REPORT

CONSENT IN THE PHYSICIAN-PATIENT RELATIONSHIP

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A. INTRODUCTION: NEW DEVELOPMENTS IN MEDICAL PRACTICE

Until recently the physician-patient relationship was governed by a "paternalistic" model developed as a product of Hippocrates' ethics subsequently interpreted or modified by a succession of physicians-philosophers like Galen, in combination with the prevailing social conditions. According to this model, the physician decides on all matters pertaining to the patient's treatment while the latter has little or no say in it at all[1]. The contemporary conditions of medical practice exhibit new qualities suggesting a need for a new model, different from the one which prevailed over the world until the '50s and the '60s.

Unlike the paternalistic model, the new one, which appears to find favor particularly with Anglo-Saxon and north European countries, emphasizes patient's autonomy. In the context of this model, the relationship physician-patient is one of cooperation with either party having more or less equal say on the making of decisions. The new characteristics of medical practice and the conditions in which it operates which affect the relationship physician-patient can be summarized as follows:

[1] Although the so-called "paternalistic" model of the relationship patient-physician is attributed to Hippocrates or to his followers, in the extant Hippocratic texts the author considers as a virtue of the physician that "he makes sure to foresee and foretell to the sick their present condition, what preceded it and what will happen in the future". He considers also that "any irrational thing that happens needs to be discussed" (Rigatos, 1997) while he argues that when the physician analyses the present condition of the patient and what he foretells for the future in the presence of the patient the latter will find it easier to believe that the physician is well acquainted with the situation and will have more confidence in him (Hippocrates, Prognostics, introduction to the text).

1. Medicine is divided into several specialties and one physician alone is no longer able to treat all the health problems of an individual.
2. The physicians of different specialties as involved to consult in the course of his/her life will not necessarily work together; therefore, the patient is the only one with a complete picture of his/her medical history. It should be noted also that in Greece, records of medical history are not kept for each patient.
3. Medicine has progressed in such a way that there is no single indicated treatment for each particular condition.
4. The level of education in our country has been improved in recent decades. As a result, most patients are able to understand the medical facts of their condition and are seeking more detailed information. Furthermore, the lay public enjoys greater, if fragmentary, access to medical information from a variety of sources.
5. People do not trust the motives of physicians unreservedly. This is mainly because the practice of medicine is sometimes known to be influenced by varying interests not necessarily compatible with the patient's interests.
6. Citizens demand more from the health system as regards the quality of services, the medical outcome and the conditions in which these services are provided. The provision of high quality services is considered by citizens as an utmost priority in our country.
7. It is now acknowledged that the way of living and the religious or other philosophical beliefs of patients must be taken into consideration when determining treatment. There is an increasing awareness of the right to autonomy and of respect for dignity in medicine.

B. LEGAL ISSUES

1. In general

The "Code of Medical Ethics" (CME, Act 3418/2005) has put in place a modern legal framework for the relationship physician-patient in Greek law[2]. The main

[2] Despite its title ("Code of Medical Ethics") this Act was not an instance of investing with legal authority a pre-existing corpus of norms accumulated by the medical profession in the context of self-regulation (a *stricto sensu* code of ethics). It was genuine lawmaking by the government and

characteristic of this law is the explicit introduction of "informed consent" albeit maintaining provisions which reflect the former "paternalistic" approach.

It must be noted that "informed consent" was already embedded in Greek law, first, through the ratification of the Oviedo Convention on Human Rights and Biomedicine (art. 5 *et seq*. Act 2619/1998) and, second, by way of express provisions in a number of laws on various medical fields[3]. Naturally, the relevant rules of the CME are more detailed. Pursuant to the CME:

- Informed consent is always required except in case of: a) emergencies, b) suicide attempts, and c) refusal to consent by the guardian of a person incapable to consent in a life- or health-threatening situation,
- The consent must be explicit though it may be informal,
- In case of minors, the consent is provided by their parents or custodian,
- In other cases of incapacity, the consent is given by the "next of kin" or the legal guardian.

Consent requires that the patient (or the patient's representative in case of incapacity) must "be informed". This information:

- Must be "complete" and "intelligible".
- Must reflect the truth.
- Must cover: a) the real condition of health, b) the content of the suggested medical act, c) the risks and likely side effects, d) alternative treatment choices, and, e) the estimated time of recovery. The aim is to enable patients to consider not only the medical but also the *social and economic factors* before reaching a decision.

