

# Technology *Report*

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Criteria for  
Selection of Adult  
Recipients for  
Heart, Cadaveric  
Kidney, and Liver  
Transplantation

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**Canadian Coordinating Office for Health Technology Assessment**

**Criteria for Selection of Adult  
Recipients for Heart, Cadaveric Kidney,  
and Liver Transplantation**

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CCOHTA

July 1999



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# SOMMAIRE

La demande d'organes entiers pour la transplantation dépasse toujours, et de loin, le nombre d'organes disponibles au Canada. En raison de l'écart considérable entre le nombre de candidats à la transplantation et le nombre de donateurs d'organes au pays, les centres de transplantation ont dû déterminer un mode d'établissement des listes d'attente.

L'objectif de la présente étude consiste à analyser, des points de vue éthique et social, les modes d'établissement actuels des listes d'attente dans les cas de transplantation de coeur, de rein d'une personne décédée et de foie. Nous avons cerné les critères de sélection courants des receveurs adultes de transplantation de ces organes par le biais d'une enquête nationale effectuée auprès des centres de transplantation du Canada.

Un questionnaire a été envoyé par la poste à 34 centres de transplantation au Canada, dont dix centres de transplantation cardiaque, 16 centres de transplantation rénale et huit centres de transplantation de foie. Le questionnaire comporte 5 sections, soit les données démographiques et relatives à l'emploi, les maladies concomitantes, la pharmacodépendance, le soutien social et communautaire, et les types de transplantation. Trente-deux centres ont fait parvenir le questionnaire dûment rempli, à savoir neuf centres de transplantation cardiaque, 16 centres de transplantation rénale et sept centres de transplantation hépatique, ce qui correspond à un taux de réponse de 94 %.

Les résultats de l'enquête indiquent que les centres de transplantation de coeur, de rein d'une personne décédée ou de foie au Canada ont recours, de façon générale, à des modes apparentés d'établissement des listes d'attente. Toutefois, le degré d'importance accordé à certains critères de sélection varie d'un centre à l'autre, tant au sein des groupes de centres effectuant le même type de transplantation, que parmi tous les centres. En ce qui concerne les centres qui effectuent le même type de transplantation, la variabilité du degré d'importance s'applique aux critères suivants : l'âge du receveur (rein), sa situation professionnelle (coeur), et la nationalité et l'aptitude mentale (foie). D'autre part, on constate une variabilité du degré d'importance entre tous les types de centres en ce qui a trait aux facteurs suivants : le tabagisme et les exigences en matière de programmes établis de soutien social et communautaire.

Au vu de ces constatations, il serait avantageux de normaliser à l'échelle nationale les critères de sélection des receveurs de transplantation de coeur, de rein d'une personne décédée et de foie afin d'assurer l'accès équitable à cette ressource publique au Canada. Cette normalisation revêt une importance primordiale étant donné les aspects d'ordre éthique et social rattachés aux critères en question. Les critères de sélection ont des répercussions sur le plan des droits de la personne, de l'accès aux soins de santé, du consentement éclairé, et du rôle de la régulation et de la responsabilisation en regard de la maladie.

# EXECUTIVE SUMMARY

The demand for solid organs for transplantation continues to exceed, by far, the supply available in Canada. As a result of the severe discrepancy between the number of transplant candidates and the number of donor organs available in Canada, it has been necessary for transplant centres to develop methods for determining which patients are selected for the waiting lists.

This study reviews current patient listing practices for heart, cadaveric kidney, and liver transplantation from ethical and social viewpoints. Current criteria for adult recipient selection for these organ types was identified through a nationwide survey of transplant centres across Canada.

A mail survey of 34 transplant centres throughout Canada was sent to ten heart centres, sixteen kidney centres, and eight liver centres. The survey consisted of five sections: demography and employment, comorbid disease, substance abuse, social and community support, and types of transplants performed. Thirty-two transplant centres responded to the survey. This corresponds to a participation rate of 94%; representing nine heart centres, sixteen kidney centres, and seven liver centres.

The survey results demonstrate that heart, cadaveric kidney, and liver centres in Canada generally practice similar methods of listing patients awaiting transplantation. However, the degree of importance given to certain patient criteria varies, both within a particular organ group and between organ types. Differences between centres within a solid organ type were observed in the priority given to such criteria as recipient age (kidney), employment status (heart), recipient nationality and mental competence (liver). The degree of importance given to factors such as tobacco use, and the requirement for established programs for social and community support, vary among the solid organ types.

Given these findings, it would be of benefit to standardize organ-specific criteria at the national level for patients waiting for heart, cadaveric kidney, and liver transplantation to ensure equitable access to this public resource in Canada. This is of paramount importance given that there are ethical and social implications associated with the factors under consideration. Criteria for patient listing have implications for human rights and access to health care, informed consent, and the role of control and responsibility for illness.





