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Medical Decision and Consent – A Review

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ABSTRACT

In medical care delivery, patient involvement, information and consent are connected with decisions to act, i.e., to examine the patient, to prescribe drugs, to undertake diagnostic or surgical intervention or to provide mechanical ventilation. However, a medical decision is not necessarily a decision to intervene. It may also imply withholding an intervention or discontinuing it. It is obvious, that such a decision may affect the interests of the patients at the beginning or during the continuation of an intervention. At the same time, this kind of decision can very easily remain hidden or be implicit. In particular it entails a complete withholdment of the treatment. This article addresses the question as to what extent the rights to information and consent should equally apply to non-treatment decisions. It encompasses all medical decisions: to initiate, not to initiate or to stop a medical intervention.

Key words: Treatment, consent

INFORMATION AND CONSENT

The rights to information and consent are considered as the patient's most important tools to participate in medical decision-making. Over the last decades, the right to informed consent has generally been accepted as a basic principle, at least at the international level, and to a large degree at the national level also. As to the international documents, reference can be made for instance to the Convention on Human Rights and Biomedicine and the WHO Declaration on the promotion of patient's rights in Europe. In the last years there have been quite a few publications based on empirical data questioning the effectiveness of informed consent. They show that "true" informed consent may sometimes be difficult to achieve. That calls for an effort to improve the communication process. It does not invalidate the principle of informed consent. The patient does not have a duty to receive information and to make his own decisions. What that principle requires is that the health care provider enables the patient to do so as to follow the four principles of medical ethics namely autonomy, justice, beneficence and non-maleficence.

The right to consent encompasses the right to refuse a medical intervention. The

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fact that a patient's previous consent must be obtained also implies that his opinion and preferences should be taken into account as to the way the intervention is to take place. Furthermore, in principle, consent may be withdrawn at any time. If a patient is incompetent, a proxy or other representative of the patient should be enabled to give or to refuse consent on behalf of the patient (1).

According to the accepted doctrine, consent is only valid if it is free and voluntary. The decision of the patient should – as far as reasonably possible given his often dependent and vulnerable position – be free from constraints.

This does not mean that there is no room for medical advice, but the physician should respect the patient as a person with his or her own values.

There seems to be a general agreement that valued informed consent presupposes adequate information. This point is further elaborated in many national and international documents, including guidelines and codes of conduct of medical associations. As an example I refer to the WHO Declaration on the promotion of patients' rights to Europe, which states that *"patients have the right to be fully informed about their health status including the medical facts about their condition; about the proposed medical procedures, together with the potential risks and benefits of each procedure; about alternatives to the proposed procedures, including the effect of non-treatment, and about the diagnosis, prognosis and progress of treatment."* The principle of informed consent may be subject to limitations. This holds not only for the right to consent but also for the right to information. A traditional, and generally accepted exception of the right to information, is the so-called therapeutic privilege. In recent documents this exception is defined narrowly, to avoid the risk that it would "swallow the rule". The WHO Declaration, for instance, states that information may only be withheld from patients exceptionally when there is good reason to believe that this information would cause them serious harm.

As far as limits to the duty of disclosure are concerned, I refer also to the right of the patient not to be informed at his explicit request, brought about by the emergence of modern genetics and other forms of predictive medicine like recently the Indian parliament passed the Prenatal Diagnostic Technique Act 1994 which prohibits disclosure of prenatal findings related with sex of the foetus to the patient. It is generally acknowledged, that this right is again absolute, and may give way to important other concerns in a situation of conflicting interests.

Summary of what can be considered the accepted rules of consent, I have drawn most of all upon international documents. If one looks at the ways the right to informed consent has been elaborated in national law, there are many, and sometimes considerable differences between countries, not only concerning the way the right to informed consent as embodied in the law (e.g., in Indian contract law or other domains of law, statute law or court decisions), but also concerning for instance the standard of disclosure, the exceptions etc.

To some extent, personal involvement of the patient in medical decision-making

can be considered a basic requirement of good medicine: apart from the fiduciary relationship between doctor and patient information and participation are likely to render the patient better motivated and cooperative. But the underlying rationale for consent goes beyond these practical considerations. Nowadays, first of all respect for human dignity and the principle of autonomy or self-determination are seen as the basis for informed consent. This is in line with what I have identified as the main function of the right to consent: to enable the patient to participate in decisions affecting him or her.