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went through the usual pipeline of law-enactment (a drafting committee was set up for that purpose; its draft text was duly tabled by the responsible Ministry for Health to go through the parliamentary procedure). In that respect, the title "Code of Medical Ethics" is not accurate, although the same wording was also used in the previous situation enacted by the royal decree 25.5/6.7.1955.

[3] See art. 10 (4) Act 2737/1999 on transplants, art. 1456 of the Civil Code (Act 3087/2002) on assisted reproduction, art. 3 of the Joint Ministerial Decision 89292/2003 (Directive 2001/20) on clinical trials.

- Patients may refuse to be informed (*right- to- not- know*) either totally or by authorizing the physician to inform others.

Even in case of incapacity, however, the law acknowledges a duty to inform the patient "to the extent possible" and an effort to ensure "voluntary participation", "active involvement" and "cooperation", especially in patients preserving some capacity of understanding.

2. Ambiguities

The complexity usually characterizing medical conditions combined with certain ambiguities in the provisions of the law raise problems of interpretation, as might be expected. These are multiplied with regard to "special cases" regulated by the law mainly concerning the application of new methods of technology in medical practice (arts. 29-34).

a) Problems pertaining to information

The main problem here is the notion of "truth". The law often repeats the term "complete" information. Combined with the "duty of truth", this seems to imply, at a first reading, that the physician must hide nothing in connection to the condition of health or to the offered methods of treatment from the patient[4]. Two questions arise in this respect:

i. If the physician believes that, by learning the "complete" truth, the patient will be either discouraged from receiving treatment or affected to such extent that it becomes threatening for his/her condition, can the information be limited or – in extreme cases – may the physician even misinform the patient[5]?

[4] Insofar as the "truth" appears clear to the physician, of course. The issue here is not whether the information provided by the physician is true but whether the physician himself/herself consciously tries to mislead the patient. See, Higgs (2001).

[5] A related question is whether the "complete" truth includes the physician's personal doubts or even a statistically insignificant risk of serious harm to health or of death, elements that may nevertheless have a critical impact on the patient's condition.

ii. In such event, may the physician choose to inform the patient's relatives instead so that they may decide[6]?

A further complication arises when the available alternatives do not clearly indicate the treatment of choice because they may be associated with serious side effects, critical perhaps for the overall quality of life of the patient (e.g. chemotherapy, radiotherapy, amputation, etc.). For patients of advanced age, in particular, even the normal side effects of an "aggressive" treatment may prove disproportionate in comparison with the real expected benefit.

The relevant question here is whether information should be limited to a "neutral" presentation of alternatives or it should be accompanied by the physician's evaluation for the particular patient. This question is again related to "completeness" of information in the sense of the law.

A "neutral" presentation, if "complete", leaves the appraisal of the situation to the patient since only the patient can balance the benefits and losses for his/her quality of life. This burden, however, may prove difficult to bear for someone who is not able to think soberly about his/her condition. On the other hand, the physician's evaluation may offer valuable help in the final decision by the patient; but this must necessarily arise from statistics – which do not take the particular patient into consideration – and, ultimately, from an "intuitive" perception of *what is "best" in concreto*, i.e. factors not immune to error.

b) Problems pertaining to consent

Problems pertaining to consent itself arise in the relationship physician-patient in case of incapacitated patients:

First, as to the derogations from informed consent accepted by the CME [art. 12(3)], there is the question of *whether a patient's relatives may, in general, refuse treatment and to what extent are they allowed to do so*. The "risk to health", as a limit prescribed by the law, is susceptible of broad interpretation and needs to be further specified. Certainly, the discretion to "refuse treatment" is *not the same* for patients and relatives as the latter are not able to *experience* the disease. On the other hand,

[6] For an example of deterioration of the patient's health because of a similar initiative by the physician, see Higgs (*op. cit.*) p. 435.

relatives may not be "obligated" to allow treatment for this would defeat the basic tenet of their freedom to consent on behalf of the patient.