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# 1. PURPOSE AND SCOPE

The following objectives were identified for study:

- (i) Identify current criteria for adult recipient selection for heart, cadaveric kidney and liver transplantation in Canada;
- (ii) Examine the ethical and social implications of criteria for selection.

This study is designed to review current listing practices for heart, cadaveric kidney, and liver transplantation from ethical and social viewpoints. This document addresses the first objective of the study through a nationwide survey of transplant centres across Canada, and the second objective through a review of the literature.

## 2. INTRODUCTION

In Canada, organ transplantation is a widely practised medical procedure, fully funded by provincial health insurance plans. The number of heart, kidney, and liver transplants performed between 1981 and 1995 covers more than 95% of solid organ transplants performed Canada-wide.<sup>1</sup> Of the more than 1,600 heart transplants performed in Canada from 1981 to 1995, 68% of recipients were alive as of December 31, 1995.<sup>1</sup> Similarly, of the more than 15,000 kidney and 2,000 liver transplants performed in Canada from 1981 to 1995, 53% and 65% of recipients respectively, were alive as of December 31, 1995.<sup>1</sup>

Despite these compelling numbers, the demand for these solid organs for transplantation continues to exceed, by far, the supply available in Canada. For example, as of September 30, 1996, there were 107, 2394, and 196 patients, awaiting heart, kidney, and liver transplants respectively, in Canada.<sup>1</sup> The shortage of donor organs is principally responsible for the gap between the supply and demand for transplantation. To primarily examine the organ donation problem in Canada and the appropriate role for the federal government in addressing this issue, the House of Commons Standing Committee on Health undertook a study of the state of organ and tissue donation and transplantation in Canada. The Committee recommended the establishment of a Canadian Transplant Network under a federal/provincial/territorial structure.<sup>2</sup> Four key considerations were identified for a national approach: 1) individual donor intent and consent; 2) donor identification, management and procurement; 3) waiting, sharing, and allocation; and 4) transplantation outcomes.<sup>2</sup> The Committee recommended the following activities for waiting, sharing, and allocation: (i) facilitate the establishment of a national real-time waiting list for all solid organs, (ii) assist in public awareness and professional education and training initiatives, (iii) monitor the development of sharing algorithms for allocation and any mechanism for enforcement of sharing, and (iv) provide a tracking system for information and encourage policy development on the import and export of organs and tissues.<sup>2</sup>

As a result of the severe discrepancy between the number of transplant candidates and the number of donor organs available in Canada at the present time,<sup>1</sup> it has been necessary for transplant centres to develop methods for determining which patients are selected for the waiting list. Although patients with end-stage kidney failure have the option of long-term hemodialysis or transplantation, those with progressive heart and liver failure will die unless they receive an organ transplant. Moreover, while dialysis is available for patients with renal failure, recipients of kidney transplants have significantly lower death rates than patients maintained on dialysis, irrespective of their age.<sup>3</sup> Transplantation of heart, kidney, and liver thus raises ethical and social issues of who shall live and who shall die.

## **3. METHODOLOGY**

### **3.1 Survey Design and Sample**

A mail survey was conducted of adult heart, kidney and liver transplant centres in Canada. The centres were primarily identified using the "Directory of Participating Dialysis Centres, Transplant Centres and Organ Procurement Organizations in Canada, 1998," published by the Canadian Institute for Health Information (1998).<sup>4</sup> A questionnaire, accompanied by a cover letter and consent form detailing the project rationale (Appendix 4), was sent to the medical director of each centre, or a designate: ten heart, sixteen kidney, and eight liver [n=34]. Transplant centres in Quebec were sent the materials in both official languages. Two weeks following the initial mailing, all centres were contacted by fax to confirm receipt of the mail survey and to determine their willingness to participate in the study. Non-respondents were further contacted by telephone and when requested, were sent another questionnaire package by mail. Respondents were given a pre-addressed, prepaid envelope to return the questionnaire with the signed consent form.

The questionnaire, comprising five pages, was divided into five sections: (1) demography and employment, (2) comorbid disease, (3) substance abuse, (4) social and community support, and (5) types of transplants performed. Response categories consisted of open- and close-ended responses including a 5-point Likert scale to rate the degree of importance (no importance [I-0]; relative importance [I-1, I-2, I-3, I-4]; and absolute importance [I-5]) of the various factors under the first three sections. Descriptive statistics were used to analyse the survey data.

To avoid excluding particular transplant programs, especially in light of the small samples of heart and liver centres in Canada, a survey pretest was not undertaken. However, a Canada-wide network of seven individuals from relevant disciplines, including two reviewers active in transplantation, assisted in both redrafting the questionnaire and consent form and updating the list of participating transplant centres in Canada. Further clarification of the nature and number of programs in existence was provided by a representative of the Canadian Society of Transplantation.

