relation to surgical operations, jurisprudence has considered the legitimacy of such a modality and the type of information that must be included:

The details of what the intervention involves, the inevitable difficulties, consequent effects and eventual risks, must be posed to the patient in such a way as to allow them to evaluate the benefits and risks, and therefore, decide whether to proceed or renounce.

This obligation is also extended to foreseeable risks, as well as possible abnormal results, due to chance events that do not assume importance according to the *id quod plerumque accidit*, as it cannot be entirely ignored that the health practitioner must obey the information requirements, while at the same time seek to avoid that the patient, for any remote reason, refuses to undergo a simple operation. With regard to the same, the importance of the interests and "property" involved takes relevance. Nevertheless, it should not be allowed that, on the basis of a mere statistical

calculation, the patient is not informed of the risks, even minimum, which could gravely influence their physical conditions, and even, the supreme value of life. The obligation to provide information is also extended to the specific risks involved when resorting to alternative therapies. With the technical and scientific assistance of the medical practitioner, this must be done in such a way that the patient may consider the available alternatives through a conscious evaluation of the relative risks and benefits that this entails and choose from one or the possible choices, through a conscious evaluation of the relative risks and benefits.

(Supreme Court. civ., 15.1.1997, n. 364, FI, 1997, I, 771).

On more than one occasion, jurisprudence has expressed its opinion on the foreseen consequences with regard to the absence of, or incomplete and inadequate information provided to the patient, generally acknowledging in such an event, the lack of skill and negligence of the medical practitioners and the health facilities.

An interesting case that merits attention, regards a sentence passed by the Supreme Court in 2000, which underlined the obligation to inform the patient, not only about the instruments used in the health facility, but to duly inform the same of any possible deficiencies. In this manner the patient may choose whether to undergo the intervention or seek a more suitable health facility.

In particular, the following case involved a health facility that did not possess the necessary equipment, and was therefore, inadequate for facing a non routine birth, or in any event, the deficiency was enough to increase the risks, seeing as the child in question was born with Encephalopathy: to this regard the following was observed:

The responsibility and the duties of the doctor do not only regard their own activities and the eventual members of the team who work under same, but is also extended to the state of efficiency and the level of the instruments and facilities of the health structure where the doctor provides his services, and should be translated as an ulterior right of the patient to receive such information. Informed consent, be it personal or to a family member, before surgery or any other specialist therapy or invasive diagnostic test, must not only cover the objective and technical risks in relation to the situation in hand, or purely the state of the art of the discipline, but also the concrete, even momentary deficiencies of the hospital with regard to performance, equipment and the normal function of the same. In this way, the patient may not only decide whether to go ahead with the operation, but also decide whether to do so in the said structure, or if desired, request transfer to another. The omission of such information may be considered as a grave act of negligence, to which the medical practitioner, together with the hospital, will be held civilly responsible, and as a consequence liable for compensation for damages, also on a professional, deontological disciplinary level.

(Supreme Court, civ., 16.5.2000, n. 6318, DResp., 2/2001, 154).

The doctrine further underlines that:

The information, as well as being clear and thorough, must also be complete, in such a way as to cover the intervention in all its complexities, during every single phase of the same and in accordance with the parameters stipulated by the *quid* of the medical practice performed. It is not admissible, after the laborious acquisition of the results that the information does not support the entire duration of the treatment until the actual intervention is made (in this case a birth). When compared to other similar professional figures, the position of the medical practitioner intuitively foresees events of a particularly delicate nature, for the fact that their activities directly and immediately involve, not abstract entities, or interests of a purely patrimonial nature, but indeed, a human body. Therefore, interventions that endanger subjects of primary importance in the hierarchical scale of values protected by the order. This accusation was in fact passed by the Court, with the relevant responsibility profile, to the medical practitioner that privately assists the expectant mother, who in themselves "certainly cannot be held guilty, being a trusted medical practitioner, for any of the deficiencies of the public structure where he practices as a hospital doctor, or held responsible for unlawful conduct of other employees of the organisation — whose organisational regulations are insensitive to the private relationship between doctor and patient. However, they are obliged to inform the patient of any eventual, even contingent, deficiency within the structure where they are admitted, and even more so, when this choice is made on the basis of the fact that a trusted medical practitioner operates in the said public structure".

