The wording of the informed consent in gynecology

M. GUIDA - U. MONTEMAGNO

Summary: In many western States medical activity is characterized by legal difficulties regarding the patients' consent. In this paper we have confronted the medical and legal problems connected to the wording of the informed consent in diagnostic and therapeutic practice in gynecology and obstetrics. In this area the role of Scientific Societies seems ever more important in that they could carry-out an important task by having the possibility of acquiring and coordinating the maximum amount of knowledge in both the specialistic medical field and the judiciary field. Here, we discuss the various aspects of the preparation of appropriate forms for correct patient information and the valid acquisition of the patient's consent for medical records.

Key words: Informed consent; Scientific societies; Forms.

INTRODUCTION

The legal necessity for the consent for health treatment is based on specific local legislation in individual states. However, it is known that the request for consent represents a deontological duty which has been recognized by doctors always [1]. As for the European countries, this argument has recently been faced in the drawing-up of the "Principi di etica medica europea" ("Principles of European Medical Ethics"), which has modified the European Guide of Medical Ethics [2].

Received 20-7-1994 from the
Gynecology and Obstetrics Department
University of Naples "Federico II"

Revised manuscript accepted for publication 20-10-1994.

Moreover, each country has felt the need to develop specific aspects. One is referred to a specialized text for a specific treatment [3, 4], but it is useful to stress that, for example, the information for patients in the Netherlands must be given on the basis of medical knowledge, in Denmark it must first evaluate the global, psychological and social situation of patients, in Spain it must be based on the sense of responsibility by the doctor, and in Portugal and Italy it must be in written form in high risk cases.

Particularly, in Italy, article 32 of the Constitution recognizes the limit of obligatory 'ex lege' treatment in the respect for human beings, and article 5 of the civil code prohibits the submission of one's body to acts that could cause permanent impairment to the body itself, while article 50 of the penal code sanctions the non punishability of those who violate a right "with the consent of the person who validly has this right".

The doctrine is unanimous in considering that the consent be implicit in normal treatment, but it becames explicity necessary in more complex, demanding, or dangerous treatment because it legitimizes the doctor's work ([5]), and represents the justifiable cause that eliminates the illegality of the injurious fact and marks the initial and final limits of legality ([6]).

All over the world, jurisprudence has many times clarified the terms by which to consider as valid the consent given for health treatment, with different gradations among the various states. For example, the criteria estabilished for Italy are summarized in Table 1.

Table 1. – *Characteristics of the consent in Italy.*

1) The consent must be given by the one "legitimized" to have the right ([7]);
2) The will of the consentee must be "freely formed" ([8]);
3) The consent must be given by a person who is "capable of understanding and willing" ([9]);
4) The consent must be "actual" ([10]);
5) It can be manifested in any wav ([11]);
6) The consent must be "informed" ([12]).

It is important to stress that in Italy the "Court of Cassation" ([13]) has established that it is even necessary "also to point out the possible results that affect life in a relationship which, lying outside the limits of the technical problem – submitted only to the doctor's choice – must be evaluated by the patient in order to consciously and therefore validly manifest his/her own consent (thus, in gynecology it becomes important also to consider the value of scars, disfigurement, disablement and limitations of the capacity for a full sexual life)".

The legal systems – especially the German – have many times pronunced with fluctuating orientations those risks that should be illustrated to the patients: only the "typical" ones (the dangerous ones that normally are connected to the type of intervention) or those dangers that are hiding behind intervention, even the most elementary intervention. A German decision ([14]) has established that an obligation exists to inform about risks that have some likelihood to occur, while there is no obligation for "typical" risks that occur rarely and are of such small importance "to make one believe that they do not hold a reasonable weight on the decision of the patient".

Difficulties may also arise in the specification of the probably of occurrence of risks: it is not always easy to establish precise percentages and therefore the risk should be divided into categories of probability (high, medium, low).

The Court of California has decreed the doctor responsible "if he minimizes the known dangers, does not propose possible alternatives, alarms with useless details" ([15]).

In Germany 66% of pending suits since 1976 concern the lack of information ([16]).

The position of French jurisprudence is different. It has a more open attitude toward the doctor to whom ample discretionary power is given to convey data to the patient: however the doctor must use simple appropriate and intelligibile expressions that allow the patient to make a decision ([17]).