### **3.2 Literature Search**

Published literature was obtained by searching a number of bibliographic databases. The specific databases, keywords and search strategies are outlined in Table 1. Retrieval was limited to human studies and covered the period from January 1994 to March 1999. Databases searched included MEDLINE, EMBASE, HealthStar, BIOSIS Previews, Pascal, PsychINFO, Sociological Abstracts, Social SciSearch and BioethicsLine.

This search was supplemented by hand-searching of selected journals and bibliographies in the CCOHTA library collection as well as regular database searches in the Current Contents, Clinical Medicine database to keep abreast of new developments.

Relevant articles were retrieved, reviewed and classified by subject. Two members of the project team independently reviewed the database searches to identify relevant articles for this report.

**Table 1: Databases Searched and Description of Searches**

DATABASES	DATE RANGE	LIMITS	STRATEGY
<i>DIALOG:</i>  MEDLINE ; PsychINFO ; Sociological Abstr ; Social SciSearch ; BIOSIS Previews ; EMBASE ; Pascal	1994 - 1999	Human	liver transplantation/de <b>OR</b> kidney transplantation/de <b>OR</b> heart transplantation/de <b>OR</b> liver(w)transplant?/ti,ab <b>OR</b> kidney(w)transplant?/ti,ab <b>OR</b> Renal(w)transplant?/ti,ab <b>OR</b> heart(w)transplant?/ti,ab <b>AND</b> patient selection/de <b>OR</b> patient(w)selection/ti,ab <b>OR</b> patient(2n)selection/ti,ab <b>OR</b> selection(2n)criteria/ti,ab <b>AND</b> adult! <b>OR</b> adult/de <b>OR</b> adulthood/de <b>OR</b> aged/de <b>OR</b> adult/ti,ab <b>OR</b> adulthood/ti,ab <b>OR</b> aged/ti,ab <b>OR</b> elderly/ti,ab <b>OR</b> middle(w)age?/ti,ab
<i>Internet Grateful MED:</i>  BioethicsLine	1994 - 1999	Human	organ transplantation <b>AND</b> (kidney? <b>OR</b> heart? <b>OR</b> liver?) <b>AND</b> (patient selection <b>OR</b> selection for treatment <b>OR</b> transplant recipient?)
<i>Internet Grateful Med:</i>  HealthStar	1994 - 1999	Human	kidney transplantation <b>OR</b> heart transplantation <b>OR</b> liver transplantation) <b>AND</b> patient selection <b>OR</b> selection for treatment <b>OR</b> transplant recipients)

## 4. RESULTS

Thirty-two (94% total) transplant centres participated in the study; representing participation from nine (of ten) heart centres, sixteen (of sixteen) kidney centres, and seven (of eight) liver centres. Of the non-respondents, two program directors (one heart and one liver) failed to respond by the survey deadline for participation.

### 4.1 Heart Transplantation

The respondents assigned degrees of importance (none [I-0]; relative [I-1, I-2, I-3, I-4]; absolute [I-5]) to the factors listed in the relevant sections, for listing patients on the waiting list (Appendix 1). Age was of relative importance [I-3] in the decision to list patients for heart transplantation for all eight centres responding to this factor (Figs. 1 & 2). In contrast, race was not of consideration [I-0] in the decision to list by any of the participating heart centres (Fig. 1). Responses to the levels of importance assigned to the other demographic and employment factors varied between heart centres: three (33% of) centres considered the patient's employment status [I-2]; one centre, sex [I-3] and insurance status [I-3]; and one centre, nationality [I-4] (as it relates to Canadian residence-citizenship) in the decision to list patients for transplantation (Fig. 1).

The presence of HIV infection and malignancy, on average, were very important [I-5] determinants in the decision to list patients for heart transplantation (Figs. 3 & 5). The presence of hepatitis B and hepatitis C infection were also of great importance [I-4] in listing (Figs. 3 & 5). All heart centres also consider, albeit through varying degrees of importance, the patient's mental competence [I-5, I-4, I-3] and psychiatric illness [I-5, I-4, I-3, I-2] in the decision to list (Fig. 4). Degrees of importance assigned to the other comorbid diseases factors varied between heart transplant centres (Figs. 3 & 4).

All nine heart centres consider alcohol abuse, active tobacco use, and illicit drug use to be of significant importance [I-4, I-4 and I-5, respectively] in the decision to list patients for heart transplantation (Figs. 6 & 7). Seventy-eight percent of the centres require that the patient follow a formal treatment program prior to activation on the waiting list (Fig. 8); however, only 29% of these centres require that the patient sign a formal contract in this regard (Fig. 9). Based on the qualitative responses, six months of abstinence before transplantation (range 3-12 months), on average, is required for patients with recent substance abuse.