If in the law informed consent is only required before a medical intervention is carried out, in fact only one, be it important aspect of patient participation in medical decision-making (i.e., the possibility to refuse the intervention after adequate information has been provided) has the status of a legal obligation for the physician. This creates the risk that in other situations involving the patient may be left at the discretion of the health professional, or that it may be considered only a matter of good practice, and not necessarily a legal duty.

One may wonder why patient participation in medical decisions has so often been incorporated in such a limited way into the law. One explanation may be that traditionally, at least in common law jurisdictions, the unlawful performance of a medical procedure was dealt with by the law of batter, i.e., the unauthorised intentional touching of another person. In our country it is dealt under Indian Penal Code and is regarded as a criminal offence. Although nowadays the emphasis is rather placed on the broader concept of negligence, the discussion about informed consent would still see very much preoccupied with medical acts as a potential invasion of the body. Consent is then essential to justify such an invasion, necessary to uphold the patient's right to physical integrity.

More important in the context of this paper, however, is the fact that connecting informed consent primarily to bodily or physical integrity, obscures the importance of medical decisions not to carry out an intervention or to discontinue it. In such decisions, serious and sometimes even vital interests of the person concerned may be at stake. In that case, the principle of self-determination and the fiduciary relationship between doctor and patient "may be undermined more dramatically when treatment is covertly withheld than when it is administered without proper consent". While invasive acts need to be justified and require previous involvement of the patient in terms of information and consent, basically the same can be said about decisions not to intervene, at least when they affect the patient's interests. Also in case of non-treatment decisions, self-determination and shared decision-making should be taken seriously: where the consequences of such decisions make this appropriate, they should be made explicit so as to enable to patient to be involved with them (2).

Withholding consent for treatment

For this purpose, it is useful to make a distinction between two kinds of clinical reasons for these non-treatment decisions. First of all, with regard to a particular patient an intervention which in other cases may be

effective, may not be expected to have a demonstrable effect. Secondly, an intervention may be considered to be of no net benefit to the patient in question. In the latter case, it is not the lack of effectiveness, but the lack of proportionality (in terms of burden and benefit for the patient concerned) which makes the intervention futile. A decision not to resuscitate a patient in the event of a cardiac or respiratory arrest may then be taken either because such an intervention is expected to be unsuccessful, or because – taking into account the overall medical situation of the patient – it would not seem to serve a reasonable purpose.

Let me first give some facts from a study on 'do not resuscitate [DNR]' orders in Dutch hospitals (3). This study reveals that DNR decisions are made in six percent of all hospital admissions in the Netherlands, and that 61 percent of all in-hospital deaths were preceded by a DNR decision. Patient involvement with these decisions appears to be very limited. The decision was discussed with the patient in 14 percent of all cases only. Of the 86 percent cases in whom DNR was not discussed, 56 percent patients were incompetent and 30 percent were competent. As to this latter group, in more than half of these cases the physician stated in one way or another that this discussion would be too burdensome for the patient, thus invoking the therapeutic privilege. As to patients who were incompetent, the family was only consulted in 37 percent of all cases.

The authors stress the point that in cases without patient (or family) involvement, the reasons for the DNR decision quite often went beyond determining the effectiveness of resuscitation, and included value judgements on the proportionality of the intervention. They conclude that "these value judgements should not be made behind a veil of objectivity, leaving patients and families in ignorance".

There is no reason to assume, that the practice in other countries will be completely different from that in Netherlands. The question then is, to what extent the apparently prevailing practices of not involving patients or their families with non-resuscitation decisions is reflected in the ethical and legal literature. On the whole, the literature is more supportive of information, consultation and even consent.

This holds already for the question as to whether the patient should be informed about an [envisaged] DNR order, in particular if resuscitation is not likely to be effective. According to Bruce-Jones, "The right to information about treatment options surely encompasses only those relevant to the clinical situation, and consideration of cardiopulmonary resuscitation is not relevant when the chances of survival are negligible." To claim otherwise, could result in a call for universal discussion of other treatments with little chance of success.

There is no unanimity, however, as to what such a discussion with the patient includes. According to some authorities, to make a judgement about the balance of the harms and benefits of attempted resuscitation for the patient should remain with the physician. The mere fact that value judgements play a role, would not necessarily imply that the consent of the patient should be sought for the decision: if physicians

have any rightful control over the interventions they offer to patients, it is only because they have the authority to act on judgements of value (2).