So that information is correct and sufficient, there is the need to mediate among the different conceptions: professional standard of knowledge (valid for scientific correctness but too complex and difficult to understand), those of the average man (immediately comprehensible for all but vague and ambiguous from the scientific standpoint), and the subjective ones (which are referred to as what individual patients can understand). The preparation of the form by the scientific societies of a given branch could have a decisive value by validly mediating met-

ween the first and second parameters. However, the evaluation of the third parameter remains entrusted to the doctor: in fact, a prearranged form cannot keep account of the possible particular difficulties of an individual patient to attain complete information.

However, jurisprudence – particularly the German one which is more rigid toward the legal position of the doctor – believes that the freedom of the form is sanctioned not to disturb the trust of the relationship between doctor and patient, and takes a suspicious attitude toward the use of blanks and wording believing that these hinder the creation of an atmosphere of cordiality and trustfulness by excessively formalizing the relationship ([18]). However, other jurisprudence has correctly stressed that lack of manifest consent through written reports does not necessarily presume that the doctor did not follow his/her duty of "Humanism medical" ([19]).

Particularly, the use of wording could provide a valid help for the protection of the doctor's trust. In fact, the need for a valid consent poses the problem of protecting the scruples of the doctor who has shown respect for the dignity and freedom of the patient and has intervened, without any guilt, while ignoring the presence of a non-valid consent: that is, one has to adapt the interest of the patient to that of the doctor who acted in good faith. In these cases it would be clearer (thanks to the forms) what the connection is between the protection of the doctor's trust and the fulfillment of the duties that hang over him (more particularly – with respect to freedom of decision by patients – this substantiates the need to convey correct information in a language which is comprehensible for the patient).

The form represents a help for the patient's freedom of choice who would thus avoid being conditioned by the favorable or contrary attitude of the doctor.

However, it must be stated precisely that the technical difficulty to predict all the possible dangerous consequences of interventions has the risk of excessively bureaucratizing the doctor-patient relationship with the consequence of distorting the trust relationship and exposing the doctor to discriminate legal actions.

In fact, the form could on one hand be generic without many details: one would go against the "principle of self-determination" which in Italy is laid down in the Constitution in article 32.

However, on the other hand, the detailed prediction of all possible consequences would raise judicial problems. In the first place one should ask if the consequences to consider are those possible or only those that are probable, and in the case that both have to be predicted, one must consider if they must be differentiated; in the second place one must ask how jurisprudence would be oriented in the case of the occurrence of a consequence which is not literally and sufficiently described, but is however, "analogically" deducible from the prediction of others.

Additionally, the use of prearranged forms to obtain the patient's consent poses the problem of the legal compatibility of such forms with the requirements reported in Table 1, that could be met as in Table 2.

A debated French orientation that emerges from the sentence of November 7, 1961 of the Cour of Cassation should then be pointed out. According to it, "the doctor should be obliged to obtain a written declaration from the patient in the case the patient refuses treatment adequate for preventing a grave health damage".

A different question is connected with the fact that the consent can be withdrawn at any time before the intervention: the consequent problem that arises is the "form" of the withdrawal, that is, if it is necessary to provide the patient

Table 2. – *Advantages of forms.*

1) *Legitimation.* No particular problem: one who legitimately has the right must sign the form.
2) *The will.* The freedom of patients is not compressed or vitiated by the use of wording.
3) *The capacity.* The capacity to understand (to perceive what occurs in the external world) and to want (to produce an effect on the perceived reality through an effort of will) is necessary, obviously also to use the form, which requires a minimum knowledge of the alphabet to that the subject be at least able to read.
4) *Actuality.* Actuality implies that the consent must be closely connected in time to the intervention, which probably is facilitated by the use of forms.
A further case may occur when there is the need for a particular further intervention subsequent to laborius diagnostic investigations: a new manifestation of the further consent of the patient then becomes necessary ([20]).
5) *Form.* Freedom of showing consent anyhow expressed – written or oral, silent (through conclusive or in some cases "presumed" behaviors) – makes the use of forms possible.
6) *Information.* Information to the patient could certainly be facilitated by a proper wording of forms: in fact, the doctrine postulates that information must be adequate "to the degree of the culture and intelligenge of the patient" ([21]).

with a form for the withdrawal or if it sufficient to use the original form.