(Cassano 2001, 154).

A sentence passed by the Venice Tribunal on the 4th October 2004, also acknowledged the medical responsibility for failure to provide information - where in this specific case, the patient

was not provided with adequate information on the risks related to the treatment provided - in a case concerning a surgical intervention for the substitution of mitral-aortic valve, with the following dispositions:

The right to self-determination of the patient with regard to their own health has been damaged and therefore the health facility will be held liable for existential damages under art. 2059 of the Civil Code Even though the health facility asked the patient to sign the form for informed consent, they were not provided with adequate information with regard to the risks and any eventual complications that the surgical intervention could cause, or the nature of the operation, and such information was not provided in consideration of the cultural level and emotional state of the patient. The probative burden with regard to the contractual compliance with the information obligations contained in art. 1218 and 1176 of the Civil Code falls upon the health facility, also in consideration of the fact that at the time this fact occurred, the latter was obliged to conserve the personal data of the patient in accordance with law 657/96.

(Venice Trib. 4.10.2004, DResp. 8-9/2005, 863).

With regard to this case, the doctrine stressed the importance of the information obligations and the representative nature of the relationship between doctor and patient underlining that:

In the concrete instance under examination, the patient signs their consent before the operation occurs (but only on the same day of their admission to hospital: a clear indication the health facility's inadequacy in evaluating and giving importance to the risk factors involved with the operation), and the anaesthesiological and surgical form, «had not even been compiled in full». (...)

Furthermore, the signature of M.P. on the informed consent form, was collected by the anaesthetist, who proceeded with the explanation of the «risks of the operation, but only with regard to the anaesthesiological aspects of the same » (undoubtedly, his area of competence), explaining to the patient «the activities to which they would be subjected, starting from the cannula when they came round after the anesthetic». As a consequence the lady in question was left practically alone with the form that had to be read and signed and the cardiologist did not explain the concrete risks of permanent lesions (...), but instead, after calming the patient in a colloquial manner, spoke of the merely routine nature of the programmed operation.

More specifically the Tribunal reveals how the medical staff were not capable of providing evidence on how the information obligation has been effected, or more precisely, how they were unable to prove they had informed the patient of the risks, and furthermore, that they had presented them in the most accessible and comprehensible manner to the patient. (...)

As a conclusion, the hospital failed to prove that there had been a «therapeutic alliance» between the doctor and the patient, where paperwork serves merely as a precautionary measure (...) of a human relationship in constant evolution, where the respect of individual self-determination is an element of fundamental importance, together with the sensitivity towards the cultural level and unique, personal experience of the individual.

(Cacace 2005, 867).

Another doctrine, also in reference to the argumentation in the aforementioned sentence of the Venice Tribunal revealed:

After investigation and evaluation of the *an* and the *quantum* of the information passed from doctor to patient, also with regard to the emotional state and the ability to understand of the patient, the Tribunal has ascertained that the «informed consent» provided to the patient on this occasion, which was signed by the same and collected by the anaesthetist, cannot be considered adequate, as it did not comply with the therapeutic measures proposed. Therefore, the health facility will be condemned for inadequate execution of the contract, also in light of the fact of its impossibility to ascertain the true circumstances of the event and the nature of the information provided to the patient by the health practitioner. The difficulty in obtaining the necessary documentation for decisional purposes, in order to understand the information that was effectively provided to the patient, does not play in favour of the health facility involved, who will be held liable for damages in accordance with art. 1218 and 1176, paragraph 2 of the Civil Code. The request for compensation is hereby accepted and will be proportional to the damages incurred: the clinic is hereby bound to reimburse the patient for the damages contained herein which «concern existential damages», in accordance with art. 2059 of the Civil Code, whereby, there is no evidence that the informative obligation, with regard to the possible post-operative complications was respected. Therefore, compromising the freedom of choice of the patient and the constitutionally guaranteed right of self-determination in their decision to undergo medical treatment.

