

## Annotation

### DONATION WITHOUT CONSENT? LEGAL DEVELOPMENTS IN BONE MARROW TRANSPLANTATION

The ethics of using children and mentally incompetent adults as bone marrow donors has long been debated. However, in the U.K. neither Parliament nor the professional bodies have provided regulations on donation by those unable to consent for themselves. Last year, the issue was given judicial consideration in the case of *Re Y (Mental Incapacity)* (1996) when the High Court ruled on the question whether a mentally handicapped 25-year-old could act as a donor for her sister.

#### *The case of Re Y*

Y was a 25-year-old woman with a profound mental handicap. She had lived at home until the age of 10, when she moved to a residential home. Her family was described as close. Y and her mother had an obviously strong relationship and the mother visited Y weekly. The sister with leukaemia was aged 36 and had a 6-year-old child. Because of her illness, she had not been able to visit Y, but she and her sisters had sent Y letters and photos and included her in family occasions. Y was the only compatible donor in the family.

It was clear, the judge ruled, that the decision in this case had to be made in accordance with Y's own welfare. In a rather convoluted chain of reasoning, he concluded that the bone marrow donation would in fact be in her interests. Y was very attached to her mother. If Y's sister were to die, this would be extremely distressing to their mother. She would also be obliged to assume the care of the sister's young daughter and this would severely curtail the amount of time she could spend with Y. Thus, taking into account not just the narrow issue of Y's physical interests, but also the broader question of her psychological well-being, the court concluded that it would be in her best interests to act as a bone marrow donor for her sister.

The judge described *Re Y* as a 'rather unusual' case; indeed, it must be rare that the only suitable tissue donor in a family is an incompetent adult. What is far more common is the use of young children as bone marrow donors for siblings. In a series of articles in the *British Medical Journal* (Delany *et al.*, 1996), all the medically-qualified authors defended the use of child donors and the right of their parents to make the decision to donate their child's bone marrow. But some oncologists feel uncomfortable about this practice and have come to rely heavily on the registers of unrelated adults held by the Anthony Nolan Research Centre or the Blood Transfusion Service if they have developed sufficient experience and expertise to enable them to deal with the risks of a less perfect match. Bristol, for example,

obtains about 80% of its donors from the registers of unrelated adults and might well choose in some cases to use an unrelated adult in preference to a sibling donor.

#### *Existing legal regulation*

There is no specific legal regulation of bone marrow transplantation. Bone marrow falls outside the scope of the *Human Organ Transplants Act 1989*, as it does not fit within the definition in section 7(2) of the Act of a 'structured arrangement of tissues which . . . cannot be replicated by the body.' Technically, the removal of healthy tissue from a person is a deliberate 'injury,' where it provides no medical benefit. But the law allows people to consent to the removal of bone marrow because it respects the donor's autonomous choice, because the donation does not in its gravity or risk of harm contravene public policy, and because it serves a socially laudable purpose. However, in cases involving children or mentally handicapped adults the incompetence of the proposed donor makes the principle of personal autonomy meaningless. If incompetent people are ever to be permitted to act as marrow donors, then it becomes important to consider who should make the decision and according to what criteria.

#### *Should incompetent people ever be donors?*

Guidance established by the World Health Organization (1991) states that national legislation may permit minors to donate regenerative tissue. Resolutions and guidelines issued by the Council of Europe (1978, 1987) also allow for bone marrow donations by incompetent people 'in exceptional cases.' However, in countries outside the U.K., incompetent adults are often excluded as organ and bone marrow donors, either expressly, or by implication through requirements calling for signed, informed consent. Occasionally, incompetent persons are permitted to donate within the restrictive conditions imposed on child donors.

