ACCESS TO ADULT LIVER TRANSPLANTATION IN CANADA: A SURVEY AND ETHICAL ANALYSIS

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Abstract • Résumé

Objectives: To describe the substantive and procedural criteria used for placing patients on the waiting list for liver transplantation and for allocating available livers to patients on the waiting list; to identify principal decision-makers and the main factors limiting liver transplantation in Canada; and to examine how closely cadaveric liver allocation resembles theoretic models of resource allocation.

Design: Mailed survey.

Participants: Medical directors of all seven Canadian adult liver transplantation centres, or their designates. Six of the questionnaires were completed.

Outcome measures: Relative importance of substantive and procedural criteria used to place patients on the waiting list for liver transplantation and to allocate available livers. Identification of principal decision-makers and main limiting factors to adult liver transplantation.

Results: Alcoholism, drug addiction, HIV positivity, primary liver cancer, noncompliance and hepatitis B were the most important criteria that had a negative influence on decisions to place patients on the waiting list for liver transplantation. Severity of disease and urgency were the most important criteria used for selecting patients on the waiting list for transplantation. Criteria that were inconsistent across the centres included social support (for deciding who is placed on the waiting list) and length of time on the waiting list (for deciding who is selected from the list). Although a variety of people were reported as being involved in these decisions, virtually all were reported to be health care professionals. Thirty-seven patients died while waiting for liver transplantation in 1991; the scarcity of cadaveric livers was the main limiting factor.

Conclusions: Criteria for resource allocation decisions regarding liver transplantation are generally consistent among the centres across Canada, although some important inconsistencies remain. Because patients die while on the waiting list and because the primary limiting factor is organ supply, increased organ acquisition efforts are needed.

Objectifs : Décrire les critères de fond et de forme suivis pour inscrire des patients sur la liste des personnes en attente d'une greffe de foie et pour affecter les foies disponibles aux patients inscrits sur la liste d'attente; identifier les principaux décideurs et les principaux facteurs qui limitent les greffes de foie au Canada; examiner jusqu'à quel point l'affectation d'un foie de cadavre suit les modèles théoriques de la répartition des ressources.

Conception : Sondage postal.

Participants : Directeurs médicaux des sept centres du Canada qui effectuent des greffes de foie chez des adultes, ou leur remplaçant désigné. Six des questionnaires ont été remplis.

Mesures des résultats : Importance relative des critères de fond et de forme utilisés pour inscrire des patients sur la liste des personnes en attente d'une greffe de foie et pour affecter les foies disponibles. Identification des principaux décideurs et des principaux facteurs qui limitent les greffes de foie chez les adultes.

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Résultats : L'alcoolisme, les toxicomanies, l'infection au VIH, le cancer primaire du foie, la non-compliance et l'hépatite B sont les plus importants critères qui ont eu une incidence négative sur la décision d'inscrire des patients sur la liste des personnes en attente d'une greffe de foie. La gravité de la maladie et l'urgence ont été les principaux critères qui ont servi à choisir parmi les patients inscrits sur la liste des personnes en attente d'une greffe. Les critères non uniformes entre les centres comprenaient l'appui social (lorsqu'il s'agit de décider qui sera inscrit sur la liste d'attente) et la durée de la période d'attente (lorsqu'il s'agit de décider qui sera choisi dans la liste). Même si l'on a affirmé que toutes sortes de personnes participaient à ces décisions, on a signalé qu'il s'agissait de professionnels des soins de santé dans à peu près tous les cas. Trente-sept patients sont morts en attendant une greffe de foie en 1991; la principale cause limitative a été la rareté des foies de cadavre.

Conclusions : Les critères qui régissent les décisions relatives à la répartition des ressources dans les cas de greffes de foie sont en général uniformes entre les centres qui effectuent des greffes au Canada, même s'il persiste certaines incohérences importantes. Comme des patients meurent pendant qu'ils attendent toujours, et comme l'offre d'organes constitue la principale limite, il faut redoubler d'efforts pour trouver des organes.