Therefore, the form must be structured in an informative part and in another part with the consent clauses.

There is no doubt that the patient must know the kind of programmed intervention and the effects that will certainly derive from it – both permanent or temporary –, and must be informed about which benefits he or she could achieve and how long they will last; but problems arise in relation to risks.

In this connection, it is useful to recall the concept recently defined as 'social consent', which closely links the overall society to the action of medicine considered as a whole: it must in fact be stressed that the consent given by society to medicine is not always obtained through correct information ([22]), often because of mass-media that provides triumphalist and dogmatic information which instead predisposes to the dissent against a single doctor by making him assume responsibility for failures ([23]).

The clauses of manifestation of consent play a twofold role: on one hand they confirm that information occurred, by reading the first part, and on the other hand they help the doctor in constructing a first pre-constituted proof that the consent occurred.

With reference to this, the role of scientific societies seems particularly important in that they could guide the doctor in the correct application of his/her own activity and, at the same time, could protect the fundamental rights of the patient.

In fact, even from the proper legal standpoint, association as a primordial human need is recognized by modern law not only as an inviolable freedom but also as a connatural expression of personality, to the point that in Italy "the Republic recognizes and guarantees the inviolable rights of man, as both a single individual and in the social formations where his personality evolves" ([24]).

Scientific societies – either formally recognized by law or only associations of fact – are one of the numerous and more modern expression of the social phenomenon of associationism profoundly protected by the legal system.

They are the expression of the freedom of an association sanctioned not only as "negative freedom", that is, as a guaranteed right not compressible by the state, but also in its "positive" aspect, for which the State must promote and favor the forms of aggregation and social pluralism.

Particularly, association for scientific purposes is included in the provisions of the law which in Italy even entrust the

Republic with the promotion and development of "culture and scientific and technical research" and sanction the freedom of arts and science as well as the freedom of their teaching ([24]).

In this context of "favor", scientific societies set themselves the twofold goal of improving the health level of patients and offering valid and constant scientific support to their associates.

In fact, the goals of these societies are generally substantiated in the points reported in Table 3.

Table 3. – *Purposes of scientific societies.*

1) Develop and improve the exchange of knowledge and information;
2) Promote and favor research and the teaching of single disciplines;
3) Promote and favor studies through congresses, refresher courses, symposia;
4) Promote cooperation with other societies facilitating cultural exchanges;
5) Develop a profitable presence in international science.

The role of Scientific Societies in the pre-arrangement of forms for informed consent is then decisive because they can have access to a larger amount of technical knowledge and pre-arrange more precise and up-dated clauses, and because they can homogeneously make uniform the kind of request for consent over the national territory. In this connection, however, the need is felt that Societies at the regional level also closely collaborate, and that the national Societies take into account that some Regions have autonomously legislated the subject.

The procedure for the formation of such schemes – which could be institutionalized in a regulatory norm of each Society – presupposes the coordinated participation of all the Scientific Societies that deal with a given branch, as happens in Gynecology with the Italian Society of Gynecology and Obstetrics, and in the many others with the purpose of studying Gynecological Oncology, Colposcopy, Echography, Endoscopy, Fertility and Sterility, and many more.

The initiative is up to the traditional Societies, which must have a role of promotion and impulse on the activities of the specialistic societies which, instead, must pre-arrange informative tables of the benefits and risks – in relation to each other – of the specialistic aspects of their own competence with respect to the single medical actions typical of the branch. These specialistic Societies must then pre-arrange some permanent control commissions with the task of continuously updating the tables for both the cases when a modification of the risk-benefit ratio occurs and when practice evidences new risks and further benefits.

The tables worked out and updated in this may must be coordinated by the traditional Society which will turn them into the final form delivered to the doctors and hospitals. The traditional Society must also have a control organ on the inside that modifies – on the basis of incoming updating – the forms.

Both the traditional Society and the specialistic Societies work in close contact with the other type of Society represented by the Associations that geographically work on the territory covering local regional and interregional areas. These other societies have, in fact, an important role due to their knowledge of regional legislation on the subject which – even if it is currently sporadic – shows a tendency to proliferate (as is demonstrated in Italy by the autonomous legislative provisions of the Regions: Liguria, Abruzzo, Toscana, Friuli Venezia Giulia).