Seventy-eight percent of the heart centres, require that the patient have established programs for social and community support prior to listing (Fig. 10). All of the heart transplant centres surveyed performed heart alone procedures; 56 % perform heart and lung, heart and cadaveric kidney, and heart and liver procedures also (Fig. 11). No clear-cut differences were observed in program criteria between single-organ versus double-organ procedures when listing patients for heart transplantation.

## 4.2 Kidney Transplantation

In listing patients for cadaveric kidney transplantation (Appendix 2), 81% of the participating centres gave relative importance to age [I-1, I-2, I-3 or I-4] (>70 years, for example), (Figs. 1 & 2). In the decision to list, 38% and 33% of kidney centres also take into consideration insurance status [I-2] and nationality [I-1] (as it relates to national/provincial residence-citizenship) respectively (Figs. 1 & 2). The remaining employment and demographic factors were either of relatively minor (employment status, [I-0, I-1]) or no importance (race [I-0]; sex [I-0]) in listing patients for cadaveric kidney transplantation (Figs. 1 & 2).

Presence of the comorbid disease factors HIV infection, malignancy, liver disease, and cardiovascular disease, on average, were considered to be of great importance [I-5, I-4, I-4 and I-4, respectively] in the decision to list a patient (Figs. 3, 4 & 5). Degrees of importance assigned to the other comorbid disease factors varied between centres (Figs. 3 & 4).

All sixteen centres considered alcohol abuse and illicit drug use to be of relative importance [I-3] in listing patients for cadaveric kidney transplantation (Figs. 6 & 7). Fifty-six percent of the kidney centres, albeit to a lesser degree of importance, also consider tobacco use in the decision to list (Figs. 6 & 7). Sixty percent of the centres require that the patient follow a formal treatment program prior to activation on the kidney waiting list (Fig. 8); however, 22% of these centres require that the patient sign a formal contract in this regard (Fig. 9). An abstinence period of six months (range 6-12 months), on average, is recommended for patients with current alcohol abuse or illicit drug use.

Nineteen percent of the centres require that the patient have established programs for social and community support prior to listing for cadaveric kidney transplantation (Fig. 10). Eighty-eight percent of centres surveyed perform cadaveric kidney only transplants; 31% perform kidney and pancreas, kidney and heart, and kidney and liver procedures (Fig. 11). Based on the qualitative responses to section five (Fig. 11), more restrictive criteria may be applied in cases of double-organ procedures related to kidney transplantation.

## 4.3 Liver Transplantation

Six of seven liver centres responded to the category of age [I-2.5] as a factor in listing patients for transplantation (Appendix 3, Figs. 1 & 2). Four (57% of) liver centres, consider patient nationality (as it relates to Canadian citizenship) [I-2] in the decision to list (Figs. 1 & 2). Insurance status was also considered of significant importance [I-3, I-5] by two (29% of) centres (Fig.1). Other employment and demographic factors were of little importance with the exception of employment status [I-1] by one liver centre (Fig. 1).



As with the other solid organ groups, on average, the presence of HIV infection and malignancy [I-5] were very important factors in the decision to list (Figs. 3 & 5). In addition, all liver centres considered cardiovascular [I-4], pulmonary [I-4], liver disease [I-4.5; n=6], mental competence [I-3] and psychiatric illness [I-3], in listing patients for transplantation (Figs. 4 & 5). Alcohol abuse and illicit drug use, were considered to be of great importance [I-4], in the decision to list, by all liver centres (Figs. 6 & 7). Five (71% of) liver centres required that a patient follow a formal treatment program prior to activation on the waiting list (Fig. 8). Only one of the seven centres presently requires that the patient sign a formal contract for candidates with recent substance abuse (Fig. 9). As with the other solid organ groups, based on the responses to section three, a six-month abstinence period seems to be the norm for patients with recent alcohol abuse or illicit drug use.

Fifty-seven percent of the liver centres require that the patient have established programs for social and community support prior to listing for transplantation (Fig. 10). All liver transplant centres surveyed perform liver and cadaveric kidney procedures, 86% perform liver only, 57% perform liver and heart, and 14% perform liver and intestine (Fig. 11). No fundamental differences were noted in the listing criteria in cases of double-organ procedures compared to liver-alone transplantation.

## 5. LIMITATIONS OF STUDY DESIGN

There are important limitations to this study. First, in terms of the 5-point Likert scale, reference to "absolute" for point five in terms of the degree of importance of the factors under the first three sections may have dissuaded some respondents in rating a factor for this point; "very important" would have been a more suitable reference for point five. Second, certain factors as defined in the survey may have been considered ambiguous. For example, under nationality, more specific responses would have been elicited if a distinction had been made between Canadian citizenship versus foreign nationality. Third, there may be a non-response bias; however, this is unlikely, since a majority of the centres were represented in our survey under each of the three solid organ types. Fourth, 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 transplant centre. Finally, these were self-reported data; our findings may have differed if other study designs, such as direct observation of the decision-making process, had been used.