Continuing on the question of derogations, it is worth noting the different approach of the CME as compared with art. 1534 of the Civil Code (CC) which allows the physician to act alone in case the parents of a minor refuse to give their consent to treatment. The Civil Code requires *authorization by the Prosecutor* whereas the CME does not. The question is whether *the provisions of the CME provide sufficient grounds to cover the physician's liability vis-à-vis the parents* especially in view of the constitutional protection of parental care (Constitution, art. 21 (1); art. 8 (1) ECHR) whose guarantor is precisely *the judiciary and not the physician* - as firmly held in legal doctrine.

Critical also is the physician's attitude in case of *disagreement between relatives* which is not unlikely since the law does not assign any priority among relatives with regard to their power to decide. Should an implicit hierarchy be inferred or is it left to the physician to decide according to his/her fundamental duty to the patient? Could an ethics board be of assistance when the patient is hospitalized? Let us recall at this point that our national health system is not familiar with ethics boards whereas in Europe and the US they are well-established – and the importance of their role is not put in question – for many years.

An even graver issue may arise when the physician is in a position to know the *patient's wishes, which were expressed before the patient became incapable to consent* either in written or orally and the relatives disagree. Since the latter have by law the right to make the final decision, the question is whether these wishes should be taken into account, and how. It is worth noting that both the CME [art. 29(2)] and the Oviedo Convention (art. 9) stipulate so though failing to specify the ensuing legal effects (see below).

Finally, there is a wider issue with the consent of minors. The law totally precludes it (art. 12 (2) (b) CME) even when minors are obviously able to exercise control over their health given that other provisions recognize their capacity to enter into legal relationships (e.g. to marry). At issue here is whether the scope of this provision should be interpreted *stricto sensu* to apply only when the intellectual immaturity of the minor obviously justifies that the consent be given by his/her parents or custodian in order to harmonize this rule with the constitutional protection of personality [Constitution, art. 5 (1)].

b) Medical liability and other legal consequences

In legal terms, the answers to all the above questions have an impact, first and foremost, on the extent of medical liability (criminal, civil and professional). Liability, in this case, is not connected with fault in the execution of a medical act (which is judged according to *lege artis* execution) but with fault at the stage preceding the act, i.e. during the legal procedure of decision-making[7].

Thus the implementation of the Oviedo Convention and the CME provisions on "informed consent" (and of the provisions of special legislation on transplants, assisted reproduction, etc.) complement the general legislation on medical liability (e.g. arts. 57, 914 CC, art. 8 Act 2251/1994) and may provide grounds for particular claims in action[8].

Secondly, the answers may have an impact on the legal situation of third parties (hospitals, relatives) insofar as compliance with the principle of consent is associated with individual rights and obligations pertaining to them.

C. SPECIAL PROBLEMS IN THE IMPLEMENTATION OF AUTONOMY WITH EMPHASIS ON THE GREEK SITUATION

The model of patient consent is based on the assumption of appropriate education on personal autonomy, on the one hand, and on the allocation of relatively adequate time for a sober evaluation of information, on the other. These assumptions rarely permit the application of the model in its pure form. As a matter of fact, special circumstances call for adjustments. Therefore, certain areas of medical practice must be considered separately.

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[7] This broad concept of fault is upheld today in Germany, France and the US. See Fountedakis (2003) pp. 210-211 who accepts the distinction between "medical error" and "information error" (p. 216).

[8] The preferred criterion for the assessment of prior information in the context of medical liability is the "average rational person", see Androulidakis-Dimitriadis (1993) p. 273. Typical in the case-law is the case *Canterbury v. Spence* [464 F.2d 772 (D.C. Cir. 1972)] which changed the initial approach of American tribunals.

1. Extent of information

As mentioned earlier, our national legislation (CME) requires informed consent prior to every medical act unless patients refuse the information by exercising their right not to know. But patient information is not limited to those cases where patients need to consent to a medical act. It also includes the patient's right to know the state of his/her condition to the extent he/she so wishes. This knowledge will eventually help patients to make all sorts of decisions about their lives and satisfy their need for sound medical information on their condition, regardless of whether they will use this information to make medical decisions.

What is the usual practice, however? Do physicians actually inform willing patients on their condition, and the diagnosis and prognosis of their illness? Are patients willing to be informed, even when the diagnosis is about a serious, or even incurable, disease or do they rather not know? Is it acceptable that physicians inform the relatives first and then the patient? What is appropriate information in terms of its content and the way it is imparted and how well trained are physicians and nurses to convey this information to those concerned?