(Guerra 2005, 872).

Recently, the Supreme Court also expressed its opinion on the consequences of the failure to acquire informed consent, even when the doctor behaves in a correct manner, and stipulates that in

the event a doctor has not adequately informed the patient, they will be held liable to pay damages even in the absence of unlawful behaviour.

The Supreme Court therefore adopted an extremely strict stance with medical practitioners, affirming that the absence of informed consent, not only damages the patients right of self-determination in their choice of treatment, but also the same right of good health and physical integrità. As a consequence, the patient has the right to obtain the same compensation that they would receive in the event of incorrect execution or negligent medical treatment.

In this sense:

In reference to the hospitals responsibility for violation of the obligation to inform the patient of the nature of the operation, the effects and extension of the results and the possibility and the probable the outcome, the correctness or incorrectness of the treatment is of no significance when defending the unlawful party. The violation of informed consent, subsists in the actual omission, damaging conduct and the injustice of the fact, for the very reason that the patient, due to a deficit of information, was not put in a position to consciously and knowledgeably give their consent to the health treatment, as they were unaware of the implications of the consequences of the same. Therefore, such medical treatment was not provided with valid consent, and has been conducted in violation of art. 32, second paragraph, Cost., (which states that no individual can be forced to undergo a specific medical treatment, if it is not in accordance with the laws in force), art. 13 Cost., (which assures the non-violation of personal freedom with reference also to the freedom of an individual to safeguard their own health and physical integrity), and art. 33, of Law n. 833 of 23 December 1978, (that excludes the possibility of the patient to be exposed to medical check-ups or treatments against their own will, if the same is capable of deciding for themselves and is not in a condition of urgent necessity according to art. 54 of the Penal Code). The information obligation must be respected by the medical practitioner: once a specific treatment has been determined, the patients consent must be totally autonomous, even in the event that the patients request is made under prescription of a specialist doctor.

(Supreme Court. civ., 14.3.2006, n. 5444, Resp. civ. on line, 2006).

More precisely, the case in examination regarded a sentence involving a hospital in Liguria that was held liable for damages by a patient who underwent radiotherapy as a complementary treatment to a surgical operation that involved a laparascopy and bilateral vasectomy that had been previously carried out for the removal of a cervical cancer.

The Sanremo Tribunal acknowledged the liability for violation of the informed consent code, whereas the responsibility for negligent execution of the operations was excluded; this decision was confirmed by the second grade Judge whereby the Appeal Court actually increased the sum of the compensation.

The Supreme Court then adopted a measure of maximum rigour with the following motivations:

The responsibility of the medical practitioner (and as a consequence the structure for whom they work) for violation of the informed consent obligations, derives from the omission of the information obligations with regard to the foreseeable consequences of the treatment to which the patient is subjected and the successive verification of the consequences of the same. Therefore, in the light of the casuality of a degeneration of the patients state of health, the correct or incorrect execution of the treatment is of no importance when defining such liability.
Indeed, in light of an illicit violation of informed consent, the correctness or incorrectness of the treatment, does not assume any importance whatsoever. The omission, damaging conduct and the injustice of the fact, subsists for the simple reason that due to a lack of information the patient was not in a position to provide consent for medical treatment, as they were not conscious of the implications of the same. Therefore, as a consequence, the treatment was not carried out with valid consent and was executed in violation of art. 32, second paragraph, of the Constitution (which states that no individual may be forced to undergo a specific medical treatment, unless it is in accordance with the law); art. 13 of the Costitution (that ensures that personal freedom, with reference also to the freedom to safeguarding of personal health and physical integrity as principles that cannot be violated); art. 33 of the law n. 833 passed on the 23 December 1978, (that excludes the possibility to carry out diagnostic tests and medical treatments against a patient's will, if the same is capable of deciding for themselves, and that they are not in a condition of urgent necessity;

according to art. 54 of the Code), and where the physical conditions and legal position of the patient, with regard to their health and physical integrity, worsen due to the execution of such treatment.

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