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Patient Involvement with Non Treatment Decisions

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1. Introduction

Patient involvement with medical decisions is closely related to information and consent. Informed consent is the main instrument to achieve such involvement, and enabling participation in medical decisions is the most important function informed consent is supposed to fulfil.

Usually, patient involvement, information and consent are discussed in connection with decisions to act, i.e. to examine the patient, to prescribe drugs, to provide mechanical ventilation or artificial feeding etc. 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 as much affect the interests of the patient as the beginning or the continuation of an intervention. At the same time, this kind of decision can very easily remain hidden or implicit, in particular if it entails a complete withholdment of the treatment.

This article addresses the question to what extent the rights to information and consent should equally apply to non treatment decisions. The latter concept is taken in a broad sense: it encompasses all medical decisions not to initiate or to stop an intervention. The argument is not about making a choice between more or less comparable alternatives (a doctor very often has to weigh the merits of different options and to decide to do one thing rather than another), but about withholding or discontinuing a particular intervention without replacing it by a comparable one. I will not deal with situations in which the patient takes the initiative for a non treatment decision, but focus on situations in which the physician envisages to refrain from treatment or to withdraw it.

Non treatment decisions may be taken for very different reasons. Basically, a distinction can be made between clinical or medical considerations (relating to the expected effect of the intervention and the benefit of that effect for the patient), and other considerations. The latter may include personal motives

not to provide care (for instance, conscientious objections), and situations in which non treatment decisions are based on the availability of care, the lack of resources or financial constraints. This article deals with non treatment decisions on clinical grounds.

In the following sections, I will first discuss informed consent as a means to involve patients with medical decisions. Subsequently, a brief survey will be given of how one of the most conspicuous types of non treatment decisions — do-not-resuscitate orders — are dealt with in the literature. In the last section, I will address the question how the rights of information and consent should apply to non treatment decisions in general. In answering that question, the concept of medical futility will play an important role.

2. Patient involvement with medical decisions

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 also at the national one. As to the international documents, reference can be made for instance to the Convention on Human Rights and Biomedicine (adopted by the Committee of Ministers of the Council of Europe in November 1996) and the WIIO Declaration on the promotion of patients' rights in Europe (adopted at the European Consultation on the Rights of Patients, Amsterdam 1994).

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 efforts 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 care provider enables the patient to do so.

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

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 valid 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 in 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 as such (for instance in connection with involuntary commitment to mental hospitals), 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. It is generally acknowledged, that this right is again not absolute, and may give way to important other concerns in a situation of conflicting interests (for instance when the safety and health of other persons would be at serious and immediate risk if information would be withheld from the patient).

Consent need not be explicit (verbal or written), it can also be implied. According to the Explanatory Report to the aforementioned Convention of the Council of Europe, which form of consent is required will largely depend on the nature of the intervention:

"... express consent would be inappropriate as regards many routine medical acts. The consent may therefore be implicit, as long as the patient is sufficiently informed. In some cases, however, e.g. invasive diagnostic acts or treatments, express consent may be required."

In this brief summary of what can be considered the accepted rules of (informed) 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 is embodied in the law (e.g. in contract law or other domains of law, statute law or court decisions), but also concerning for instance the standard of disclosure, the exceptions etc.¹

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 (which would not survive without a minimum of openness), information and participation are likely to render the patient better motivated and cooperative. But the underlying rationale for (informed) 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.

Nevertheless, in much of the literature, in statements of international organisations and in many national legal documents, informed consent is not related to the concept of 'medical decisions', but to the narrower concept of 'interventions' or even 'treatment'. See for instance Section 5 of the aforementioned Convention on Human Rights and Biomedicine, which reads: "An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it."² According to the WHO Declaration, "the informed consent of the patient is a prerequisite for any medical intervention" (Section 3.1). As to national documents, I refer to the recent Dutch Act on the Medical Contract (entered into force in 1995), which states that the patient's consent shall always be required for activities in pursuance of a medical contract.³

Sometimes a wider concept of patient involvement is incorporated in documents concerning the rights of the patient. Examples are the French Charter of the rights of hospitalised patients (1995) which states that "the patient participates in the therapeutical decisions concerning him"⁴, the Finnish Law on patient's rights (1993) which lays down the right to self-determination⁵ and requires a "mutual understanding" between patient and care-giver⁵, and the Spanish General Law on health (1986) which in addition to a right to refuse treatment explicitly acknowledges "the right to free choice among the options presented by the physician"⁶. In some other documents, at least the right to information is given a wider scope (see e.g. the above quoted WHO Declaration which also requires information on "the effect of non treatment" and the Dutch Act on the Medical Contract).