These questions do not always have easy answers and have being debated for years by physicians, philosophers, jurists, sociologists and other experts. The "best" answers – as will become evident below – often vary according to the particular conditions of countries, the cultural traditions of social groups within the same country and the personality, age, gender and education of patients themselves.

There is plenty of international literature both on what patients want and on the perceptions of the medical community on honesty and information (review by Herbert *et al.*, 1997; Tuckett, 2004). This literature is based on research conducted on different severe or incurable diseases in various countries, age groups and nationalities. The most frequently used example is the attitude of patients and physicians to disclosure of diagnosis in case of cancer. Other entities have also been investigated like Alzheimer's and multiple sclerosis.

a) International experience

One of the first studies attempting to record the views of the medical community on patient information conducted in the early '60s in the US showed that the

overwhelming majority of physicians (90% in a sample of 219 people) did not disclose the diagnosis of cancer to their patients (Oken, 1961). A study on the same topic carried out approximately 20 years later marked a radical change in the views of the US medical community. In a total reversal of the results of the previous study, 97% of the interviewees stated that they reveal the diagnosis to their patients (Novack *et al.*, 1979). A similar turn was witnessed in the other Anglo-Saxon countries.

This turn-about in the views of the medical community followed in time the desire of patients to know the truth. In a study published in 1957 involving 560 cancer patients and their families, the participants in their great majority (87%) argued that patients should be informed that they suffer from cancer (Samp and Curreri, 1957). Subsequent research on multiple sclerosis (before any treatment became available) (Elian and Dean, 1985) and Alzheimer's disease (Erde *et al.*, 1988) also reported an increasing wish among participants to know the truth about their condition (83% and 90% respectively). It should be noted, however, that different ethnic groups seem to hold divergent views. For example, a related study conducted in the US recorded significant variation on preferences of information among old patients of declared Mexican or Korean origin as against patients of European or African (African-Americans) origin (Blackhall *et al.*, 1995).

In contrast to Anglo-Saxon and north-European countries, in southern and eastern European countries, as well as in Asian countries like China, Japan, etc., this change in the attitude of physicians on the disclosure of truth about the diagnosis of serious diseases has not taken place yet or, to say the least, the process of change has not been completed. According to the results of studies, a high percentage of physicians avoid disclosing the diagnosis of cancer (Thomsen *et al.*, 1993; Mystakidou *et al.*, 2004).

At any rate, international literature on disclosure of the diagnosis of serious, chronic or/and incurable conditions suggests that the attitude of physicians depends on the likelihood of social stigmatization, prejudice or particular emotions (metaphysical or other) associated with a particular disease, the availability of treatment and other relevant factors that may generate a feeling of "powerlessness" in the physicians themselves with regard to the disease. For example, while the disclosure of truth in case of cancer has been almost universal since the late '70s in the US, this was not the case with neural diseases such as multiple sclerosis (Elian M. and Dean G., 1985).

b) The situation in Greece

According to related surveys, the number of oncologists in Greece who disclose the truth to their patients (according to their own admissions) seems to have remained small (review by Mystakidou *et al.*, 2005): 7% in 1980 (Manos and Christakis, 1980), 12.5% in 1986 (Dosios *et al.*, 1986), 11% in 1996 (Mystakidou *et al.*, 1996), 22% in 1999 (Mystakidou *et al.*, 1999). Most surveys offer a choice between "almost or almost always" and "never or rarely" and their results do not vary through time. The comparison between two surveys which offered the answer "sometimes", however, reveals a noticeable increase in the rate of physicians ticking this answer in recent research (20% in 1980, 78% in 1996).

Thus, a change in the attitude of physicians appears to have taken place from the '80s to the end of the '90s in our country but this change does not involve all patients. It is revealing that most physicians declare that the extent of information they provide to their patients depends on the personality of the patient (74%) and his/her expected reaction (54%) rather than on the physician's personal views. Interestingly also, though not unexpectedly, even when they do inform patients of their diagnosis with cancer, most physicians in Greece choose to inform the relatives first and then the patient (Mystakidou *et al.,* 1996).

