

## Priority Setting in the Assessment for Kidney Transplant Candidacy: A Canadian Case Study

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### Abstract

The benefits of kidney transplantation for treating kidney failure are well documented in terms of life expectancy, quality of life, and cost savings, making it the treatment of choice. It is however limited by the chronic shortage of kidneys. This study's objective is to examine the fairness of the priority setting process underpinning the assessment for kidney transplant candidacy in one of Canada's largest transplant programs at the Toronto General Hospital (TGH). This is done in reference to the Accountability for Reasonableness; a leading international framework in health care priority setting.

The study relies on three sources for data collection: semi structured interviews, process observation, and review of relevant documents.

The process underpinning the assessment for kidney transplantation is based on clusters of medical criteria reflecting the Canadian national consensus guidelines on eligibility for kidney transplantation. The process is permeated by ethical principles such as: maximizing benefit, equal treatment, and respect for autonomy; which are widely considered relevant in the distribution of scarce medical resources and in medical ethics generally. The criteria for assessment are well publicized and easily accessible while appeals through second opinions are well developed and supported. The process underpinning access to kidney transplantation at the TGH readily satisfies the conditions for fairness in references to the Accountability for Reasonableness framework.

### Introduction

In 2009 38,000 Canadians were living with kidney failure, 11,000 more than two decades earlier [1]. In the same period the number of people waiting for kidney transplantation increased from 1600 to 3000 [1]. The increase is driven by multiple factors including an aging population, and a higher incidence of conditions contributing to kidney failure such as diabetes and obesity [1]. The availability of kidneys required for transplantation has not increased at the same rate. Kidney transplantation has the distinction of being both the most widely performed type of solid organ transplantation in Canada, and the one with the longest waiting times [1]. The benefits of kidney transplantation for the treatment of kidney failure are well documented in terms of life expectancy, quality of life, and cost savings, making it the treatment of choice [2-4]. Various efforts have been made to bridge the gap, including but not limited to, extended criteria donation, domino transplants, and easing relationship restrictions for living donation. [5]. Unfortunately these efforts remain insufficient to meet the need, and not all who can benefit from a transplant currently receive one. With the persistent shortfall arise important questions regarding fairness in the distribution of kidney transplantation as a scarce medical resource.

Fairness in the distribution of scarce medical resources is a pervasive concern for patients and health care systems alike. Fairness may be viewed in different ways, as such disagreements amongst various claims on fairness are not uncommon [6]. It can be claimed that fairness is seeking out the greatest utility from donated kidneys, as a scarce medical resource, by transplanting them where the longest graft life is achieved [7,8]. Fairness may also be seen as giving priority to those worst off or those expected to be worst off without a transplant [7,8]. Both these arguments for fairness are cogent and based on morally relevant values, but neither can independently satisfy our complex moral values [8]. When no single ethical principle can guarantee that our complex moral values are satisfied, decisions are

often based on multiple principles where values are traded off for an appropriate balance.

Transplant programs give weight to competing moral principles when allocating scarce resources. Recognizing this plurality of ethical principles governing priority setting in the distribution of scarce medical resources, it may be more suitable to evaluate priority setting in this context from a procedural approach rather than focusing on outcomes alone. This is because we may reasonably disagree on what outcomes are desirable depending on the philosophical and moral point of departure (e.g. maximizing utility vs favoring the worst off) [6,9]. A leading paradigm within this approach is the Accountability for Reasonableness framework developed by Daniels and Sabin [6]. This ethical framework has been widely used over the past decade and proven useful when addressing procedural aspects of fairness in priority setting processes [9-12]. The framework stipulates four necessary conditions for a fair and legitimate process for priority setting (Table 1).

This study's objective is to comment on the fairness of the priority setting process in the assessment for kidney transplant candidacy, (using kidneys from deceased donors) in one of Canada's largest kidney transplant programs at the Toronto General Hospital (TGH).

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This will be done in reference to the Accountability for Reasonableness framework (Table 1), [6].