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 an 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 'battery', i.e. the unauthorised, intentional touching of another person. Although nowadays the emphasis is rather placed on the broader concept of negligence, the discussion about informed consent would still seem very much preoccupied with medical acts as a potential invasion of the body. Consent is then essential to justify such an invasion, and necessary to uphold the patient's right to physical integrity. For several reasons this approach is too restrictive.

First of all, medical interventions always also engender information on the health status of the patient. This holds not only for diagnostic acts, but also for treatment since the way the patient responds to it will yield (further) data on his health and on the prospects for recovery. In case of some medical acts, the integrity of the body may not even be at stake, for instance when new information is derived from examination of blood or tissues which are already available. The recent developments in medical diagnostics and the emergence of what has been called predictive or prospective medicine, make it increasingly relevant to perceive medicine (also) as a process of collecting information. In this perspective, the function of consent is always also — and sometimes even exclusively — to give the patient a say in which personal health information is brought into existence. Consent is then the basic instrument to exercise the right to know or not to know about one's health. The nature of medical acts as a source of personal health information underlines that the basis of informed consent in medical decisions is not only to be found in the right to decide on one's own body, but rather in the more encompassing principles of self-determination and respect for the human person.

More important in the context of this paper, however, is the fact that connecting informed consent primarily (or even exclusively) 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".⁸ 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.

3. Non treatment decisions: do -not - resuscitate orders as an example

Do - not - resuscitate orders are an interesting category of non treatment decisions. Because it has to be decided upon in advance and needs to be entered in the medical chart of the patient, such a decision has by definition an explicit character. It is not by chance, therefore, that to the extent that non treatment decisions are being discussed in the literature, it is mostly non-resuscitation decisions which are dealt with. What can the debate on such decisions learn us about patient involvement?

For this purpose, it is useful to make a distinction between two kinds of clinical reasons for these (and other) 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.⁹ 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 DNR orders in Dutch hospitals.¹⁰ 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.¹¹ The 86 percent of cases in which DNR was not discussed, include 56 percent in which patients were incompetent and 30 percent in which they 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 incompetent patients, 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 the Netherlands. The question then is, to what extent the apparently prevailing practice 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, than the aforementioned data suggest. This being said, it must be noted that there is considerable disagreement on how and to what extent patients or their representatives should be enabled to participate in decisions on resuscitation.

This holds already for the question as to whether the patient should be informed about an (envisaged) do-not-resuscitate 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 call¹² for universal discussion of other treatments with little chance of success.

While other authors agree that in such a situation the clinician's judgement may be decisive and a do-not-resuscitate order a unilateral medical decision, most of them still hold the opinion, that the patient (or his surrogate) should at least be informed. According to Youngner, for instance, "once physicians have determined that cardiopulmonary resuscitation is futile and will not be performed, they should so inform patient and families."¹³ Others, while accepting the policy of informing patients in principle, emphasize that it should be applied in a careful way, allowing for exceptions when a patient does not seem capable of coping with the realities of his situation, and discussion of the decision with the patient would be painful and only lead to psychological distress and anxiety.¹⁴

As to the grounds for openness towards the patient, in the literature reference

is made to the fact that respect for human dignity and the fiduciary relationship between doctor and patient require truth-telling. Furthermore, information would be necessary to achieve understanding and acceptance: discussions about the futility of resuscitation may provide just the opportunity to help patients and families to cope better with the inevitability of impending death.¹⁵

If resuscitation is not futile in the strict sense of being non-effective, but the decision to refrain from it is rather based on value judgements concerning its proportionality, the patient has a direct interest in being enabled to express his own views on his situation. In that case, the opinion that the decision should at least be discussed with the patient (or his family if he is incompetent) seems to prevail.