This attitude as documented in surveys based on the admissions of physicians themselves is confirmed in practice. A survey conducted in Athenian hospitals showed that most cancer patients (120 out of 203 interviewed) are unaware of their diagnosis (Brokalaki *et al.,* 2005). However, the same survey recorded a clear wish for more information on part of most patients (69%) whereas of the patients who knew their diagnosis only a small number (13%) said that they would rather not to have been informed. Also, most patients wanted their relatives to be informed of their condition.

These findings coincide with the findings of another survey conducted in a Patras hospital which also documented high ignorance rates among patients (59%) and a wish for more information (Iconomou *et al.*, 2002). This survey also investigated the quality of life and the psychological state of patients associated with their getting or not the full picture of their condition and concluded that the patients were not affected psychologically by knowing the truth. Despite the high ignorance rates reported by the two surveys cited above, these were significantly lower as compared with older

data according to which only 15.5% of the patients who participated in relevant research knew they suffered from cancer (Lavrentiadis *et al.*, 1988).

All the above show a considerable distance in our country between a wish by patients to receive more information and the attitude of physicians. The causes of this divergence, in particular, the reasons leading physicians to hide the truth from their patients, need to be investigated in order to develop guidelines based on the patients' interests.

a) Honesty in the physician-patient relationship

There is disagreement as to the usefulness of honesty in the relationship physician-patient, especially when disclosing the diagnosis of serious diseases. A lot of international literature supports the view that honesty and information are beneficial to patients because they strengthen their confidence in the physician, increase the chances of compliance, reduce pain and suffering from medical interventions, increase satisfaction for the provided medical care and reduce the chances of change of physician (review by Hebert *et al.,* 1997). By contrast, the concealment of truth from the patient may lead to an attitude of suspicion vis-à-vis the physician while its disclosure to relatives may isolate the sufferer from his/her surroundings.

The opposite, however, can also be argued: that in some cases complete information may be detrimental to certain patients and have a negative psychological and physical impact. A compromise between these contradictions can be reached if we admit that there is no single "correct" approach to the issue of honesty but every patient must be dealt with according to his/her needs. To meet this goal, it is important to dedicate time to the development of a relationship of communication between the physician and the patient such that the former will understand the needs of the latter and the patient will feel free to express his/her wishes. Appropriate training on communication with patients and on ways to announce an ominous diagnosis is equally important for an efficient physician-patient relationship. The lack of such training is stressed by many Greek authors who have investigated honesty and patient information (Mystakidou *et al.*, 1996; Rigatos, 1997).

2. *The problem of time*

According to a frequent argument, it is difficult to implement the model of consent in the limited time available to case management. Experience shows that this time shortage is due either to the nature of the case itself ("emergencies") or to the inadequate organization of health services especially when faced with occasional peaks of demand.

It is worth noting that, in the first case, it is generally admitted – and expressly stipulated by the law – that physicians may act alone, namely "informed consent" does not apply. The notion of "emergency" is very broad and needs to be further specified. Assuming that its use must be regarded as exceptional, its scope is limited to: i) cases posing an immediate threat against the patient's life, or, ii) cases where even the slightest delay in effecting the indicated medical act will definitely cause serious harm to health. Thus, moderate harm to health, even when demanding immediate action, or serious but chronic pathological conditions (e.g. many forms of cancer, diabetes, etc.) cannot qualify as "emergencies". In-between these two extremes, there is an area in which the rule of consent *must apply* with the necessary adjustments to the available margins of time[9].

As far as inadequate organization of health services is concerned, the possibility to allocate the required time depends mostly on objective, often non-elastic, parameters (e.g. restricted resources to employ additional medical staff). Especially here, however, the issue of appropriate training and sensitization of civil health services to patient autonomy is crucial. For, if patient consent is not to be considered a "luxury" but an essential condition for the protection of health and, ultimately, for quality of life, then this requirement obviously affects the priorities of the organization of services in a way that makes finding the required time feasible.

3. *Education – Training*

Among the reasons invoked by physicians to justify the concealment of diagnosis from their patients in Greece, as well as in other countries which share the same practice, is the lack of training (Mystakidou 1996; Iconomou 2002).