Liver transplantation is now the treatment of choice for end-stage liver disease. Survival rates in Canada exceed 75% at 1 year and 50% at 5 years after transplantation, and about 80% of recipients are able to return to full-time work.[1] In liver transplantation centres dilemmas arise from the need to allocate a very scarce and nonrenewable resource — human cadaveric livers. Since demand greatly exceeds supply, ethical questions arise as to which criteria should be used for deciding who should be placed on the waiting list and who should receive the next available liver, and who should be involved in making these decisions.

Levenson and Olbrisch[2] studied psychosocial selection criteria used in kidney, heart and liver transplantation programs in the United States. For liver transplantation the following criteria were listed as absolute contraindications by at least 50% of the respondents: active schizophrenia, current suicidal ideation, dementia, current heavy alcohol use and current addictive drug use. The authors did not examine how patients were selected from the waiting list and they did not survey Canadian centres.

The frame of reference appropriate to the evaluation of resource allocation decisions is theories of justice. The main theories of justice include utilitarian theories (which lead to effectiveness-based resource allocation decisions), egalitarian theories (which lead to needs-based decisions), libertarian theories (which lead to fair procedures-based decisions) and feminist theories (which focus on power relationships between participants in resource allocation decisions).[3–5]

We surveyed the directors of all adult liver transplantation centres across Canada to determine the substantive and procedural criteria used for placing patients on the waiting list and for allocating available livers to patients on the waiting list. We also wanted to identify the principal decision-makers and the main factors limiting liver transplantation in Canada and to examine how closely cadaveric liver allocation resembles theoretic models of resource allocation.

Methods

Study design and sample

We performed a mailed survey, according to the methods of Dillman,[6] of adult liver transplantation centres in Canada. A questionnaire was sent in September 1992 to the medical director of each centre, or a designate. Since there are only seven centres no exclusion criteria were used, and all seven centres were invited to participate. Four weeks after the initial mailing nonrespondents were contacted by telephone and sent another copy of the questionnaire by mail. Respondents were given a pre-addressed, prepaid envelope to return the questionnaire.

The study was approved by the University of Toronto Human Subjects Review Committee.

Questionnaire

The questionnaire explored six domains corresponding to the study objectives: (a) description of transplantation data for the calendar year 1991, (b) substantive criteria used to place patients on the waiting list, (c) procedural criteria used to place patients on the waiting list, (d) substantive criteria used to allocate livers to patients on the waiting list, (e) procedural criteria used to allocate livers to patients on the list and (f) factors that limit patient access to liver transplantation. Response categories consisted of fixed numeric responses (for descriptions of the transplantation data), fixed selection of decision-making participants and a 5-point Likert scale to rate the relative importance of the substantive and procedural criteria.

The very small sample precluded a survey pretest; however, one of us (L.B.) is active in liver transplantation and assisted in redrafting the questionnaire in relation to face validity. (The questionnaire is available from the authors upon request.)

Statistical analysis

Owing to the exploratory nature of the study and the small sample, descriptive statistics were used to analyse the data. Weighted substantive criteria were collapsed into three categories for analysis: extremely or very important, somewhat important and not very or not important. We considered the use of a criterion to be inconsistent across centres if there were scores for that criterion in each of the two extreme collapsed categories; otherwise, we considered the use to be consistent across centres.

Allocation criteria and decision-making processes were also compared to theoretic models of resource allocation such as utilitarian, egalitarian, libertarian and feminist theories of justice.

Results

Six of the seven centres participated in the study. No information was received from the seventh centre to explain nonparticipation.