## Study Setting

In Canada, universal access to publicly funded health care is mandated by the Canada Health Act of 1984. The actual provision of health care services, however, is the responsibility of the 10 provincial and 3 territorial governments which together make up the Canadian Federation [13]. Ontario is the most populous province with the Greater Toronto Area having a population of approximately 6 million.. As with most other provinces Ontario has an Organ procurement organization, the Trillium Gift of Life Network, which is responsible for maintaining waiting lists and overlooking the allocation of organs. However individual transplant centers retain discretion over the listing of patients on transplant waiting lists. Toronto has two adult kidney transplant centers, St. Michael’s Hospital, and the TGH where this study took place.

TGH is a teaching hospital, and is part of the University Health Network whose multi-organ transplant program is the largest in Canada [14]. The hospital offers a number of different modalities of dialysis treatment alongside the 150-170 kidney transplants performed annually. A Kidney transplant team is responsible for assessing candidates for kidney transplantation. The team is heterogeneous in a number of regards. There is a wide variety of ages and professional experiences ranging from a few years to over three decades of experience. A number of professions are represented including nephrologists, surgeons, nurses, socials workers, and immunologists; who are involved in clinical, academic, and research activities.

## Methods

The project relied on three sources for data collection: semi structured interviews, process observation, and review of relevant documents. In depth semi structured interviews were conducted with key members in the Kidney Transplant program at TGH. Questions were designed to elucidate priority setting decisions in the kidney transplant assessment and were broadly designed to cover the four conditions of the Accountability for Reasonableness framework. Seven interviews included transplant nephrologists, transplant surgeons, a transplant coordinator, and a non-transplant nephrologist (responsible for referring patients to the transplant team). All Interviews were recorded and transcribed verbatim. The method used to analyze the interviews was thematic analysis, an approach that facilitates identifying patterns within data relating to the research questions [15]. A secondary source of data was process observation whereby the primary researcher observed for 4 months the weekly listing meetings where decisions on acceptance to the waiting list are made. Meetings attendees included transplant nephrologists, transplant surgeons,

transplant coordinator nurses, and social workers. Documents and guidelines concerning the assessment for transplant candidacy were reviewed as a tertiary source of data. The use of three data sources allowed for triangulation, comparing and validating information from one data source with information from the other data sources [16]. The project was approved by the University Health Network Research Ethics Board.

## Results

The results will be presented in two parts. First we describe the context in which listing decisions are made. Then we will expound the priority setting process in relation to the Accountability for Reasonableness ethical framework.

### Decision making context

“Well first of all you are more likely to catch issues that you need to think about if there are several people thinking about it. Second of all ...we can all share in on the decisions. And for some of the tougher cases I am much happier if it’s not just me that is deciding, but if I am deciding with several of my colleagues. It also allows for the non MDs to play a role. So I think it is good for all those reasons.”

Listing decisions are made in a weekly meeting by a multidisciplinary team. Meetings begin with general department updates and administrative discussions. This is an opportunity to publicize activities within the department not tied to particular patients and to invite opinions on new developments. The group then transitions onto individual patient cases. Some of the team will have already met the patient, whose case is presented, having undergone a standard evaluation. Relevant issues in each patient case are presented to the meeting attendees, followed by a discussion. In “straightforward cases” such as patients with no serious co- morbidities the presentations and discussions are brief. Where there are issues which can cause concern more in-depth discussion is necessary. Team members raise concerns, from their particular professional perspectives. This can be a nephrologist’s concern about the absence of a certain medical investigation which they feel is indicated before a final decision on admission to the list is made. Another example could be a social worker’s need for assurance that a patient will have access to the necessary social networks post transplantation, to increase rates of compliance with post-operative regiments. In instances where further information is required, the case is slated to be revisited pending results from the relevant investigation or other necessary updates. Alternatively all details about a case can be discussed in full during the meeting and a final decision regarding listing reached. When a final decision is made, phrases such as “so we are in agreement that” or “it sounds like what we are saying is” were used to secure group consensus in decisions. These terms serve both to publicize the final decision taken, and ensure mutual agreement on the final decision and factors used for making the decision. This shared decision making invited new perspectives which a single decision maker may not consider on their own. Furthermore it allows them to share accountability for the final decision, which is particularly important in cases where patients are denied admission to the list. The decision making environment was interactive and inclusive. The relationship between decision makers was always palpably courteous and interactive. Team members from the various professions all reported feeling that their perspectives are seen as valuable. The prevailing sense within the listing meetings regarding patient cases was that the team did not look for reasons to disqualify a patient from being placed on the list, but rather of trying to make the case for how a patient could be placed on the list.