[9] However, for a discussion on whether summary information provided to a patient capable to consent qualifies as "appropriate" in emergency circumstances see also *Young, 2001.*

The question of deficient training of physicians in patient autonomy in Greece has at least two sides. The first concerns the knowledge of the rights of patients and the second the implementation of these rights and the effective communication with patients. Typically, in the Medical School of the University of Athens, medical ethics remains an optional subject. The same deficit permeates all the national curricula in regard to learning how to approach patients and develop meaningful relationships with them taking into account the whole spectrum of the patient's needs and respecting his/her autonomy.

The new model of the physician-patient relationship involves active participation on the part of the patient. Patients need appropriate education too, if they are to respond to this role. Therefore, education is an issue not only for physicians but for society as a whole.

4. Epidemiology: Vaccination

In the prevention of infectious diseases, especially in the example of vaccination, free will of the individual must be weighed against the interest of society as a whole. Should the Commission decide to consider the question of patient consent to vaccination the following observations may be of use.

The success of mass vaccination is based on the greatest possible participation; in democratic societies, however, people may not be coerced to participate (Asveld, 2008). Here, the State, on the one hand, and the scientific community, on the other, while obliged to respect individual autonomy, are called upon to ensure the greatest possible participation, provided the benefits of vaccination and the safety of the vaccine have been foreseen and documented as far as possible. But individual citizens also bear a responsibility to society, and their decision to participate or not in a vaccination program cannot be based solely on the argument of autonomy. Individual people themselves will probably not benefit directly from participating in a vaccination program, but they contribute to the protection of society and of vulnerable groups in particular.

The importance of confidence in the safety of vaccines and the major role of the State and of the scientific community were recently illustrated in Great Britain in the MMR vaccine against measles, mumps and rubella. Before the beginning of mass vaccination, measles cost Britain an average of 100 casualties annually. In 1988 the

rate of participation in mass vaccination was 76%. The launching of the triple vaccine that year in replacement of the three separate ones increased the rate of participation to 91% until 1998. At that moment, however, fears began to spread about side-effects; autism in particular. Although the vaccine had been tested for many years and there was no data commonly accepted by the scientific community suggesting any side effects, certain studies published by a medical researcher undermined the confidence of parents and participation in the vaccination program dwindled significantly after 1998. The study which supported the allegations of some parents about side effects proved fallacious; in fact, it contained fabricated data. The slump in participation rates, however, led to the loss of the so-called *indirect* or *herd immunity* causing an important increase in measles cases before confidence in the vaccine was restored and broad participation resumed (Jansen *et al.*, 2003).

Whereas in case of tested vaccines, the decision to abstain is not ethically neutral, the example of new and insufficiently tested vaccines is different. The experience of mass vaccination against swine influenza in the US in 1976 illustrates the risks inherent in a reckless decision for extended vaccination based on unfounded, as it proved, fears of a pandemics, and with inadequately tested vaccines at that. While the influenza claimed only one victim, the side effects from the vaccine caused 25 casualties and may have led to permanent damage (it was associated with the auto-immune syndrome of *Guillain-Barré*). Such examples justify the reluctance to participate and the ethical duty to society as a whole cannot remain as strong if weighed against an increased likelihood of unknown side-effects from the vaccine.

5. Patients in hospitals – The case of ICUs

Implementing the model of consent in hospitals is met with certain limits to patient autonomy.

First of all, the hospitalized patient is situated in a public environment which does not allow full freedom of movement, expression and communication while drastically restricting privacy and family life. In these circumstances, patients are particularly vulnerable. Especially in the ICU, these restrictions are much more encroaching; moreover, patients are under psychological stress due to their critical condition. Taking into account that the potential for a sober appraisal of the situation by the patient – and in extension, for a rational decision on the course of treatment – is

significantly curtailed by the hospital environment, the role of the medical and nursing staff becomes even more decisive.

Hospitalized patients, however, even patients in the ICU, are usually capable to give an informed consent. This means that physicians remain fully liable for allowing patients to participate in the course of the particular treatment and may not legitimately act alone. In conditions of "internment" – especially in ICUs – the risks of manipulation of the patient's will by the physician are increased. Patients can be easily forced into accepting things for they are understandably eager to have their health restored as soon as possible in order to return to the freedom of everyday life and recover the full exercise of their autonomy.