## 6. DISCUSSION

Our data demonstrate that although heart, cadaveric kidney, and liver centres in Canada generally practice similar methods of listing patients, there is variability in the degree of importance given to certain criteria. Variability in selection criteria is demonstrated both within a particular organ group and between organ types.

There was variability between kidney centres in the degree of importance given to the factor of age in the decision to list patients for transplantation. Variability in age restrictions was observed in an earlier survey of 25 (of 29 adult and pediatric) renal transplantation programs undertaken by Organ Sharing Canada (1994).<sup>5</sup> The use of age as a selection criterion for transplantation is a controversial issue. Although patients over 60 years of age have similar cadaveric graft survivals to younger patients for kidney transplantation, the former demonstrate poorer overall survival.<sup>3,6</sup> In a study on resource utilization in kidney transplantation, age did not negatively affect the results. Over a two-year time period, transplantation was more effective and less costly than dialysis for all subgroups of patients examined, including patients older than 60 years.<sup>7</sup> In a recent study of factors that affect hospital resource utilization in liver transplantation,<sup>8</sup> however, treatment of older patients ( $\geq 60$  years) was more expensive and their hospital stays were longer than those of other patients with whom they were compared.

Using age as a selection criterion is justified by some theorists and rejected by others. Arguments in favour of the age criterion are usually motivated by medical utility and the scarcity of cadaveric organs. These arguments are based on the lower long-term elderly patient survival,<sup>3,6</sup> and a growing number of elderly patients and advancements in medical technology and immunosuppressive regimens which make greater health care services suitable for the aged population.<sup>9-11</sup> Moreover, some ethicists state that using age as a selection criterion should not be called discrimination. According to this argument, unlike other personal characteristics, age is not fixed, for young people grow old. In the case of selection according to patient age, people may be at a disadvantage at some life stage, but will be given preference while at another.<sup>12</sup>

Although using age as a selection criterion can have undesirable social consequences, given the prevailing shortage of cadaveric kidneys, renal transplantation should not be applied indiscriminately in the elderly. Ismail et al (1994),<sup>13</sup> proposed that patients 65 to 70 years of age be offered renal transplantation as an option for treatment of end-stage renal disease if they are not a high surgical risk. However, when considering transplantation for the "older" elderly patient, aged 70 to 75, the ethical dilemma remains in deciding whether to allocate the scarce resource of a cadaveric kidney to a patient for whom total life expectancy would predict that even with good graft function, there would be inevitable ultimate graft loss due to death.

To avoid the inherent unfairness of an arbitrary age limit, yet retain some aspect of medical utility in the decision to transplant, much consideration is placed on the biological age of the patient. The concept of biological age, however, needs to be better defined when used for risk assessment in selection of elderly patients for transplantation. For example, biological age could be referred to as a combination of comorbid disease and chronological age, or to life expectancy and the benefits of transplantation.<sup>12</sup>

One-third of the heart centres surveyed consider employment status in the decision to list patients for transplantation while the remainder did not consider employment as a factor in this decision. Occupational outcome has been used to indicate the quality and degree of rehabilitation among survivors of transplantation; however, heart transplant recipients encounter a number of difficulties that affect employment.<sup>14</sup> Literature suggests that lower patient income has been associated with nonacceptance for cardiac transplantation. A study of sex differences in patient acceptance of cardiac transplant candidacy in the United States demonstrates that patients in the lowest income profile were less likely to be accepted for transplant listing, despite demonstrated insurance and the absence of substance abuse.<sup>15</sup> Similarly, there are reports of differences in access to cadaveric kidney based on income.<sup>16,17</sup> While transplant centres may use the factor of employment status as an index of social re-integration, or to ensure compliance with immunosuppressive regimens, disincentives such as disability insurance, and educational, language and cultural barriers make the use of employment status as a selection criterion for transplant candidacy problematic.