Liver transplantation data

On average, each centre received 8 new referrals (range 3 to 23) for liver transplantation each month and placed 7.5 patients (range 3 to 16) on the waiting list each month. Of the new referrals 42% on average were accepted for placement on the waiting list (range 24% to 100%). The average time from placement on the waiting list to transplantation was 4 months (range 1 to 9 months). In 1991, 35 liver transplantations on average (range 0 to 65) were performed at each centre; the total number was 177. Seven patients on average (range 0 to 20) at each centre died while on the waiting list; the total number who died was 37. (One centre neither placed patients on the waiting list nor performed liver transplantations in 1991, pending program review; thus, the number of procedures and deaths was averaged over five centres.)

Placement on the waiting list

Substantive criteria

The levels of importance assigned by the respondents to substantive criteria for placing patients on the waiting list are shown in Table 1. Criteria that were consistent across the centres and that had a negative influence on decisions to place patients on the waiting list were alcoholism, drug addiction, HIV positivity, primary liver cancer, noncompliance and hepatitis B. All of the centres had special criteria for the acceptance of alcoholic patients (e.g., documented "dry" periods of 6 to 24 months and participation in programs such as Alcoholics Anonymous). Criteria that were inconsistent from centre to centre were lack of social support, psychiatric status, drug overdose and acute hepatic failure. Age was not an extremely or very important criterion at any of the centres; two respondents reported special criteria for older patients (e.g., absence of other important chronic illness and neurologic impairment).

Procedural criteria

The respondents were asked "Which of the following persons have input into the decision to place a patient on the waiting list for liver transplantation?" All six reported that the transplant surgeon, the transplant physician and the social worker are involved. However, participation by others varied between centres: five respondents reported that the patient and the transplant nurse were involved in these decisions; four, the patient's family; three, a psychiatrist; and one, clergy. None reported involvement of an ethicist, a hospital ethics committee or a lawyer.

Allocation of available livers

Substantive criteria

The levels of importance assigned to the substantive

Table 1: Level of importance assigned to substantive criteria for placing patients on the waiting list at Canadian adult liver transplantation centres

Criterion	Response; no. of centres		
	Extremely or very important	Somewhat important	Not very or not important
Alcoholism*	6	0	0
Drug addiction	6	0	0
HIV positivity	6	0	0
Primary liver cancer	6	0	0
Noncompliance	5	1	0
Hepatitis B	4	2	0
Lack of social support	3	1	2
Psychiatric status	3	0	2
Drug overdose	2	3	1
Acute hepatic failure	2	1	3
Age†	0	4	2
Social status	0	1	5
Diabetes mellitus	0	0	6

*All centres have special criteria for alchoholic patients.
†Two centres have special criteria for older patients.

criteria used for allocating available livers to patients on the waiting list are shown in Table 2; one of the respondents did not respond to these questions. Criteria that were consistent between the centres and had a positive influence on allocation decisions were severity of disease, urgency and blood type. Criteria that were inconsistent from centre to centre included primary liver cancer, length of time on the waiting list, non-Canadian patient, prognosis and cause of liver failure.

Procedural criteria

Four of the six respondents reported that their centre used some type of a point or rank system to prioritize patients on the waiting list. All of the respondents indicated that the transplant surgeon and the consulting transplant physician were the important decision-makers in the allocation of available livers.

Principal limiting factors to liver transplantation

The respondents were asked "What is the main limitation to patient access to liver transplantation?" Four reported that it was availability of organs, one cited program funding, and one did not answer. One respondent also cited the lack of timely referral from community physicians.

Discussion

To our knowledge this exploratory study represents the first examination of decision making concerning liver transplantation among adults in Canada. The allocation of extremely scarce health care resources, such as transplant organs, raises ethical challenges. The appropriate ethical frame of reference for evaluating such allocation decisions is theories of justice.