Internationally, the approach to child tissue donors is varied: at one end of the spectrum are countries where the only condition is parental consent; at the other end are states which seem to impose a total ban on all donation by minors, whether involving solid organs or regenerative tissue. Many jurisdictions prohibit donation of solid organs but allow bone marrow to be donated. In some countries tissue donation by minors is allowed only where the minor is able to add his or her own valid consent to that of the parent; others make it an express condition of donation that without the treatment the recipient would die. France allows minors to donate organs and Belgium and Greece bone marrow, but only when the donor is the recipient's brother or sister. Often cases involving children must be referred to a court, tribunal or

committee for approval. In Norway, Sweden and Finland all cases involving donation by minors of 'organs and other biological materials' must be reviewed by a national board of health. South Australia permits children to donate only non-regenerative tissue and refers all cases to a committee of experts; France allows organ donation by minors and also requires the approval of such a committee (World Health Organization, 1994).

The European Bioethics Convention (Council of Europe, 1997) has now been signed by a number of member states (although not by the U.K.). It incorporates principles from some of the national legislation described above. It allows only regenerative tissue to be removed from minors and incompetent adults – and only in situations where the donation has the potential to be life-saving. Furthermore, there must be no compatible competent adult donor, the recipient must be a brother or sister of the donor, the potential donor must not object to the proposed procedure, and written proxy consent must be sought from a parent, legal representative or other competent authority.

#### *Devising restrictions on donation by incompetent people*

*The 'best interests' test.* The Children Act 1989 states that when courts make a ruling in family proceedings the welfare of the child is to be the paramount consideration. The 'best interests test' has also been applied by courts to decisions relating to the care of mentally incompetent adults (*Re F*, 1990). However, the application of this test is far from straight-forward. Applied strictly, it prohibits any kind of non-therapeutic medical intervention, for it cannot be said to be in the interests of an incompetent person to be subjected to the physical or psychological discomfort associated with bone marrow donation. A wide interpretation of the best interests test runs the opposite risk: the test may be stretched or manipulated in order to achieve the results desired. In the guise of the welfare test, risks may be taken with the health of those we should be protecting.

The court in *Re Y* interpreted 'best interests' to include both physical and psychological interests. This is consistent with the view taken in a number of similar American cases in which courts have permitted incompetent people to act as donors. In *Hart v Brown* (1972) both parents agreed to the use of a 7-year-old girl as a kidney donor for her identical twin sister. The court approved the transplant as there was parental consent and a 'strong identification' between the donor and her sister. The donor would be better off in a happy family than a distressed one. In *Strunk v Strunk* (1969) the court used similar concepts to justify a kidney donation from a mentally handicapped adult to his brother. However, in *Curran v Bosze* (1990) the court was asked to consider the refusal by the mother of 3-year-old twins to have them tested as potential bone marrow donors for their father's child by a previous relationship. The father had left both mothers and the twins had met the prospective recipient only twice. The court decided against the testing; it held that the notion of psychological benefit required grounding in the close family relationship of donor and recipient – this did not extend to 'altruism in an abstract, theoretical sense.'

However one interprets the best interests test, there are still many unknown factors and conflicting evidence as to what will best serve the welfare of the child or incompetent adult. Most of the court decisions have concentrated on the benefits for all concerned, given the hope of a satisfactory outcome. They fail to consider what will happen if the transplant is unsuccessful. It may be a devastating experience for a young donor who feels that the death of a sibling is somehow now his or her responsibility. Also some parents may be inclined to push their own hopes, however slim, beyond the bounds of what is in the best interests of either the donor or the recipient in cases where the transplant is very unlikely to succeed.

*The 'substituted judgement' test.* The test of 'substituted judgement' allows the decision-maker (in this case a court) to choose what it thinks the person would have decided, were he or she competent. This test has some obvious advantages. It admits, for example, evidence of 'living wills' and other advance directives of varying degrees of formality. For a person who has never been able to give such autonomous directions, the substituted judgement test has more limited value and the court in *Re Y* specifically rejected the application of substituted judgement. This would seem entirely correct. Taken to extremes, the test could authorize taking considerable risks after an allegation, entirely incapable of proof, that the person would have chosen to be helpful or altruistic had he or she been able to do so.

