

Organ transplantation from marginal and non-standard risk donors: ethical requisites for consent from recipients

Carlo Petrini

Unità di Bioetica, Presidenza, Istituto Superiore di Sanità, Rome, Italy

Abstract

In order to close the gap between available organs and patients needing transplants, the selection criteria for donors have gradually become more relaxed and many countries have defined expanded criteria for donor variables. However, the use of organs from marginal and non-standard risk donors poses considerable ethical issues. The acceptability of the risk/benefit ratio depends primarily on a clinical assessment, and information given to the recipient and his/her eventual consent are crucial. Some of the requisites concerning information and consent are mandatory. Once these requisites have been defined in binding regulations, adequate margins must be allowed for their personalisation and to account for the unique nature of each physician/patient relationship. Each decision should be specific for a particular person, and it must be accepted that similar clinical situations may give rise to differing solutions that are nonetheless agreed by the physician and the patient.

Key words

- ethics
- informed consent
- risk
- transplantation

INTRODUCTION

Against a background of a shortage of organs for transplantation, the expansion of the donor pool continues to be a priority.

The shortage of organs and the consequent imbalance between available organs and candidates for transplantation has led to a relaxation of donor selection criteria and the adoption of extended criteria allografts [1]. Expanded criteria allow the use, in specific circumstances, of poorer-quality organs. By expanding the criteria and using marginal donors – in other words, by accepting organs from individuals who might otherwise be considered unsuitable – a meaningful expansion of the pool of both deceased and living donors has been made possible.

The terms “marginal donor” and “expanded criteria donor” are often taken as being equivalent. In the specialist literature the former is used mainly when referring to living donors, while the latter refers mostly to deceased donors. Though the latter expression appears to prevail, there is as yet no agreement regarding the proper term, and other expressions, such as “donors with isolated medical abnormalities” [2] and “complex donors” [3] are also found. Generally speaking, all these terms refer to the quality of organs (from living or deceased donors), while the expression “non-standard risk donor” refers mostly to the risk of transmission of infections or malignancies to the recipient [4].

Several countries have adopted programmes to use organs from marginal and non-standard risk donors [5]: these have generally been well received, though criticism is not lacking. It has been pointed out that downstream strategies, which are not without risk, are, or may be, a direct result of a failure to implement upstream solutions: if sufficient “good” organs were available for transplantation it would not be necessary to use “less good” organs [6].

The use of organs for transplantation from marginal and non-standard risk donors poses problems to both the living donor and the recipient. The issues regarding consent given by living donors are addressed elsewhere [7]: the present article focuses on consent given by the recipient.

The question of using organs from marginal and non-standard risk donors is primarily a *clinical issue*. There is, obviously, no such thing as a zero-risk transplant: donor quality is more a continuum of risk than a choice between “good or bad”, and efforts to keep the risks to a minimum are always necessary. Where a donor is considered a standard risk, specific assessment criteria to identify the likelihood of transmitting an infectious and/or neoplastic pathology are not applied. Yet the very same criteria are used to identify factors that would represent such a high risk of transmitting serious diseases as to justify keeping the potential recipient on the waiting list. Within these two extremes is a grey area

that includes risks which are known to be present but which are not considered such as to preclude *a priori* the possibility of using organs for transplantation.

But the question of risk is also *an ethical issue*, though the ethical and clinical aspects are closely interwoven [8]. In order to save a patient's life or offer the possibility of an improved quality of life, is it permissible knowingly to put the patient at risk of contracting a communicable or neoplastic disease? The principle of beneficence implies an active attempt to advocate strongly for the best medical treatment for patients. Complicating this duty, however, is the principle of non-maleficence, in other words the notion that medical professionals have a duty to "do no harm". The finding of beneficence and non-maleficence in direct opposition is an unusual ethical scenario. Yet the two principles are at odds in this case, and therefore provide relatively little ethical clarity without deferring to the other core bioethical values. Of particular relevance is the question of whether the organ transplantation is an immediately life-saving measure, as in cases of liver, heart and lung transplants, as this profoundly affects the balance between the principles of beneficence and non-maleficence. As a rule the use of marginal organs represents a greater probability of a poorer outcome. However, the outcomes of such marginal transplants are generally expected to be considerably better than the available alternatives, i.e. treatment with dialysis or death on the waiting list.