There was variability in the degree of importance given to recipient nationality both among liver centres, and among the three organ types. This variability could be partially attributed to whether individual programs abide by the Canadian Liver Transplant Study Group (CLTSG) agreement on international recipient selection.<sup>18</sup>

Variability in the degree of importance given to the factor of mental competence as a selection criterion in decision to list was most evident between liver centres. Issues around a patient's mental health create difficult dilemmas when allocating a scarce resource such as livers especially among patients with alcoholic liver disease.<sup>8,19,20</sup> A patient's mental health is judged to be of importance in the transplant setting in relation to compliance with therapeutic strategies. Compliance with postoperative immunosuppressive drug regimens and follow-up treatments is generally considered a major factor in the successful outcome of organ transplantation. Similarly, non-compliance is a primary reason for patient morbidity and mortality.<sup>18, 21,22</sup> Compliance with follow-up regimens is considered an essential element of informed consent during recipient evaluation.<sup>23</sup> A previous survey of six Canadian adult liver transplant centres demonstrated that non-compliance negatively influenced the decision to list patients for liver transplantation.<sup>24</sup> In spite of primary concern for all organ types, transplantation research has yet to sufficiently explore how factors such as culture-based characteristics affect patient compliance.<sup>25-27</sup> In addition, patient compliance or non-compliance has also been implicated to confound such factors as the success or failure of the ability of hospital staff to communicate effectively with patients and their families.<sup>28</sup>

Alcohol and illicit drug use were important factors in the decision to list patients for all organ types. Tobacco use was also of importance in the decision to list patients for heart transplantation. Similarly, the survey by Organ Sharing Canada (1994) indicated that transplant centres take addictions into consideration in adult recipients.<sup>5,18,29</sup> It has been demonstrated that behavioural problems related to alcoholism and drug addiction have negatively influenced the decision to list patients for liver transplantation by the survey of Mullen et al (1996).<sup>24</sup> Alcoholic liver disease, a major cause of cirrhosis and a leading cause of death from end-stage liver disease in most of the Western world,<sup>30</sup> represents 12% of patients transplanted at one Canadian liver centre.<sup>31</sup> It is the possibility of returning to alcohol abuse, or substance abuse in general, that separates patients with alcoholic liver disease from those with other forms of chronic liver dysfunctions.

The issue of alcohol abuse is an example of a broader concern about whether people who "abuse" themselves or engage in "self-destructive" behaviour should be eligible for liver transplantation, and transplantation in general.<sup>19,32</sup> A number of criteria have been proposed in the literature that would exclude such individuals from eligibility for transplantation. Foremost among these is the fault-based position, which suggest that those who are in need of transplantation through some fault of their own should be given lower priority as a candidate for transplantation, which in the case of scarcity, effectively excludes them from receiving a transplanted organ.<sup>20,33,34</sup> The fact that an individual voluntarily created his or her need for a scarce resource is what drives the fault-based criterion. This is buttressed by legitimate social concerns such as the utilization of more hospital resources by patients with substance abuse than other patients.<sup>8</sup>

In spite of the plausibility of the fault-based position, excluding patients with substance abuse from transplants because they have harmed themselves is problematic for at least two reasons. Firstly, the question of individual responsibility is not as clear-cut; genetic, social, and legal factors are involved in the aetiology of substance abuse. For example, alcohol dependence, is routinely categorized as a "disease," with no reliable cure.<sup>35,36</sup> Secondly, there would be difficulty in applying the fault-based criterion to transplant candidates in a way that is consistent with current medical practice.<sup>37,38</sup> All sorts of patients, having harmed themselves through risky self-abusive behaviours, are routinely treated in the present health care environment. Such patients include those who have harmed themselves through over-indulgent diets, reckless driving, suicide attempt, and risky sexual behaviour.

Given the difficulty arising from the adoption of the fault-based criterion, transplant centres use carefully selected factors in listing patients with substance abuse. Foremost among these factors is a duration of abstinence for six months prior to transplantation.<sup>31,36,39</sup> The impact of the requirement of a six-month abstinence period on the rate of post transplant substance use, however, is controversial.<sup>35,40,41</sup> As a result, there is widespread agreement in the literature to suggest that additional factors, such as psycho-social support, need to be considered in listing patients with substance abuse.<sup>31,35,39-41</sup>

Data from this nationwide survey of adult transplant centres indicated varying degrees of requirement for social and community support between organ types prior to listing patients for transplantation. Heart centres considered social and community support to be of significance in the decision to list patients for transplantation, while these factors were ranked of lesser importance by kidney centres. Similarly, varying degrees of psycho-social support among the three organ types were reported in the survey of transplant centres by Organ Sharing Canada (1994).<sup>5,18,29</sup> Psycho-social support for transplant recipients is relevant among all study organ types, predominantly in relation to compliance and informed consent capability and substance-related issues.<sup>42-47</sup> Heart transplant candidates have been found to display impaired verbal memory and a tendency toward depression and anxiety,<sup>45</sup> while renal transplant candidates are found to have hypoactive sexual desire disorder and impaired cognitive function post-operatively.<sup>44</sup> Moreover, immunosuppressive-related neurotoxicity is an important etiological factor in liver transplant recipients in the period post-transplant.<sup>42</sup>

## 7. CONCLUSION

These data demonstrate that although heart, cadaveric kidney, and liver centres in Canada generally practice similar methods of listing patients, variability exists in the degree of importance given to certain criteria. Variability in selection criteria is demonstrated both within a particular organ group and between organ types. Differences among centres within individual solid organ groups were observed in the degree of the importance given to the factors of recipient age (kidney), employment status (heart), nationality and mental competence (liver). There was also variation among the solid organ types in the degree of importance given to criteria such as tobacco use, and the requirement of established programs for social and community support.

