

REVIEW

Rationing life-saving resources – how should allocation policies be assessed in solid organ transplantation

James Neuberger

Organ Donation and Transplantation, NHS Blood and Transplant, Bristol, UK

Keywords

allocation, policy.

Correspondence

James Neuberger, Associate Medical Director, Organ Donation and Transplantation, NHS Blood and Transplant, Fox Den Road, Bristol, BS34 8RR and Consultant Physician, Queen Elizabeth Hospital, Birmingham, B15 2TH, UK. Tel.: (44) 117 975 7488; fax: 44 121 627 2414; e-mail: james.neuberger@nhsbt.nhs.uk

Conflict of Interest

There is no conflicts of interest.

Received: 20 April 2011

Revision requested: 20 June 2011

Accepted: 1 August 2011

Published online: 8 September 2011

doi:10.1111/j.1432-2277.2011.01327.x

Summary

Because the demand for solid organ transplantation exceeds the availability of donated grafts, there needs to be rationing for this life-saving procedures. Criteria for selection of patients to a national transplant list and allocation of donated organs should be transparent yet there is no consistent approach to the development of such guidelines. It is suggested that selection and allocation policies should comply with minimum standards including defining of aims of the allocation process and desired outcome (whether maximizing benefit or utility or ensuring equity of access), inclusion and exclusion criteria, criteria for futility and suspension and removal from the transplant list, appeals processes, arrangements for monitoring and auditing outcomes and processes for dealing with noncompliance. Furthermore, guidelines must be consistent with legislation even though this may compete with public preference. Guidelines must be supported by all stakeholders (including health-care professionals, donor families and potential transplant candidates). However, there must also be flexibility to allow for exceptions and to support innovation and development.

Solid organ transplantation is primarily a life-saving procedure. Because of the shortfall between the number of people who could benefit from a transplant and the availability of organs, this life-saving procedure must be rationed. Therefore, there needs to be clear criteria for selection (who gets on to the transplant list) and allocation (who receives a donated organ) of organs from deceased donors.

The aim of this review is to suggest criteria by which such policies should be assessed rather than suggest which approach should be adopted.

Criteria for selection

Listing everyone who might benefit will reflect the need for transplantation but will make managing the list difficult and give many an unrealistic hope of a graft, although some may feel that a small chance is better than none. If access to the list is to be restricted to the avail-

ability of organs, then that basis needs to be determined and revised as organ availability changes.

Criteria for allocation

There are several different approaches to organ allocation. In the US, livers from deceased donors are allocated using an approach to reduce the mortality on the waiting list; in contrast, donated lungs are allocated according to a model of transplant benefit.

Need

A needs-based policy prioritizes those at greatest risk of death. While the impact of such a policy has had varying success, in general it has been successful [1] but is associated with increased cost and denies access to transplantation to those with good organ function but an unacceptable quality of life that is corrected by transplan-

tation. The rights of the dying to a life-saving graft must be balanced with those with an intolerable quality of life.

Outcome

Outcomes can be considered in various ways: from listing or transplantation, for patient or graft, absolute or adjusted for quality of life; choice of outcomes will impact on criteria and may be difficult to predict [2].

Utility

Allocation according to utility, in effect, places the survival of the graft as the priority.

Benefit

Allocation according to benefit will give the graft to that recipient who will have the maximum benefit when survival without and with transplant are estimated. Because the recipient with the shortest anticipated survival without transplantation may well be the sickest, the post transplant survival may be reduced compared with a less sick recipient and so the utility reduced and health-care costs increased [3]. To avoid futility, the concept of minimum benefit is generally accepted: for liver recipients, this is usually and arbitrarily taken as at least a 50% probability of surviving 5 years with a quality of life that is acceptable to the recipient [4].

Equity

In this context, equity has a variety of meanings. Equity of access may mean that every person in need of a transplant will have a similar opportunity, regardless of other factors such as age, gender, co-morbidities and expected survival with or without a transplant. Organs could be allocated on a first-come first-served basis; however, this approach would have to be modified to include those factors that significantly affect outcome such as blood group or donor-recipient size match. Equity of access may mean that those with similar characteristics will all be treated in the same way. Geographic equity implies people awaiting a graft will have the same chance of getting a graft irrespective of where they live or receive treatment.