Once the process of weighing the risks and benefits of transplantations using organs from marginal or non-standard risk donors has established their clinical feasibility, there arise problematic ethical issues regarding the information given to patients and their consent to transplantations of these organs [9].

Medical deontology is unambiguously agreed on the need that potential recipients should be informed about the risks of transplantations [10], so there should be no doubt regarding the duty of medical personnel to inform them. The challenge is to establish how and when this information should be given [11], in other words, i) its content, and ii) the procedure to be followed.

THE CONTENT OF INFORMATION FOR CONSENT

The provision of information does not, *per se*, guarantee that consent is given in full awareness: consent is founded not only on clinical data, but also on a series of both objective and subjective considerations that depend, among other factors, on the fact that harm in the context of transplantations is a comparative concept [12]. Other factors also have a negative impact on the quality and completeness of information. The risk potentially arising from the use of organs from marginal or non-standard risk donors, for example, is not easily quantifiable, especially when it is associated with some aspect of the donor's behaviour of which clinicians, and even at times family members, are not fully aware. Again, the fact that in the case of transplant surgery every effort must necessarily be made to limit delays also reduces the time available to complete the information and consent procedure, as any postponement

could have irreparable consequences for the success of the operation.

The judgment handed down on 11 March 2015 by the Supreme Court of the United Kingdom [13] can help to solve the dilemma of how much and which information should be given to patients concerning the risks associated with clinical treatment. Although this judgment refers to a totally different setting it nonetheless can be applied to any medical context and signalled a turning point in physician/patient relations where information and consent are involved. The British Medical Journal called it a "historic step" in overcoming medical paternalism [14]. The ruling referred to a case brought by Nadine Montgomery, a diabetic who in October 1999 gave birth to a son at Bellshill Maternity Hospital (UK). The risk of a dystocic birth is recognised as being approximately 10% higher in diabetic women and in this case Mrs. Montgomery's delivery was dystocic and her son suffered serious neurological injuries. Damages were sought on the grounds that if Mrs. Montgomery had been correctly informed by Dr. McLellan, who had assisted her throughout, of the possible risks associated with her condition, she would have chosen to give birth by caesarean section. Dr. McLellan asserted that her decision not to inform Mrs. Montgomery was based on the smallness of the risk and that she had acted correctly. Mrs. Montgomery's appeal was upheld by the court and she was awarded damages of 5 million pounds. The ruling in this case requires doctors to consider that a risk is material if "a reasonable person in the patient's position (...) would be likely to attach significance to it, or if the medical practitioner is or should reasonably be aware that the particular patient (...) would be likely to attach significance to it" [13].

Prior to the above ruling decisions in the UK concerning information to be given to patients were based on the approach laid down in the 1985 "Sidaway case" [15], which envisaged application of the so-called "Bolam principle" [16] first adopted in 1957, which in turn recognised the judgment of medical experts as the main criterion for deciding which risks should be communicated to patients regarding a particular treatment. The Montgomery ruling represents a shift of emphasis from the "reasonable medical practitioner" to the "reasonable patient". Physicians are no longer expected to act in accordance with the opinions prevailing among their colleagues, but rather to consider each case from the point of view of the particular patient involved: they should therefore "take reasonable care to ensure that the patient is aware of any material risks involved in a recommended treatment and of any reasonable alternative or variant treatments". They should consider such questions as: whether the patient is fully aware of the potential risks involved in a particular treatment being proposed; which risks a person in a specific patient's circumstances might reasonably wish to know; and whether they have been diligent in ensuring that a particular patient knows everything that he or she would consider it useful to know.

This approach not only embodies the principle of autonomy: it is also a call for stronger relations between physicians and patients.