Given these findings, it would be of benefit to standardize organ-specific criteria at the national level for patient listing for heart, cadaveric kidney, and liver transplantation to ensure equitable access to this scarce public resource in Canada. This is of paramount importance given that there are ethical and social implications associated with the criteria under consideration. Factors for patient listing have implications for human rights and access to health care, informed consent, and the role of control and responsibility for illness.

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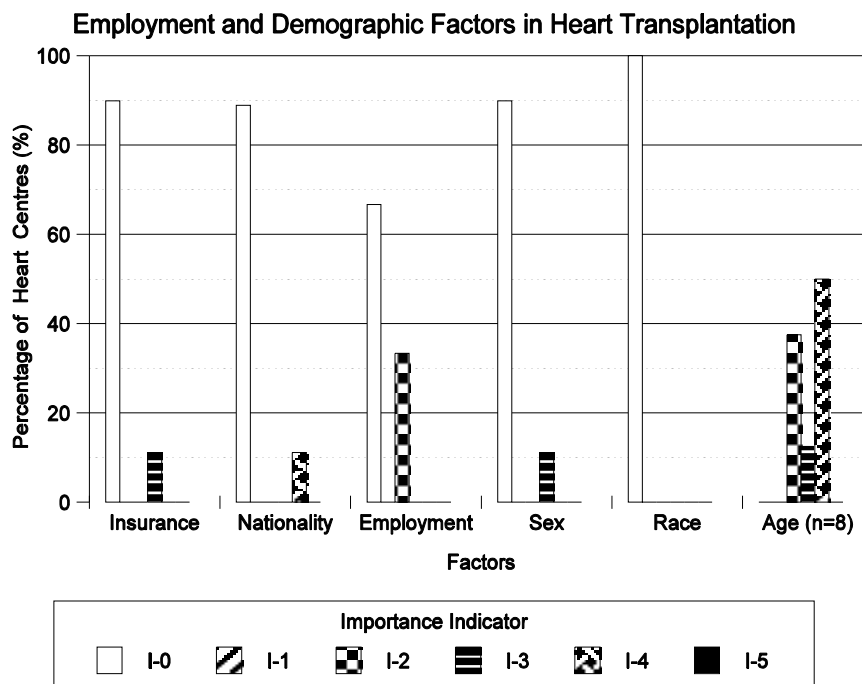
# APPENDIX 1

## Criteria for Selection of Adult Recipients for Heart Transplantation

Below are the responses to our recent survey of 9 transplant centres in Canada. The numbers are based on the percentage of responses to each question.

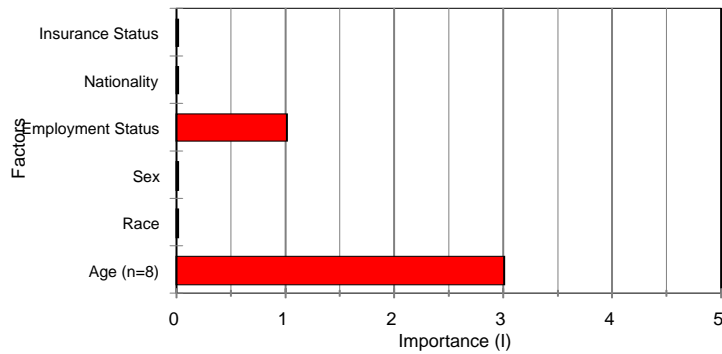
### 1. Demography and Employment

In listing patients for heart transplantation, how important are the following factors in this decision:



**Fig. 1.** Bar graph depicting the importance of employment and demographic factors in the decision to list patients for heart transplantation. Each bar in a row pertaining to a factor represents the percentage of heart centres (n=9) that rated the factor of no importance [I-0]; relative importance [I-1, I-2, I-3, I-4]; or of absolute importance [I-5] in the decision to list patients for heart transplantation. Eight of the nine transplant centres surveyed responded to the factor of age as a criterion for listing.

## Average Employment and Demographic Factors



**Fig. 2.** Bar graph illustrating the proportion that each demographic factor and employment plays in the decision to list patients for heart transplantation. Each bar represents the average importance of a factor based on the response of nine heart centres. In contrast to the factors of race, sex, nationality and insurance status, which were of no importance [I-0], the factors of age and employment were of relative importance [I-3 and I-1 respectively] in the decision to list. Eight of the nine heart transplant centres surveyed responded to the factor of age as a criterion for listing patients.

If applicable, please provide *details* on your requirements regarding the above categories.