Some authors even warn against an exception to informed consent based on medical futility (4). According to Miller (5), as long as physicians are still reluctant to speak with patients about resuscitation, any exception on therapeutic or futility grounds is almost certain to be the escape hatch for physicians seeking to avoid conversations they have never understood as integral to the obligation to care for dying patients. Scofield(6) puts it even stronger: "The futility exception's suggestion of presumed consent will likely swallow the rule of actual consent in decisions to limit resuscitation, thereby enabling the medical profession to rein itself unilaterally and unaccountably".

CONCLUSION

If patient involvement is necessary, it means that in general at least the minimum level of involvement, i.e., being informed about the decision, is required. This also holds if no demonstrable effect can be expected from the treatment in question. In the Dutch literature on the subject, the view is expressed that if the patient is competent, he should be informed of such a decision and supported to cope with it; the physician should explain and if necessary-justify his decision; he should enable the patient to informed resignation or acquiescence. The patient's consent is not necessary in this case. If the intervention will have no effect at all, the physician will not even be entitled to carry it out. Still the patient should be informed. In addition to the reasons mentioned before, the patient may also have a personal interest to know, for instance he may want time to arrange his affairs if death is imminent (7).

If the intervention may have an effect, the patient should at least be consulted, i.e., the decision should be discussed with him. This is in line with the guidelines developed by the Appleton International Conference: "Where a doctor considers a life prolonging treatment not to be physiologically futile, but nonetheless 'futile' in another sense of the word because of the low probability of success or because of the low quality of life that would remain, then discussions about the withholding or withdrawal of such treatments should be made in the context of full and open discussion of the nature and extent of the 'futility' of the treatment with the patient or the patient's representative" (8).

Is consent to the decision required? As set out in the preceding section, some would say yes. In our view, a distinction should be made between situations in which a universal medical opinion exists that a certain intervention, although effective in physiological terms is futile in terms of the net benefit or proportionality, and other situations in which there is no predominant medical standard and the benefit of an intervention is open to doubt. An example of the first is resuscitation of a patient in a persistent vegetative state, an example of the second is the same intervention in an elderly patient who is severely ill and disabled, but may still live for several months if the intervention is successful.

If there is wide agreement that treatment is not medically indicated, the physician should still have the discretion to honour the demand of an-insisting patient, iftaking all circumstances into account - he feels that there are particular reasons to do so (for instance, a patient may have a personal non-medical interest to live a few days longer). However, he should not be obliged to do so and be allowed - after discussing his envisaged decision with the patient - to refrain from intervening, even if the patient would request otherwise. Therefore, in the final analysis, informed consent for the [non-treatment] decision would not be required. A doctor should not be forced to embark on an intervention which, according to the professional standard, would serve no reasonable purpose. If it is a medical duty to benefit the patient and not to do harm, and if – furthermore – society expects from physicians that they provide only appropriate care (and not care which is not medically indicated), at least to some extent doctors must be allowed to make unilateral value judgements and to act upon those judgements, like certification of brain stem death as per Transplantation of Human Organs Act 1994 passed by Indian Parliament which provides the power to the treating physician to refuse the patient to be kept on a ventilator.

This situation is different if there is no prevailing body of medical opinion against a particular intervention in a specific situation. In case of doubt, unilateral decision-making is not justified. If the clinician's judgement is not backed by the profession and has more the character of a personal decision, it should not be imposed, however careful it is made, and the patient should be enabled to an informed refusal of the non treatment option, and be allowed to make another choice.

To the extent that information and consent are required with respect to non treatment decisions, the general rules concerning informed consent apply. The information provided should be adequate, i.e., the patient should not only be informed about the [envisaged] decision itself, but also about the effects of non-treatment and about alternative options. In exceptional circumstances, when there is good reason to believe that the information would cause serious harm, the therapeutic privilege may be invoked. Information may also be withheld, if the patient has expressed a clear preference not to be informed.

When the patient is incompetent, the relevant information should be offered to, and consultation should take place with his representative [appointed by the patients or designated by the law]. The same holds for obtaining consent. In giving substitute consent, the representative should take into account what is known, and to the greatest extent possible, what may be presumed about the wishes of the patient.

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