The focus on a specific person, as illustrated in the Montgomery ruling, does not exempt physicians from always providing crucial information. In the case of organs from marginal or non-standard risk donors, the information given to patients should necessarily be explicit concerning a few basic elements, in particular:

- refusal to accept an organ from a marginal or non-standard risk donor may lead to a longer time on the waiting list, which, in cases of life-saving transplants, may lead to death;
- there is no such thing as complete knowledge of risk factors; risks can be estimated but not quantified precisely;
- there is a possibility of unidentified risks (for instance, new infections unidentified at the time of transplantation) becoming manifest in the long term.

A distinction between the risk of graft failure and the risk of disease transmission should also be emphasised as part of the informed consent procedure [17].

This general information should always be provided when a patient is registered on a waiting list. Additional information relating specifically to a particular patient, in accordance with the approach laid down in the Montgomery judgment, could be given when an organ becomes available. The principle of autonomy requires that patients be informed and consent requested for a specific available organ, but generates problematic organizational issues with important ethical implications. It is thus necessary to define the procedures for giving consent.

The consent procedure

The issues surrounding the procedures for giving consent, and the related consequences, are considerably more complex than those concerning the content. The variety of the solutions adopted in various countries and districts is evidence of the difficulties involved in finding a standard approach. The possibility of receiving an organ from a marginal or non-standard risk donor should clearly be mentioned when a patient is registered on a waiting list, at which time consent to receiving one should be affirmed; this should in no way affect the patient's right to review this decision at any time, whether on personal grounds or, even more importantly, on account of intervening clinical considerations. There are nonetheless some advantages to the acceptance or rejection of organs from marginal or non-standard risk donors as a category rather than of single organs [18], including the following:

- consent for a specific organ generates a misplaced perception of knowing for certain how much each risk factor contributes to the absolute or relative risk associated with it, whereas the risk associated with individual factors is in fact not easy to quantify. One of the reasons for this uncertainty is that it is generally difficult to acquire precise and exhaustive information regarding the donor's lifestyle characteristics, of which even family members may not be aware;
- providing detailed information concerning a specific organ at the moment one becomes available requires time, an element that is in short supply at a moment

when every effort is being made to keep delays to a minimum;

- the possibility to consent to receive or refuse a specific type of organ could result in an injustice. Consider the case, for instance, of a life-saving transplant for which some patients (Group A) initially consented to receive an organ from a marginal or non-standard risk donor and others (Group B) initially declined. An organ from a marginal or non-standard risk donor becomes available and is offered to the first patient on the list, who is from Group B but who changes his/her mind and accepts it. This would result in an advantage to the Group B patient, who receives an organ earlier than would otherwise have been the case and whose right to autonomy and to change his/her mind is thus respected, but in an injustice for the Group A patients, who will have to wait longer for an organ.

Requesting consent for the whole category of "at risk organs" rather than for a specific organ thus offers practical advantages and can even promote fairness. However, it must be acknowledged that allowing a patient to express consent for a specific organ at the time it becomes available complies with the principle of individual autonomy, which is a cornerstone of medical ethics, and it is therefore the duty of physicians to ask for consent at the time an organ becomes available.

CONCLUSIONS

There is a need to establish policies that safeguard autonomy without compromising other basic ethical principles, and such policies should necessarily establish certain binding operational clinical criteria. However, even when the scientific community has defined the clinical requisites (to be complied with at all times), the special relationship between physician and patient should never be ignored [19]. While the Montgomery ruling cannot be reduced to a reminder to physicians to respect their patients' autonomy, it is nonetheless a wake-up call for an improvement in physician-patient relations. It should be acceptable, within the limits defined by guidelines and protocols, for similar clinical circumstances to produce differing options, which should nevertheless be agreed upon by doctor and patient [20]. Once the scientific requisites have been met the decision becomes a personal one, specific to each single case. In the final analysis it is the responsibility of the personal physician of a person on the waiting list for an organ transplant to weigh the risk of remaining on the list for an indeterminate interval against that of receiving an organ which could potentially transmit disease: it is the physician's duty to ensure that the patient receives all the information necessary to give his or her free and fully informed consent.

Conflict of interest statement

There are no potential conflicts of interest or any financial or personal relationships with other people or organizations that could inappropriately bias conduct and findings of this study.

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