Justice, fairness and prejudice

Most people have clear opinions that selection and allocation should be fair and just yet such concepts are poorly defined. The public gives high priority to children (irrespective of benefit) and low priority to those with self-induced (or perceived self-induced) disease: value to society and ability to pay should not be factors [5,6]. Public opinion, as expressed by the media, is inconsistent: anger

was expressed both when a liver was given and denied to individuals with alcohol-related liver injury [7,8].

Most allocation processes are dependent on models that predict outcome. Models give potentially misleading reassurance as survival probabilities have wide confidence intervals and are based on historical data; data may be incomplete and collected differently in different units, key data may not be collected or even recognized. There are other considerations. Most models of survival are static ones and their validity in a dynamic situation, with repeated application over time, should be confirmed before widespread adoption. Furthermore, because there are usually many potential recipients for an offered organ, ranking based on small differences may lead to inequity. More importantly perhaps, extrapolation from matched donor/recipient pair to a nonmatched combination may give misleading information.

Although transplantation is usually associated with a significant improvement in the quality of life, yet there are relatively few studies assessing the quality of life and outcomes have usually focussed on survival. It could be argued that allocation should be based not just on survival (absolute or benefit) but quality of life adjusted life-years gained.

It should be clear whether survival is considered for the patient (from either listing or transplant), for the graft. If the focus of allocation is based on most efficient use of scarce resources (organs), then the prime outcome should be graft survival.

Local or national allocation?

Donated organs may be allocated on a national, regional or local basis. National allocation systems require the development and acceptance of validated, objective models of ranking patients according to agreed criteria. Advantages include objectivity and transparency: however, a significant proportion of offers are not accepted for the first candidate [9]. Selection of the next ranked recipient may add to the cold ischaemic time and so reduce the viability of the graft. Local allocation requires the local team to select the recipient: this will allow inclusion of clinical factors that are not included in the models and possibly better matching of donor and recipient. This approach is usually not as objective or transparent as national allocation, requires an audit trail and a process to ensure fairness between centres.

Transplantation and the law

Transplantation is, quite rightly, subject to legal constraints and challenge. Discrimination is illegal where it is based on age, gender, ethnicity or disability. Access to transplanta-

tion should be independent of occupation, life-style, ability to pay, value to society. Disability and age are relevant if, and only if, they affect the outcome of transplantation and cannot be obviated by available interventions.

Other issues

Exceptions

Few policies can encompass every eventuality so provision has to be made for consideration of the exceptional case. Most clinicians consider their duty of care to the patient in front of them and will rightly act as the patient's advocate. Where there is a rationed resource, allocation of a life-saving organ to one individual will deny another. Thus, the advocate should not make a unilateral decision to list or not an individual but there needs to be a clear, defined process to balance the rights of the exceptional case with the rights of others.

Innovation and research

There are concerns that strict policies will prevent innovation and research [10]. Thus, policies must allow evaluation of new indications and procedures.

Age

The public prioritizes younger recipients although this is counter to age discrimination legislation. The 'good innings' argument supports disadvantaging the older recipient. Younger recipients could be prioritized as transplantation may allow catch-up growth and less time on dialysis may prevent psychological and behavioural problems later [11,12]. The younger recipient is more likely to tolerate surgery than the older recipient and is more likely to have greater benefit in terms of life-time survival [13]. Thus, there may be justification for prioritizing younger recipients; this should be done on the basis of utility or benefit rather than age.

Ethnicity

Discrimination on the grounds of ethnicity is both morally and legally unacceptable. The relatively low donation rates amongst some ethnic groups [14] may lead to lower rates of transplantation where blood group and tissue type are relevant. It needs to be agreed whether equity (in terms of waiting time) should compete with utility.

Compliance

There needs to be clear systems in place to assess and respond to noncompliance.

Unforeseen outcomes

Following the example of the US, many countries have adopted an allocation system based on the MELD score, which is used to prioritise livers to those at greatest risk of death awaiting transplantation. The approach is transparent and based on objective laboratory measurements. There are well described limitations, such as concerns about the accuracy of the model, the measurement of the constituent analytes, but there are other limitations: the model virtually excludes from deceased donor transplantation those with good liver function but a poor quality of life from, for example, chronic encephalopathy or intractable pruritus, but also in some countries, notably Germany, is said to have contributed to worse outcomes [15].

How should policies be assessed?