Our data show that the primary justification for placing a patient on the waiting list is probable effectiveness — the likelihood of a positive clinical outcome. Criteria that were consistent across the centres and that had a negative influence on decisions to place a patient on the waiting list were alcoholism, drug addiction, HIV positivity, primary liver cancer, noncompliance and hepatitis B. The first two were also found to be important criteria in US liver transplantation centres in the study by Levenson and Olbrisch.[2] Presumably, the reasoning is that liver transplantation for patients with these characteristics would have a low chance of success, although there are data to indicate that alcoholic patients who receive a liver can have a favourable outcome.[7] The resource allocation decision-making model here most closely resembles that of utilitarian justice.

Criteria that were used inconsistently from centre to centre in deciding which patients to place on the waiting list were lack of social support, psychiatric status, drug overdose and acute hepatic failure. We did not assess why these inconsistencies existed. Perhaps the stipulation of the criterion in the survey was imprecise; for instance, we did not differentiate between acute psychiatric illness and a history of psychiatric illness. However, some of these inconsistencies merit further discussion among representatives from transplantation centres. Why was social support an important criterion at three of the centres but not at two others? These inconsistencies may account, at least in part, for the striking variation in reported rates of acceptance of referred patients onto the waiting list.

It was reassuring that age and social status were not considered extremely or very important criteria for placing a patient on the waiting list at any of the centres. These criteria have important implications for human rights and access to health care, which seem to be recognized by the centres.

In contrast to the rationale for placing patients on the waiting list, the primary justification for allocating a liver to a patient on the waiting list was need. The criteria that consistently influenced this decision were severity of disease, urgency and blood type. Thus, the primary resource allocation decision-making model here is

Table 2: Level of importance assigned to substantive criteria for allocating available livers to patients on the waiting list

Criterion	Response; no. of centres*		
	Extremely or very important	Somewhat important	Not very or not important
Severity of disease	5	0	0
Urgency	5	0	0
Blood type *n* = 4	3	1	0
Primary liver cancer	3	1	1
Length of time on waiting list	3	0	2
Non-Canadian patient	2	0	3
Prognosis	1	2	2
Cause of liver failure	1	1	3
Hepatic vein thrombosis *n* = 4	0	1	3
Geographic location of patient	0	0	5
HLA† phenotype match	0	0	5

*Unless otherwise stated, responses were received from five of the six centres.
†HLA = histocompatibility leukocyte antigen.

grounded in egalitarian theories of justice (severity of disease and urgency), although utilitarian considerations also come into play (blood type).

Certain criteria were used inconsistently from centre to centre in deciding which patients on the waiting list underwent transplantation. These were primary liver cancer, length time on the waiting list, non-Canadian patient, prognosis and cause of liver failure. Again, we did not assess why these inconsistencies existed; they could have been due to an imprecise stipulation of the criterion in the survey. Nevertheless, these inconsistencies represent potential differences in access to liver transplantation. Why did length of time on the waiting list, which can be justified by recourse to libertarian theories of justice, influence selection decisions at three of the centres but not at two others?

It is reassuring that the geographic location of the patient consistently had little or no effect on the decision to prioritize patients on the waiting list. Unequal access among Canadians from different geographic regions to a public resource like liver transplantation would be troubling.

Selection of patients on the waiting list for transplantation is an area where the US experience is illuminating. Every liver (and other organ) transplantation is governed by the policies of the United Network for Organ Sharing (UNOS). UNOS policies are followed to prioritize patients on the waiting list for liver transplantation according to the following criteria: urgency, blood type, length of time on waiting list and donor size.[8] Specific numbers of points are awarded for various levels in each of these categories, and the person with the most points receives the next available liver. Although a report from the US General Accounting Office has raised questions about how consistently UNOS criteria are applied,[8] the UNOS approach has the advantage of producing policies that are consistent, explicit and open to public scrutiny.[9] Four of the respondents in our survey said that their centre already follows some type of point or ranking system to prioritize patients on the waiting list. A national allocation strategy, perhaps modelled on UNOS, could ensure that these point or ranking systems were consistent.

