NATIONAL BIOETHICS COMMISSION

OPINION

CONSENT IN THE PATIENT-PHYSICIAN RELATIONSHIP

The National Bioethics Commission considered the scope of personal autonomy in the provision of medical care in repeated meetings. The issue arises in regard to all medical acts either preventive or therapeutic. Furthermore, it lies at the heart of a contemporary reflection in bioethics as the model of the so-called "paternalistic" medicine tends to be replaced world-wide by the model of "informed consent".

Having considered the modified approach to the patient-physician relationship, brought about by this change, and conscious of the wide scope of autonomy, the Commission highlights a number of typical problems and suggests solutions to address them.

I. In general

A. Paternalism and autonomy in medicine

The ethics governing the relationship patient-physician has been going through a change of model since the second half of the XX Century. Traditionally, this relationship was defined by the dominant position of the physician as the only responsible to appraise the situation and to decide on the course of treatment. Patients were merely able to select the treating physician; as for the rest, they had to rely on the latter's knowledge and skills without any say in therapy. This absolute dominion of physicians did not imply any form of arbitrariness on their part since they pledged themselves through the Hippocratic Oath to act in the best interests of patients.

Following the end of World War II – and spurred by the dismal experience of the experiments performed on the prisoners of the Nazi regime among others – this model of medical "self-commitment" was seriously questioned. It was realized that self-commitment on the part of physicians does not ensure the protection of patients. It became obvious that the participation of patients themselves in the course of treatment as active agents at all stages is the best guarantee for their well-being.

But first and foremost, the development of medicine itself has made the active involvement of patients a practical necessity in view of the fragmentation in the provision of health services brought about by increasing medical specialization and the broad introduction of new technologies that multiply possible alternative treatments.

It is almost certain that no treatment is free of adverse effects. Therefore, the classical principle of “doing good or not doing harm” is no longer sufficient to determine treatment. Patients need to be involved to determine the treatment whose likely adverse effects are more acceptable to them. Especially in our country, the need for this involvement becomes all the more urgent due to the absence, until now, of a single registration system to record the complete history of patients which deprives physicians from unmediated access to consistent and reliable data.

The adoption of “informed consent” presupposes that patients are informed by physicians and in principle, they consent prior to all medical acts. In this way, they can consider their condition in the context of their general way of living not as passive recipients but as independent agents who are involved in the whole process as much as possible. A good knowledge of the values and needs a patient would like the physician to take into account when determining treatment is an essential part of this process. It is worth noting that the requirement of participation is complied with even when patients express the wish to follow the suggested treatment without further information (*right- not- to- know*).

B. The law

Initially, the new model of “informed consent” appeared in codes of ethics on clinical trials (Nuremberg Code, Helsinki Declaration) because, on this occasion, the risks for the volunteers are greater. Gradually, however, its effects were recognized in all areas of medical practice.

The Oviedo Convention on Human Rights and Biomedicine is the first example of binding international law incorporating “informed consent” in all medical acts. In addition to the Convention, express provisions in Greece have been included both in the Code of Medical Ethics (CME – Act 3418/2005) and in special legislation (assisted reproduction, transplants, etc).

Both the Oviedo Convention and the CME provide for the event of incompetence to consent (in which case consent is given by relatives after prior information) whereas they hold that consent does not apply in emergency situations. However, the example of the CME stipulating that: *"In the exercise of medicine, physicians act with total freedom within the generally accepted rules and methods of medical science… They may choose the method of treatment which in their view is significantly better against all others for the particular patient based on modern rules of medical science…"*[1], demonstrates that the traditional model of the patient-physician relationship has not been fully abandoned in Greece as it has in other jurisdictions.

II. Implementation of autonomy and related proposals

A. The problem in general

Although the need for active involvement of patients in determining treatment is now widely acknowledged, it is often defeated in medical practice. The main reasons for this failure are the following:

- Limited time for communication between physician and patient,
- Lack of clarity on the appropriate extent of information,
- Deficient training of physicians on the relationships they need to develop with patients, and,
- Occasionally, lack of familiarization of the general public with the rights and possibilities of every user of health services to cooperate with physicians in order to reach the result best suited for the patient's way of living.

a) Time

Scarcity of time is, at first sight, a purely practical matter arising mostly in first aid and emergency situations.

The Commission thinks that, even in these circumstances, understanding the needs of patients and exercise of autonomy should be considered as an integral part of medical acts so that the allocation of the available time – even if limited – can be adjusted accordingly insofar as full communication with the patient is possible.

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[1] Art. 3 (3).

b) Extent of information

Pursuant to the CME "*the physician has a duty of truth to the patient*"[2]. But the patient has the *right to refuse information (right –not- to- know)* and *ask the physician to inform exclusively one or more other persons to be indicated by the patient.*[3]

But the extent of information that qualifies as appropriate to enable the patient to decide freely remains unclear. As the available empirical data indicates[4], the majority of patients in our country apparently want more extensive and more sincere information compared to what some physicians currently provide or believe they have to provide.

