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COMMENTARY
On the paradoxes of informed consent: strictness with unlikely risks, tolerance with certain harm

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Abstract
The different approaches of two nations to the issues surrounding informed consent by persons with no or limited capacity of understanding are compared. It is important that efforts to ensure formal compliance with consent procedures should not be allowed to distract attention from the risks of harm to individuals.

Key words
- bioethics
- human experimentation
- legislation
- organ transplantation

Informed consent is a cornerstone of clinical practice [1] and biomedical research [2]. However, for various reasons some people may not be able to give properly valid informed consent: typical examples are children, persons suffering from neurological or psychiatric pathologies, elderly individuals with cognitive deficits, patients with unresponsive wakefulness syndrome (otherwise known as a "vegetative state") and other categories of persons generally referred to as "vulnerable subjects". The peculiar problems posed by each of these categories are heterogeneous: legal representation, the possibility to give consent and the validity of prior instructions are but a few [3]. Other problems may derive from external factors: for example, patients in institutions pose additional problems compared with those living in a domestic environment. Whenever possible, every effort is normally made to allow these subjects to make their wishes understood and to make the best possible use of their apparent feelings [4]. For example, it is recommended that careful attention be given to assent or dissent expressed by children when they are old enough to form at least a summary understanding of the circumstances [5].

Tests and scales have been developed to measure cognitive and decisional impairments, though these naturally cannot fully account for unquantifiable subjective factors [6], their applicability is limited and they are subject to intrinsic and methodological shortcomings. It is not easy to establish a threshold of competence beyond which consent can be considered to be valid. However, notwithstanding their limitations, these tools are useful in practice.

The question of informed consent looms large in ethical debates regarding who is or is not able properly to understand the issues at stake and make their feelings known [7]. Of the many considerations raised by this issue, two will be addressed here.

The first is recognition that the various solutions adopted range from the most restrictive to the most liberal, as can be seen by a comparison between the Italian regulations governing clinical trials and Belgian regulations regarding the removal of organs from living persons for purposes of transplantation.

In Italy Article 5 of Legislative Decree no. 211 of 24th June 2003 states that "Clinical trials on incapacitated adults not able to give informed legal consent (….) shall be allowed only if: (….) the informed consent of the legal representative has been obtained (….)" [8]. This restrictive approach prevents persons who are not legally represented from participating in any trials, regardless of the magnitude or probability of the risks they may incur.

According to the Belgian regulations regarding transplants (pursuant to Article 6, no. 2 of the Law of 13th June 1986 [9] as amended on 25th February 2007 [10]), if the removal of organs from a major living donor can have consequences for the donor or involves non-regenerative organs and the donor is unable to give informed consent by reason of his or her mental age, it is conditional on the obtaining of consent from the legal representative or other person designated by the patient or, if there is no such person or the person so designated does not wish to intervene, from a cohabiting spouse, a legally recognised or *de facto* domestic partner or, secondarily and in subsequent order, from a major child, a parent or a major sibling. In Belgium not only is it thus possible to remove organs from a living donor who is unable to give informed consent, but there is no absolute need to consult a legal representative: the consent of a relative is sufficient. In addition,

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organs may be removed not only when the risk for the incapacitated "donor" is small (it is known, for example, that the removal of a kidney often has no significant consequences [11]), but even when the "donor" is expected to suffer harm.

It is interesting to note not only the different approaches adopted by the two states regarding the acceptability of proxy consent, but also the different approach to the potential risks involved: the Italian veto also applies to clinical trials with minimum risk, while the Belgian consent is valid forthe removel of organs from living donors not only in optimal conditions but also when the donor may be expected to suffer fairly serious clinical effects.

Both the restrictive Italian and the more liberal Belgian regulations have raised concerns, obviously for different reasons.

In the case of Italy it has been pointed out that the regulations make clinical trials with incapacitated subjects virtually impossible, except in the (extremely rare) cases where a guardian or tutor has been legally appointed [12].

In the case of Belgium, the Belgian Comité Consultatif de Bioéthique has sharply criticised the law: "All the members of the Committee reject, from an ethical point of view, the current legal provisions concerning the removal of organs from living majors who are unable to give informed consent, given that such removal is permitted even when the donor is exposed to serious health risks" [13].

The second consideration proceeds directly from the first: without turning the spotlight away from the validity of the consent procedure, it would perhaps be appropriate to focus more on the magnitude of the risks involved.

Many trials involve only minimal risks, in which cases consent based on only partial information and awareness could be acceptable. When the risk is significant, however, the consent acceptability threshold must be raised and stricter criteria imposed, such as, for example, the need to involve a legally appointed representative.

In other words, while it is important to attempt to quantify the degree of awareness of the person, it is also necessary to assess the magnitude of the risks.

In deciding whether or not an intervention is acceptable the level of risk may be more important than the level of awareness. Instead, there is often a perception that the focus of attention on the quality of the patient's decisional processes distracts attention from the consequences of the decision. Careful consideration of the consequences of a decision does not necessarily mean adopting a consequentialist or utilitarian ethical stance: it is, instead, a due recognition of the complexity of the factors at stake and of the fact that the physical consequences for the persons involved may often be more important than formal compliance with the procedures.

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