At this point we must underline that physicians have a heightened ethical duty to provide complete information. The more comprehensive the information, the greater the likelihood for an independent appraisal of the situation – and decision-making – by a *de facto* vulnerable will. By contrast, limited information can more easily lead to manipulation of the patient by the physician since the patient is called upon to evaluate and decide in an unfamiliar environment of internment, more prone to "blind obedience" rather than genuine exercise of autonomy.

6. *Incapacity to consent*

The legal capacity to consent must be distinguished from the corresponding physical capacity. Patients with full legal competence to consent may suffer a temporary disorder of their mental functions which prevents the forming and expression of free will (e.g. under the influence of alcohol or narcotics or in state of shock because of an accident or the announcement of a serious disease, etc.)[10].

In these circumstances acting alone is again not justified for physicians except in emergency situations. They must concentrate their efforts on the speedy recovery of the patient's mental lucidity so that the patient can be informed in time and decide about treatment by himself/herself. Besides, it is not legitimate to substitute the patient's relatives for the patient's own will for patients may disagree with their relatives' decision once their mental capacities are restored.

[10] This is a case for the application of art. 131 CC which stipulates the nullity of expression of will in such circumstances. See generally on the problem of "irrational" decisions by patients capable to consent and on the mental faculties, which are critical for consent (*Elliot, 2001*).

Respectively, persons who are legally incompetent to consent may be physically fully capable of forming and expressing their will on matters concerning their health. We already mentioned the example of minors, especially from the beginning of adolescence; similar, however, is the situation of persons under legal guardianship (even full-fledged) whereas mild mental disorders or impairments do not by definition exclude the exercise of self-control over one's health.

In the case of minors, it would be more appropriate to recognize their capacity for self-consent after a certain age (thus precluding consent by the minor's legal representatives) for there is an objective presumption of sufficient maturity in contemporary societal life that can hardly be put in question (e.g. from the age 15 years). Meanwhile the assent of minors must be given considerable weight in relevant decisions, especially if coinciding with the physician's advice, even when the parents disagree.

For adults, it is difficult to assume a similar objective presumption. Therefore, the view of the concerned person must be given particular attention (as must the appropriateness of prior information) and evaluated on a case-by-case basis although the power of legal representatives to decide cannot be questioned.

The problem of advance directives is a much harder nut to crack. The event of becoming incompetent to consent often leads people to issue directions on how they wish to be treated ahead of time. These directions are usually addressed to close relatives or close friends, or even to the physician, if one is already ill. They are usually informal (oral and eventually with no witnesses) but some countries have provided a modality to safeguard the validity of their will ("living wills"). Usually, these directions are about the refusal of certain unpleasant or painful treatments (e.g. haemodialysis, cardiopulmonary resuscitation)[11] or even the interruption of artificial life support (e.g. refusal of feeding, hydration, etc.)[12].

Bearing in mind the fact that the law in our country is ambiguous[13] the question is what happens when a physician is aware of such directions and the legal

[11] The so-called DNR Orders («Do-Not-Resuscitate") are an example. To comply with these orders is to commit passive euthanasia.

[12] See Vidalis (2007), p. 113 *et seq.*, for a discussion of the issue and relevant literature.

[13] Under art. 9 of the Oviedo Convention, the physician must take such wishes "into consideration". However, there is no specific legislation on a typology of such wishes from which legal consequences may be inferred, especially as regards medical liability.

representatives of the patient, who by law are responsible to give their consent, disagree.

In ethical terms, it is certain that these directions must, in principle, be *communicated* to the patient's relatives in the context of prior information to them. If they still disagree after that, again the physician may *not* wholly disregard the patient's wishes. For insofar as there is a presumed *authentic manifestation* of the patient's autonomy - even if expressed ahead of time – the "substitute" consent of the patient's legal representatives appears weak. Indeed, the representatives in this case do not decide based on "what the patient would have wanted" (since he/she have already expressed their wishes) but based on what *they* believe is best for him/her or for anyone in their situation, something which is substantially far removed from respecting the principle of autonomy even if under different circumstances it might be the only choice.

In legal terms, the physician may not challenge the power of the legal representatives to decide. But the physician has a moral duty to discuss the patient's wishes with them in an effort to even out disagreements independently of his/her own view about therapy. Nevertheless, if the physician agrees with the patient's directions, he/she may give up treating the patient and let another physician take charge[14].