Relevance condition	Rationales for limit setting decisions must rest on reasons and principles that fair minded people can agree are relevant in meeting the diverse needs of the population, in the context of reasonable resource constraints. Fair minded people seek mutually justifiable grounds for cooperation.
Publicity condition	Limit setting decisions and their rationales must be publicly accessible
Revisions& appeals condition	There is a mechanism for challenging and disputing decisions of limit setting , as well as the opportunity to revisit decisions in light of further evidence
Enforcement condition	There is voluntary or public regulation to ensure that the first three conditions are met

**Table 1:** Conditions of the Accountability for Reasonableness framework [6].

## Assessment process and the accountability for reasonableness

**Relevance:** Decisions regarding listing are based on clusters of factors which together shape the final decisions. The criteria which are used for carrying out the assessment are generally those which have been created in 2005 by the Canadian Society of Transplantation in the form of national consensus guidelines [17]. Table 2 contains a list of criteria outlined in the consensus guidelines. Factors considered during the weekly listing meetings and factors discussed by decision makers during interviews were reflective of the general criteria found in table 2. The criteria outlined in the consensus guidelines have undergone a robust process by key scientists involved in kidney transplantation and have been agreed to be the relevant issues in the assessment for transplant candidacy across the nation. The guidelines cover several areas each of which underwent a rigorous literature review by members of a guidelines committee representing various parts of the country. The recommendations are rated according to the level of evidence available (from A to D), and recommendations were critiqued and revised until consensus was reached on the contents of the guidelines (For a detailed account of the recommendations and rating of the evidence base for them refer to Canadian consensus guidelines) [17].

Those interviewed indicated that the practices at the center generally reflect the guidelines; they were viewed positively as captured here by one of the transplant nephrologists:

“any attempt to systematically assemble information whether the information is good or bad to try and guide practice is a positive thing. I think generally the evidence base in this area is fairly weak so much of it is as much data as it is opinion. At the same time I don’t think that opinion is a negative thing as long as opinion comes from a good place i.e.: it tends to be collective and is based on some rationale and data preferably”

The consensus guidelines were believed to contribute to the transparency, accountability, and legitimacy of the priority setting process: “we are not practicing out of left field. We are practicing in a way that is felt to be in line nationally”.

Alongside the factors covered in the consensus guidelines the decision making was permeated by underlying ethical principles. To illustrate how ethical values figure into the decision making we present some scenarios (similar to those encountered in the listing meeting or based on examples discussed during interviews) and pinpoint

•	Timing of referral
•	Renal function
•	Age and functional capacity
•	Obesity
•	Systemic diseases
•	Infections
•	Malignancy
•	Pulmonary disease
•	Cardiac disease
•	Cerebral vascular disease
•	Peripheral vascular disease
•	Gastrointestinal disease
•	Liver disease
•	Genitourinary disease
•	Hematologic disorders
•	Hyperparathyroidism
•	Psychosocial considerations

**Table 2:** List of considerations in the assessment for kidney transplant candidacy Factors.

what ethical principles help shape the decision making. The ethical principles presented here are not meant to be exhaustive of all possible ethical principles considered in assessment for transplant candidacy, but rather to give an overview of what emerged as the major categories of ethical considerations impacting on the decision making process.