There is no unanimity, however, as to what such a discussion with the patient includes. According to some authors, the authority 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 judgments 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, thus Tomlinson and Brody.¹⁶ In brief: there should be consultation with patient or family, but not in the context of the consent process. See also Tomlinson and Czlonka:

“Adamant demands for futile resuscitation are less likely when the goal of discussion is not to have the patient or the family make a choice, but rather to gain their understanding and acceptance of the choice already made and presented by the physician against attempting resuscitation.”¹⁷

Others are of the opinion, that clinicians' judgements cannot be decisive, if they are about the benefit of an intervention for the patient rather than about its effect.¹⁸ In that case, in the last resort the opinion of the patient should take precedence. In this sense also the American President's Commission can be read: “When cardiac arrest is likely, a patient ... should usually be informed and offered the chance specifically to decide for or against resuscitation.”¹⁹

Some authors even warn against an exception to informed consent based on medical futility. According to Miller, 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.²⁰ Scofield 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.”²¹

4. Non treatment decisions: information and consent

In the preceding section, I have briefly referred to the grounds for patient involvement with non resuscitation decisions which are mentioned in the literature: the need to achieve understanding and acceptance if the intervention is considered futile in the strict sense, and to take the views of the patient into account when value judgements play a role. In my opinion, the same grounds are relevant with respect to medical decisions concerning refraining from treatment more generally. Furthermore, irrespective of the clinical reason for withholding an intervention, respect for the patient as a person would already for its own sake call for openness and communication whenever possible.

This holds also for the trust placed by the patient in the hands of the physician. By taking a patient in his care, the physician raises certain expectations: the patient will expect to receive the care which is generally provided to patients of the same category. When withholding care would result in the death of the patient, also the traditional presumption in favour of preserving life could be called upon by the patient as a basis for his expectations. If for clinical reasons the doctor decides contrary to those expectations, the patient is entitled to be advised on that decision. The same applies when the care giver has already started treatment or another intervention. According to Eser, by beginning treatment the physician is placed in the so-called role of 'guarantor' with respect to the patient, and cannot simply stop treatment on his own account.²²

If patient involvement is necessary, that means that in general at least the minimum level of involvement, i.e. being informed about the decision, is required. This holds also if no demonstrable effect can be expected from the treatment in question. In the (scarce) 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 it²³; the physician should explain and — if necessary — justify his decision²⁴; he should enable the patient to informed resignation or acquiescence.²⁵ 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.

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."²⁶

Is consent to the decision required? As set out in the preceding section, some would say yes (because when it comes to value judgments the patient is to decide) and others no (since even if values play a role, deciding on futility is still a medical task). In my view, a distinction should be made between situations in which a universal (or at least widely accepted) medical opinion exists that a certain intervention, although effective in physiological terms, is futile in terms of 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,²⁷ 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, if — taking 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 judgments and to act upon those judgments.

The 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 judgment 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.²⁸

To the extent that information and consent are required with respect to non treatment decisions, the general rules concerning informed consent apply (see the second section of this article). 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 (if available). 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 (and should) also be withheld, if the patient has expressed a clear preference not to be informed.

Discussion of the decision with the patient should be frank and open, and if his consent is required, the physician should see to it that it is voluntary and free from constraints. Consent may be implied if the decision has no major consequences for the patient, provided that he is sufficiently informed. It should not be presumed however, when the consequences of non treatment are significant.

When the patient is incompetent, the relevant information should be offered to, and consultation should take place with his representative (appointed by the patient himself 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.

How the duty to inform and to obtain consent in case of non treatment decisions is to be legally enforced, and in which case a physician will be liable under common or civil law, disciplinary law, or criminal law for not acting according to his obligations will — in the final analysis — of course depend on national law. Basically, patients (or their representatives) should be able to hold a doctor liable for non disclosure of a non treatment decision which has meaningful consequences for them. Just as in case of non disclosure of the risks of an intervention and the alternatives for it²², such a failure denies the patient the right to rational participation in his health care.

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