It is worth noting that the above will remain effective even if special legislation is eventually enacted on the validity of advance directives which will mean that "informal" directions will not generate legal effects for the physician or for the legal representatives of the patient. And this because, apart from the fact that people may freely express their wishes on the future management of issues regarding their health at any time – i.e. without observing some official "form" – it must be stressed that what is at issue here is not medical liability but the physician's moral duty. Thus, even though physicians will be legally bound to comply with "formally" manifested directions only, in ethical terms, they may not disregard any directions that were expressed informally by the patient.

[14] Cf. arts . 2(5), 9(4) CME which leave room for such an attitude on the part of a physician.

7. The health system

The health system determines the quality of provided services and has a decisive impact on the model of relationship developed between the patient and the patient's physician. The primary objective is the optimal use of human resources and material assets to meet the needs of citizens whose contributions finance the system's operation. The operation of the health system is not, at first sight, directly connected with consent in the relationship patient-physician. However, we will provide some information the Commission might find useful in order to decide whether to consider issuing an opinion on the subject.

In 2000, in the context of a worldwide evaluation of health systems, the World Health Organization (WHO) used "responsibility" as the basic benchmark (World Health Organization, 2000; Hartzband and Groopman, 2009). This criterion encompasses respect for the dignity of persons and their families, and the protection of their autonomy when making decisions about their health. Thus, the WHO places patient autonomy and medical humanism at the heart of health systems.

Apart from customizing medical care according to the needs and preferences of individual persons, another international trend in medical practice directly linked to the objectives of health systems is "evidence-based medicine" (Timmermans *et al.*, 2005). Evidence-based medicine is the "conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients" (Sackett *et al.*, 1996). Implementing this type of medical practice requires active medical societies in all specialties to assist physicians by developing specific guidelines.

At first glance, evidence-based medicine does not seem to oppose a concept of medicine that places the individual at its core insofar as the guidelines are meant to orientate decisions towards the best scientific treatment for a particular patient and a particular disease and not to impose specific treatments or restrictions. In some of the countries where evidence-based medicine is practiced, however, its operation seems sometimes to restrict medical practice since the guidelines are mandatory and, in some cases, physicians are not able to disregard them even when they believe it would be best for their patients.

By contrast, no such guidelines or restrictions have been established in our country. This omission may lead to inadequate treatments in light of the latest scientific

discoveries and, eventually, to a waste of resources. *A fair and effective use of the specific and limited resources of health systems is a fundamental request of great urgency in our country*. The foundations for an optimal implementation of evidence-based medicine while respecting individual autonomy may be laid by capitalizing on international experience and analysing the advantages and the problems observed in other health systems.

D. EPILOGUE

Patient autonomy is a fundamental issue in bioethics. It was, in fact, instrumental – beginning with the study of the ethics of clinical trials – for the development of bioethics as an independent subject-matter of Ethics. The aim of the present report was to give a summary account of how patient autonomy is ensured in medical practice today and to identify the main problems with its application emphasizing those more relevant to Greece.

As demonstrated in the preceding chapters, the physician-patient relationship is cardinal for safeguarding autonomy. In recent decades, this relationship has been changing, passing from the traditional paternalistic model whereby the physician is primarily responsible to decide what best serves the patient's interest and to act accordingly to a new model, the model of informed consent whereby the physician and the patient are called upon to engage together in the making of medical decisions.

In medical practice, respect for autonomy aims at the best possible application of modern medicine but in a way that respects the patient's needs and wishes. The complexity of modern medicine and, more often than not, the uncertain borders of "what" constitute treatment challenge the theory that the "doctor knows better" and create a need for new relationships requiring cooperation and participation by both "parties" in order to reach the best possible outcome.

On the other hand, patient information is indispensable for developing such a relationship of cooperation between physician-patient; once again, however, the boundaries of appropriate information are often blurred. One of the major problems

with implementing autonomy in medical practice is the divergence of opinion as implied by empirical data between physicians and patients on the extent of information. In their majority, the latter would rather have more information than the former provide.

The most important causes – according to the view of the authors of the present report – for this divergence of opinion between physicians and patients were identified and discussed in the previous chapters. Primary among them are the lack of appropriate training for physicians and the lack of time. It is important to look for practical solutions to implement respect for patient autonomy in practice not only as a value in itself but also as a safety valve for the efficiency of health services.

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