If donated organs are considered a national, life-saving resource, policies should be transparent and clear to all those involved. Against this background, how should selection and allocation policies be developed and evaluated? There is no reason why similar considerations for all organs. For example, in renal failure, patients can be managed with dialysis even though quality of life and length of life is inferior to transplantation; some of those in heart failure may be helped by ventricular assist devices whereas there exists no support for those in liver failure.

Although the responsibility for selection and allocation policies are given to a statutory body, their development and endorsement should be by several stakeholders, including not only those health-care clinicians who look after potential and actual transplant patients, but representatives of patients, their families and carers, donor representatives, ethicists and other interested parties.

It is suggested that the policies on selection and allocation should address the following questions:

- 1 Are the aims of the policy defined?
- 2 Have the competing aims of allocation been considered and balanced? The aims of allocation may be single or multiple
- 3 Are the aims supported by the health-care clinicians, ethicists, representatives from patient groups, donor families and the informed general public.
- 4 Is there a minimum level of benefit and, if so, what is this benefit and how is this defined?
- 5 Are there criteria for futility?
- 6 Are the policies based on objective and validated criteria?
- 7 Are the policies compatible with current national legislation?
- 8 How and when will the outcomes be reviewed

- 9 How often are the aims, implementation reviewed (and revised if appropriate)?
- 10 What is the process for managing exceptions?
- 11 How will the policies be adapted to support innovation and development?
- 12 How will noncompliance be managed?

Funding

There was no external funding for this review.

References

1. Bernardi M, Gitto S, Biselli M. The MELD score in patients awaiting liver transplants: strengths and weaknesses. *J Hepatol* 2010; **54**: 1297.
2. Hippen BE, Thistlethwaite R, Ross LF. Risk, prognosis and unintended consequences in kidney allocation. *N Engl J Med* 2011; **364**: 1285.
3. Foxton MR, Al-Freah MA, Portal AJ, *et al*. Increased model for end-stage liver disease score at the time of transplant results in prolonged hospitalization and overall intensive care unit costs. *Liver Transpl* 2010; **16**: 668.
4. Neuberger J, Adams D, MacMaster P, Maidment A, Speed M. Assessing priorities for allocation of donor liver grafts: survey of public and clinicians. *BMJ* 1998; **317**: 172.
5. Chan HM, Cheung GM, Yip AK. Selection criteria for recipients of scarce donor livers: a public opinion survey in Hong Kong. *Hong Kong Med J* 2006; **12**: 40.
6. Neuberger J, James O. Guidelines for selection of patients for liver transplantation in the era of donor-organ shortage. *Lancet* 1999; **354**: 1639.
7. Criticism grows of Best liver decision. News.scotsman.com <http://news.scotsman.com/georgebest/Criticism-grows-of-Best-liver.2443759.jp> (accessed on April 6, 2011).
8. Viewpoint: is Gareth Anderson a suitable case for liver transplant? Belfast telegraph. <http://www.belfasttelegraph.co.uk/opinion/viewpoint/viewpoint-is-gareth-anderson-a-suitable-case-for-a-liver-transplant-1467028.html> (accessed on April 6, 2011).
9. 2009 OPTN/SRTR Annual Report. http://optn.hrsa.gov/ar2009/Chapter_II_AR_CD.htm?cp=3 (accessed on April 6, 2011).
10. Neuberger J, Madden S, Collett D. Review of methods for measuring and comparing center performance after organ transplantation. *Liver Transpl* 2010; **16**: 1119.
11. Fine RN, Martz K, Stablein D. What have 20 years of data from the North American Pediatric Renal Transplant Cooperative Study taught us about growth following renal transplants in infants, children and adolescents with end-stage renal disease? *Pediatr Nephrol* 2010; **25**: 739.
12. Mohammed S, Alonso EM. Approach to optimizing growth, rehabilitation and neurodevelopmental outcomes in children after solid organ transplantation. *Pediatr Clin North Am* 2010; **57**: 539.
13. Cecka JM. The UNOS scientific renal transplant registry. *Clin Transpl* 1999; **1**.
14. Barber K, Falvey S, Hamilton C, Collett D, Rudge C. Potential for organ donation in the United Kingdom: an audit of intensive care unit records. *BMJ* 2006; **332**: 1124.
15. Schlitt HJ, Loss M, Scherer MN, *et al*. Current developments in liver transplantation in Germany: MELD based organ allocation and incentives for transplant centres. *Z Gastroenterol* 2011; **49**: 30.