Consider a patient with advanced cardiac disease, a condition which can have an adverse effect on post-transplant prognosis, graft survival and can pose an immediate and heightened risk to the patient during the transplant surgery. In such a case the team will consider a number of different factors simultaneously i.e. the chance of patient and graft survival. The team will consult a cardiologist regarding the chances of the patient dying purely due to their heart disease. If the chance of this is extremely high, the transplant will not proceed. This decision is based on two principles: non maleficence (not harming the patient), the risk to the patient is not justifiable and secondly the desire to maximize benefit by not transplanting a patient if the predicted graft life is extremely low.

Consider another patient with cardiac disease, also high risk which, however, falls within a reasonable range. This patient is informed of the risks, and allowed to make a decision regarding kidney transplantation with that information in mind. This patient may be predicted to live a much shorter time than a low risk candidate whose graft survival may be measured in decades. As one respondent indicated, this is not the important fact. Rather consideration is framed thus: “not what is your risk compared with the lowest risk patients, but what the odds are (of survival) for yourself of getting a transplant compared with staying on dialysis”. Here the maximization of benefit is balanced against the respect for autonomy for the patient to accept a certain level of risk, and allow the patient to have an equal opportunity to have their medical needs met.

Finally consider a scenario of a patient being considered for a third transplant, while other patients have yet to receive their first. Allowing such a patient to be relisted is a matter which can generate considerable disagreement since it can seem unfair to give some individuals multiple kidneys, while they are in short supply. The TGH kidney transplant program does not rule out such patients for transplant and will give them equal consideration with other candidates. This is driven by the principle of equal treatment via equal opportunity for having current needs met irrespective of previous history of transplantation.

**Publicity:** The eligibility criteria for the assessment of patients for transplantation are readily accessible through a simple search on the internet. The 2005 consensus guidelines are available through the Canadian Medical Association Journal. Other publicity initiatives include outreach visits by transplant nephrologists to the larger dialysis units whose patients are evaluated for transplant at TGH. Outreach meetings provide an opportunity to explain the evaluation process to the ESRD population, and to answer patients’ questions or concerns about the evaluation process. Actual decisions, and the criteria used to reach them within the department, are well publicized. Decisions are communicated to the patients individually.

The fact that the eligibility criteria are explicit and easily accessible as consensus guidelines was seen by members of the transplant team as a helpful mechanism for patients and professionals alike; one which contributes to transparency and legitimacy:

“If we can show the patient and say look we have national guidelines that say if you have terrible heart diseases and you should not be on the transplant list, so it makes it a much more transparent process. The patients can look at something and kind of see what the standards are

if they are worried that their physician is not being appropriate. So I think it is helpful.”

**Appeals:** Patients denied admissions to the waiting list are informed about the decision personally. When there are further questions or concerns, they are invited to the center for a meeting with a transplant nephrologist. If the patient wishes to seek a second opinion they are given the opportunity to have their files sent to St. Michael’s Hospital or to a transplant center of their choice within the province. Second opinions were viewed as an important patient right, and were supported at all levels of the department. This is the primary mechanism of appeals in the system. However there are opportunities to overturn a denial decision within the center if new relevant information emerges which can alter the original denial.

**Enforcement:** Certain mechanisms enforce consistency in the decision making. Listing meetings were a clear example of this. By making all decisions within a group setting, variances which can arise from a particular decision maker can be minimized leading to more equalized treatment between patients. Annual retreats for the kidney transplant team act as another program level enforcement mechanism. In these retreats the team reviews existing practices and policies to judge their continuing relevance and enact necessary changes such as follow up care for wait listed patients. Considering the long waiting times for transplantation, the team observed that some patients were medically unfit when called in for the transplant. A policy was developed to recall patients for evaluation within a year of their pending transplant to ensure suitability for transplantation.

The consensus guidelines contribute to enforcing the first three conditions of the framework. The guidelines help ensure that factors agreed as relevant are used in decision making. Furthermore the ease of accessibility of these guidelines to both professionals and the general public helps to meet the publicity condition of the framework. Finally, the guidelines explicitly state the right to second opinions (appeals) to patients who have been denied admission to the list (Table 2),[17].