To help the doctor in proving the legality of his/her own behavior, societies should also pre-arrange redeeming clauses in case of refusal of consent.

In fact, also in Italy different regional laws have locally sanctioned the need of a patient's redeeming declaration for the

doctor when the patient refuses to be checked for an indispensable intervention ([25, 26]).

It would be useful that the redeeming clauses provided the explicit mention of the reasons for the refusal, the possible alternative services, and the technical grounds for the possible transfer of the patients ([27]).

The traditional Society should then create a stable connection with the Judiciary Archives to monitor the activity of jurisdictional organs, and establish relations with the different Insurance Companies so to manage the possible cases and provide the adequate assistance to their associates.

Internationally, an important role will then be played by the traditional Society by absorbing the most updated scientific indications and cultivating the necessary relations with the legal experts of other nations to study the developments and the consequences in the judicialy field.

The traditional Society should then take care of the relations with the Associations of craft Unions as well as the Medical Association in order to protect the public image of the gynecologist in the press and mass-media. Finally, it should verify the conformity of the abovementioned "social consensus" to the forms of consent really required by the patients, if necessary with the constitution of a proper Commission for the analysis of messages proposed by mass-media in the delicate fields of gynecology and reproductive medicine.

REFERENCES

1) Comitato Nazionale per la Bioetica: "Informazione e consenso all'atto medico". Premiership of the Italian Council of Ministers, 1992.
2) "Principi di etica medica europea". Parigi, 1987.
3) Nannini U. G.: "Il consenso al trattamento medico". Giuffrè, Milano, 1989.
4) De Pietro O.: "Il consenso dell'avente diritto e il consenso del paziente". Martinuci, Napoli, 1988.
5) Cattaneo G.: "Il consenso del paziente al trattamento medico-chirurgo". *Riv. Trim. Dir. e Proc. Civ.,* 1957, 949.
6) Riz R.: "Libertà individuale e tutela della salute". *Riv. It. Med. Leg.,* 1983, XI.
7) Corte di assise di Firenze, 10-10-1990, in: *Riv. It. Med. Leg.,* 1991, XIII.
8) Trib. Sup. Mil., 27-10-1967, in: *Giust. Pen.,* 1969, *II,* 590.
9) Pret. Gross., 17-1-1957, in: *Giust. Pen.,* 1980, *II,* 80.
10) Cass. 23-3-1974, in: *Giust. Pen.,* 1974, *II,* 116.
11) Cass. 7-12-1977, in: *Rep. F. It.,* 1978, 299.
12) Corte d'App. Milano 21-3-1939. Cass. 18-6-1975, in: *Giust. Civ.,* 1975, 1839.
13) Cass. 26-3-1981, n. 1173.
14) B. H. G., 9-12-1958.
15) Crawford M.: "Critical factor in preparing for the defense of physician". In: Meaney T. F., Lalli A. F., Alfili R. J.: 'Complications and legal implications of radiologic special procedures". *Mosby Co., St. Louis,* 1973.
16) Gabrielli M., Fineschi V.: "Informazione e consenso all'atto medico". *Fed. Med.,* 1986, 3.
17) Savatier R.: Cass. II, n. 12129, J. C. P., II, 1961.
18) KG 12 U 1260/78, in: Vers. R., 1979, 260.
19) BGH VI ZR 15/83, in: N.I.W., 1985, 2192.
20) Trib. Milano, 17-4-1961, in: Resp. Civ. Prev., 1961, 205.
21) Chiodi V.: "Il consenso del paziente". In: 'La responsabilità medica', Giuffrè, Milano, 1982.
22) Beretta Anguissola A.: "Sul consenso informato". *Fed. Med.,* 1994, 3.
23) Fiori A.: "Medicina e morale". 1993, 6.
24) "Costituzione italiana", artt. 2, 9, 18, 33.
25) Reg. Toscana, L. 1-6-1983, n. 36.
26) Reg. Abruzzo, L. 2-4-1985, n. 20.
27) Reg. Friuli Venezia Giulia, L. 1-6-1985, n. 23.

Address reprint requests to:
M. GUIDA
Università di Napoli "Federico II"
II Fac. Medicina e Chirurgia
Ginecologia e Ostetricia
Via Pansini, 5
80131 Napoli (Italy)