#### *Who is to decide?*

*The child as decision-maker.* It is well established that in certain situations minors are themselves able to give legally valid consent. Since the *Family Law Reform Act 1969*, minors over 16 have been permitted to consent to 'medical, dental or surgical treatment.' However, in *Re W* (1992), Lord Donaldson suggested that organ donation could not be described as 'medical treatment.' The decision in *Gillick v. West Norfolk and Wisbech AHA* (1985) extended the right to consent to certain mature children even if they fell outside the specific provisions of the Family Law Reform Act. But Lord Donaldson has also subsequently held that, even if a minor were 'Gillick-competent,' it was 'inconceivable' that a doctor should proceed with a tissue donation without the consent of both the young person and the parents. He also advised that it would be sensible to apply to the court in such a case (*Re W*, 1992).

When a child is not competent to give full valid consent, authorization for medical treatment must be obtained from the child's parent. Although, as a matter of good practice, doctors explain to the child the procedure which is to take place, they need not take account of the child's wishes. This is an acceptable model for ordinary treatment intended to benefit the health of the child. Is it acceptable as well in the case of a procedure such as bone marrow donation, which is not therapeutic?

The professional guidelines used in the case of non-therapeutic medical research may be of assistance here. There is a growing tendency to recommend not only parental consent but also informal assent, even from young children. The Medical Research Council (1991) states

that non-therapeutic research is permissible on incompetent children where the children 'do not object or appear to object in either words or action.' The British Paediatric Association (1992) imposes a requirement of assent from the child, where it would be 'meaningful.' Although few young siblings may express reluctance or anxiety about the idea of donating bone marrow, it seems clear that if a child were to oppose the idea, enforced participation would sit uneasily with the idea that the donation was in his or her psychological interests.

*The courts as decision-makers.* In *Re F* (1990) the House of Lords considered the question of the sterilization of mentally handicapped people and held that, as this was a controversial and irreversible procedure, it ought in every case to be subject to judicial scrutiny. Two judges in *Re F* (1990) took the view that organ donation fell within the same special category. The court in *Re Y* (1996) has now included bone marrow donation within the cases which must be reviewed by a court before they are carried out on mentally incompetent adults. This is a sensible precaution. There is no legal mechanism for proxy decision-making on behalf of incompetent adults, as no adult may consent on behalf of another. In the case of a child it may be presumed that parents care in more or less equal shares for all their offspring and would not seriously harm one in order to benefit another. But the parents of handicapped adults may no longer be alive and the family unity and closeness which might justify allowing a donation cannot automatically be presumed, especially where the prospective donor does not live with the rest of the family. The recent Government Green Paper, *Who Decides? Making decisions on behalf of mentally incapacitated adults* (Lord Chancellor's Department, 1997) states that 'The government accepts the principle and the current common law position that the court should rule on any treatment or procedure to facilitate the donation of non-regenerative tissue or bone marrow from an adult incapable of giving consent.' (The government is presently seeking views on the restrictions or safeguards appropriate for blood and solid organ donation by such adults.)

The case of children may be different. We normally rely on parents to protect their offspring and so vest them with proxy decision-making powers. This reliance is, of course, not absolute. For example, the House of Lords in *Re B* (1987), another case dealing with the question of involuntary sterilization, ruled that cases involving minors must be also be referred to the High Court for judicial consideration. If sterilization cases must come to court, should the same be true for bone marrow donation? The potential infringement of human liberty caused by marrow donation may be distinguished both in nature and degree from that involved in sterilization. But is bone marrow donation nevertheless something which ought to be subject in each instance to scrutiny beyond that offered by the child's parents?

*Parents as decision-makers.* It is clear that a parent deciding to take bone marrow from a healthy child to donate it to a sick one will have both children in mind – and will in effect be choosing to sacrifice the comfort of one child for the health of the other. The primary reason for allowing the donation is not the donor's best interests but those of the sick child and of the family. Of course, the donor will also benefit

from an intact family. In many other areas of family life we allow parents to set the interests of one child against those of others or of the family. Every parental decision may not, strictly speaking, be in each child's best interests, but it is in general in a child's best interests to live in his or her own family and so we allow that family some flexibility in balancing the concerns of its members.