## Discussion

Fairness is a concern shared by health care systems and patients alike. This issue becomes more pronounced in light of resource scarcity, be it due to budgetary cutbacks, or the persistent shortage in organs needed for transplantation. The fact that some patients will not have access to kidney transplantation either at all, or in time with serious ramifications on health and life, forces scrutiny of the setting of priorities to distribute scarce resources in a fair and legitimate manner. This can be challenging since society’s moral values are multiple and it is difficult to find one moral principle which will satisfy our complex moral values [8]. Health care systems must set priorities by trading off values to reach a balance between our moral differences. This is where the Accountability for Reasonableness framework makes its most important contribution by shifting attention to the fairness and legitimacy of the process in which decision making occurs. The hope is that if we agree on the fairness of the process, we are more likely to agree on decision outcomes also. In our opinion, the priority setting process underpinning the assessment for admission to the kidney transplant waiting list at the Toronto General Hospital readily satisfies the relevance conditions of the Accountability for Reasonableness framework. The process underpinning the assessment for kidney transplantation is based on clusters of medical criteria, a finding which reflects the literature dealing with clinical level priority setting [11,12]. The criteria used for decision making are in accordance with evidence based medicine and established medical experience and

have been produced in a transparent process, aimed to create national consensus. The underlying principles which are balanced, such as the maximization of benefit and equal treatment, are in accordance with principles considered relevant in the distribution of scarce medical resources. Further principles which were observed such as non-maleficence and respect for autonomy are also widely recognized as relevant decision making principles in medical ethics [18].

It is important that these principles be balanced in a way that is considered fair. This is an area where reasonable disagreement can be expected, and why the conditions of publicity and appeals become central. We believe these conditions are adequately met in the current case study. The criteria used for decision making are well publicized on multiple levels. Publicity is achieved within the center during listing meetings. Externally, the information relating to evaluation criteria is readily available as the consensus guidelines, and outreach activities attempt to engage in dialogue with patient groups and other professionals. The decision re listing is relayed to patients directly and opportunities for further discussion, and second opinions are readily offered.

The existence of explicit guidelines acts as an enforcement mechanism since they can be used to repeal and challenge overly divergent practices which encroach on the right to access to the kidney transplant waiting list. They also explicitly require that decisions and rationales be made transparent, and second opinions offered, further meeting this requirement of the Accountability for Reasonableness framework. We believe the explicit consensus guidelines are a clear indicator of good practice which deserves to be highlighted. Another good practice is the listing meetings which were observed by the primary researcher. Not all transplant programs discuss every patient case in a heterogeneous multi professional team. These multiple perspectives invite more relevant factors to the decision process, also insuring that differences in decision making between professionals are minimized. This practice lends to the fairness and legitimacy of the priority setting process by creating consensus amongst multiple decision makers. Outreach activities, for the purpose of patient engagement, by the transplant program also deserved mention as a good practice. Efforts to engage patient groups have the potential to contribute to transparency and increasing the perceived fairness of the priority setting process.

A limitation of the study is that it is a single case study of one kidney transplant center in Toronto. There is little to ensure that the practice is the same elsewhere. However, all transplant programs grapple with similar challenges and the findings of this study will have implications for most kidney transplant programs. This study was concerned with fairness from an institutional perspective. Further research should involve patient groups since perceived fairness of decision making by those effected by decisions lends to the legitimacy of the decision making process [19]. A critique of the Accountability for Reasonableness framework is the limited role it assigns to a wider deliberative process by limiting public input [20,21]. Including patient and even public views on fairness in listing for kidney transplantation could address this limitation.

Finally admission to the waiting list is the initial stage in a process to access kidney transplantation. As this waiting list can reach up to 10 years, kidney allocation practices are important because some patients may not live long enough to be transplanted. Future research capturing the priority setting process in the allocation of kidneys would provide a more comprehensive picture of the complete process.

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