The Commission points out that:

i) Unless the right- not- to- know is invoked, the physician must provide all those elements that will enable the patient to form a full and, mainly, an intelligible picture of the situation so that he/she may be assisted in making a decision. Elementary information alone will not do. In any case, the information must be appropriate and graduated according to the mental condition of the patient. Given that the "appropriateness" of information is necessarily associated with the peculiarities of each patient, dialogue between patient and physician is indispensable.

ii) The information must not be "neutral". A mere description by the physician of the expected benefits and likely risks from treatment is not enough. An essential part of the information consists in an *ad hoc* evaluation of benefits/risks based on the particular patient. But this evaluation may not anticipate the final decision manipulating the will of the patient.

iii) It is usual practice to conceal information from patients and disclose it to relatives either because the treating physician is afraid the information may disturb the patient's psychological balance during therapy or because relatives request it. However, if the patient is capable to consent, this practice disrupts the fundamental

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[2] Art. 11 (1) (a).

[3] See art. 11(2).

[4] For a summary of this data, see the accompanying report.

connection between information and consent and may cause confusion. This is not to underestimate the need of cooperation between physicians and families, especially in order to understand the personality and needs of patients.

c) Training for physicians

Appropriate training on the importance of autonomy for physicians and other health care professionals is a crucial problem.

Physicians often view the procedure of consent as a piece of bureaucracy leading them to treat it as a mere formality. Contrary to this practice, consent is not to be considered as a safeguard for the protection of physicians but as a token of respect for the patient's autonomy. However, even when physicians are conscious of the need to respect patient autonomy, they feel uncertain on how they should act, since perceptions of autonomy vary from patient to patient and from physician to physician.

Developing relationships of cooperation and trust with patients requires appropriate education for physicians. The aim is not some "formal" accommodation of the patient's rights but to obtain the best outcome in dealing with health problems taking into account the values and overall way of living of patients. Seen in this light, the participation of patients in their treatment, far from being an impediment, helps to reach the best possible medical outcome.

In view of the above the Commission thinks that emphasis needs to be placed on ethics and its implementation in clinical practice both in university education and in ongoing training for physicians. Equally important is to ensure meaningful education in communication with patients for physicians of all specialties focusing on the benefits of honesty. Lifelong training of physicians on the subject matter is also required (a relevant duty is stipulated by the CME). Hospital ethics committees, scientific societies and medical associations must arise to the task and take the initiative.

d) Education and information for citizens

The above points out a need for appropriate citizen education aiming at the optimal application of the new model. Patients who are suitably informed "ahead of time" are more likely to cooperate actively, assisting physicians in their work and enhancing the efficacy of treatment.

Citizen education can be promoted through elementary education, information campaigns by local authorities, local associations, regional hospitals and volunteer organizations. Educational programs from the media under the hospices of the Ministries for Health and Education could also be of assistance.

B. Particular problems

a) Power to consent and limits of autonomy

The Commission believes that when patients who are capable to consent are committed to hospital they should appoint a representative in writing, if possible.

In case of patients incapable to consent who have not appointed a representative, the Commission thinks that:

i) The legal representatives of the patient may select one of alternative treatment methods but may not refuse all treatments if the treating physician believes that the continuation of therapy is beneficial. Only patients who are capable for self-consent may refuse treatment.

ii) In case of disagreement between the legal representatives, the treating physician should be able to decide taking into account the opinion of the hospital ethics committees, an institution that must be made mandatory in our country.

iii) The physician must take into consideration any prior wishes of patient (*id est*, any wishes the patient expressed prior to becoming incapable to consent).

iv) The opinion of mentally mature minors on issues regarding their health must be taken into account in order to comply with the constitutional protection of personality.

v) In case of refusal of parents to consent to the treatment of minors – and in case of threat against their lives or serious harm to their health – the physician must proceed to the indicated treatment complying with the legal procedure.

vi) In case of patients with limited capacity to consent (minors, mental patients, persons with mental disability), the attitude of the physician must consist in favoring as much as possible the expression of an opinion by the patients themselves according to the level of their capacity to comprehend their situation. Therefore, the information to be provided to the patient must be adjusted accordingly in cooperation with the legal representatives.

vii) The Commission believes that, even under the circumstances of intensive care units, physicians must not act alone ignoring the will of the patient. On the contrary, the physician's moral duty is to ensure the free expression of the patient's will by providing complete, timely and intelligible information whenever feasible.

b) Right of physician to refuse treatment

The Commission points out that physicians reserve the right to refuse a treatment which is not medically indicated in their view, even if the patient insists upon it.

Athens, March 2010
The Chairman, the Deputy Chairman and the Members
of the National Bioethics Commission

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