This suggests that the decision to have a child donate bone marrow to a sibling might be left in the hands of the parents. In the case of *S v S; W v Official Solicitor* (1970), where the House of Lords considered the question of blood testing of children for paternity purposes, Lord Reid, rather than applying a strict 'best interests' test to parents' decisions to allow testing, suggested instead that a 'reasonable parent' test was more appropriate; the reasonable parent might choose to consider wider motives than the child's physical protection, such as the public interest. As an alternative test, the court in *S v S; W v Official Solicitor* (1970) suggested that procedures could be allowed as long as they were not 'clearly against the interests' of the child. This is somewhat different from the traditional welfare test. However, it may be more realistic in allowing the sort of balancing that happens within a family where decisions cannot always protect the physical welfare of each child equally.

It is important to consider the limits of the decision in *S v S; W v Official Solicitor* (1970). Recent professional guidelines on medical research involving healthy children stipulate that it may be 'against the interests' of a child to compromise in any way 'more than minimal' the child's physical or psychological comfort (British Paediatric Association, 1992). Hence, the flexibility we give to families to sacrifice their child's interests for those of the public good may extend only to areas where the harm is considered to be minimal. But bone marrow donation for the treatment of a sibling is not the same as participation in research. In the case of treatment there is some benefit to the donor and also to the family as a whole. And it is because of this that we may permit a wider latitude to parents in choosing to make a 'family decision' than we would in choosing to volunteer their child for medical research. On the other hand, the decision to have one's child donate bone marrow may be one which we would wish to constrain and monitor, in order to ensure that there is a benefit to the donor and that other conditions have been met.

#### *Proposals for a new legal framework*

For those whose work involves the use of donated bone marrow, it is important that the law be clear and comprehensible. The court in *Re Y* (1996) has already given some guidance on the use of incompetent adults as donors. Cases involving incompetent adults may be complex; one cannot assume the presence of a decision-maker who will take the protective role fulfilled by parents in the case of young children. Hence, the requirement of court approval seems reasonable. What might be helpful, both for families and for doctors, would be a set of guidelines as to the circumstances in which bone marrow may be donated by children. I propose that such guidelines might contain the following points:

(1) In international and professional guidelines relating to medical research it is often stated that children should not be used as research subjects unless there is no alternative. It is suggested that the same condition be imposed on bone marrow transplantation. No child may be a donor unless a bone marrow transplant is necessary to allow a chance of significant improvement in the recipient's condition and no adult donor is available.

(2) Case law has consistently drawn a sharp distinction between situations in which the donor and recipient were in a close family relationship with each other and those in which they were not. It is therefore recommended that bone marrow transplantation be allowed only in cases where there is a close family bond between the donor and the recipient. This might exclude donations by institutionalized children who do not know their siblings, or donations to little-known cousins or step-siblings.

(3) The tenor of recent developments in child law and the recommendations of professional bodies concerned with non-therapeutic research is to give attention not only to the interests of children but also to their wishes. Therefore it is proposed that no child should participate as a bone marrow donor if it appears that he or she is clearly unwilling to do so.

(4) Although existing practice may already incorporate many of the points made above, it is important to provide the outward assurance that we are protecting child donors adequately. Therefore a further administrative process is recommended. Parents would be required to apply to a specialized national or regional ethics committee set up in order to review such cases and to ensure that the donation was not against the interests of the donor. The application would be a brief one, but would require the endorsement of the doctor who was to harvest the bone marrow and a social worker who had met the prospective donor. If, on the application, it was clear that the guidelines had been fulfilled, the committee would give its approval. If the committee had any question, for example in the case of a child-to-adult donation or one involving a more distant relative, they would have the power to interview the parties. If it formed the opinion that the transplant was against the interests of the donor in that it provided no benefit to the child, it might ultimately reject the application. This decision could, of course, be subject to judicial review.

The idea of a special committee or tribunal is not an entirely new one. The application to a 'committee of experts' in France, and in particular the format adopted in South Australia, provide similar safeguards, as do the boards of health in the Scandinavian countries. Application to a central ethics committee would provide a formal review of the circumstances of each prospective donation, by those familiar with the issues. Combined with the proposed set of

guidelines, it would provide a framework for ensuring that children were adequately protected, without having to make use of the family courts in each of the hundreds of cases arising each year.

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