In our survey a wide variety of people were reported as being involved in deciding who is placed on the waiting list and who is selected from that list. However, almost all of the people were health care professionals, and there was little evidence of involvement of people outside the health care team. On a feminist theory of justice, it could be argued that health care professionals are in a position of power relative to patients and that this power imbalance could be redressed by having transplant recipients participate in the decision making about access to liver transplantation. Moreover, since donated organs represent a public resource, it would make sense to include representatives from the public, or even from donor families, in the decision making. Although perhaps difficult to achieve, involvement of patients, members of donor families or members of the public in setting criteria for placing patients on the waiting list or for selecting recipients from the list seems justified.

A fundamental problem in justice theory is the absence of an overarching theory that will reconcile utilitarian, egalitarian, libertarian and feminist approaches. Therefore, it is of considerable interest that resource allocation with regard to liver transplantation in Canada involves aspects of all these approaches. Is it appropriate that the initial decisions regarding placement of patients on the waiting list are effectiveness-driven and that the subsequent decisions of who on the list are selected for transplantation are needs-driven? In the absence of an overarching theory of justice, there is no principled way in which one could answer this question. However, strategies like that of UNOS are possible and arguably desirable. Moreover, liver transplantation provides an excellent model for philosophic scholars to explore how the various theories of justice might be reconciled.

In 1991 at least 37 patients died while waiting for a liver. The availability of cadaveric organs appears to be the principal limiting factor to adult liver transplantation in Canada. This suggests that it is time to re-examine alternative approaches to organ retrieval in the Canadian context. The American Medical Association's Council on Ethical and Judicial Affairs has recently recommended a system of mandated choice, in which everyone would be asked whether they consent to organ donation.[10] The Council of Europe has adopted a policy in 13 countries of presumed consent in which the onus is on the person to "opt out" of cadaveric organ donation.[11] As a matter of public policy, mandated choice or presumed consent rely very much on social acceptability, and public education and discussion are essential.

There are important limitations to our study. First, these were self-reported data; the findings might have differed if other data-collection strategies, such as direct observation of decision making, had been used. For example, although all of the respondents reported that a variety of health care providers are involved in deciding who is placed on the waiting list for liver transplantation, the influence of different kinds of caregivers may vary substantially. Second, there may be a nonresponse bias; however, this is unlikely, since six of the seven centres were represented in the survey. Third, because of social desirability bias, the respondents may have answered the questions on the basis of what they thought was expected of them rather than what actually occurs in their centre. Finally, this study could not address a variety of issues that would provide a richer appreciation of re-

source allocation for liver transplantation in Canada: how patients are initially referred to liver transplantation centres in the first place; the reasons why 58% on average of those referred are not placed on the waiting list; awareness and willingness of community hospitals to participate in provincial organ retrieval programs; whether operational definitions of terms such as "alcoholism" and "drug addiction" are uniform across centres. These questions provide the basis for continuing empirical research in this area.

Conclusion

Our data suggest that resource allocation decisions regarding liver transplantation in Canada are generally being made in a consistent manner, although there is striking variation across centres in the importance given to certain criteria such as social support (for deciding who is placed on the waiting list) and length of time on the waiting list (for deciding who is selected from the list). Almost all participants in decision making are health care professionals; participation from potential or past transplant recipients, members of donor families or members of the public may be warranted. Philosophic scholarship will be needed to determine whether the balance struck between effectiveness-based and needs-based approaches is appropriate; the liver transplantation model might serve as a helpful context for this work. Finally, because patients die while on the waiting list and because the primary limiting factor is organ supply, increased organ acquisition efforts are needed.

The University of Toronto Joint Centre for Bioethics is supported by a grant from the Ontario Ministry of Health (no. 03006). Dr. Mullen held a doctoral fellowship from the Social Sciences and Humanities Research Council of Canada at the time of writing. Dr. Singer is supported by the National Health Research Development Program through a National Health Research Scholar award.

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