### Age:

- i. "though not an absolute issue clearly relates to presence of comorbid conditions & therefore is always a consideration"
- ii. "[before age 60- we consider those 60-65 years of age if they do not have other medical problems"]
- iii. "age <65"

### Sex:

- iv. "[antibody levels are performed on women]"

### Employment Status:

- v. "relates to social support systems in place"

### Nationality:

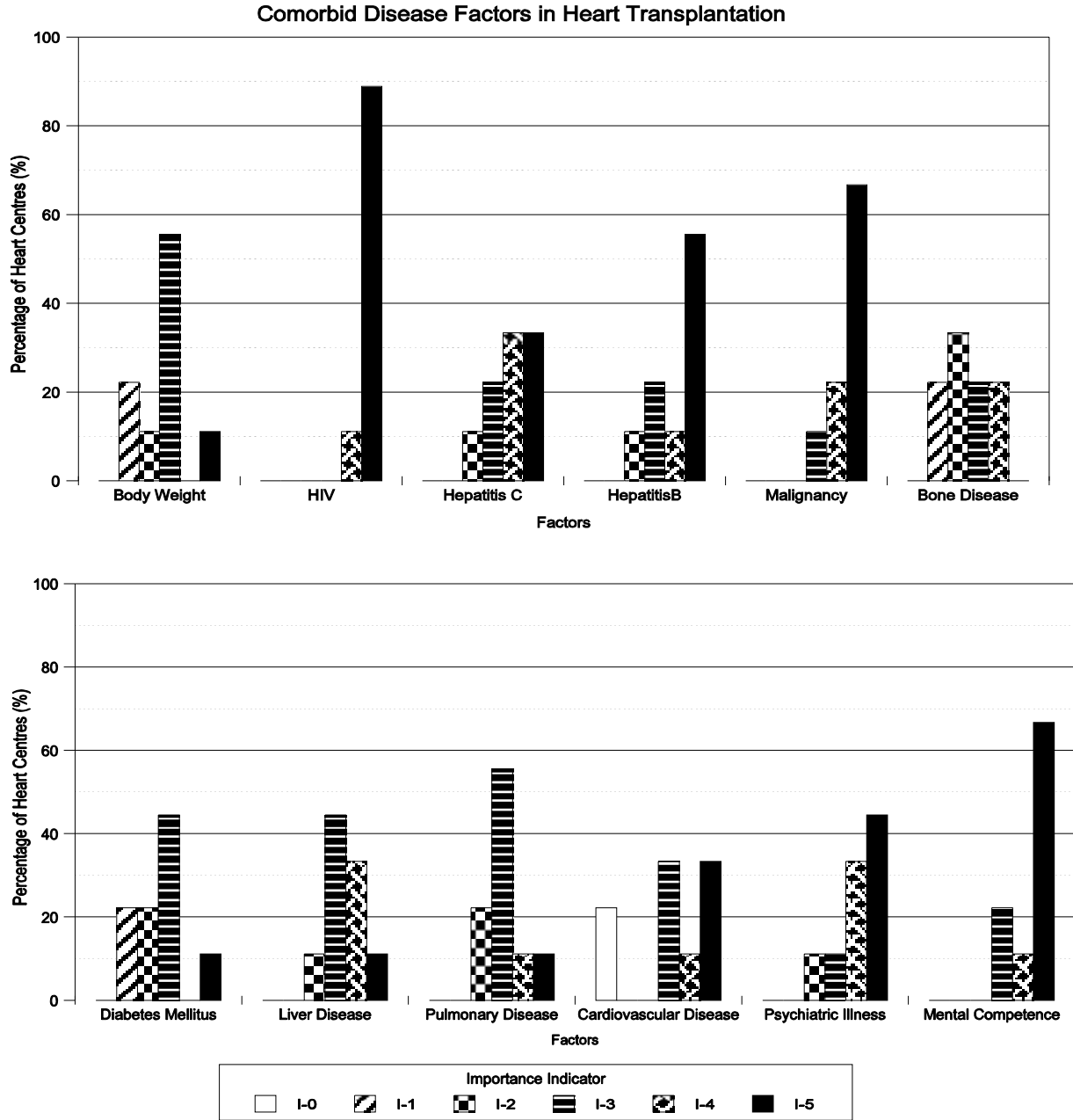
- vi. "Canadian citizenship implies government health insurance- nationality has been discussed by the Clinical Ethics Committee. We have and are willing to carry out heart transplantation on patients who are not Canadian citizens who present [at the centre] as a medical emergency. However, due to the limited number of donor organs, we would not ordinarily consider an elective heart transplant in a person who is not a Canadian citizen or landed immigrant"

### Insurance Status:

- vii. "[financial status is evaluated]"
- viii. "see enclosed 'criteria for candidate selection'"

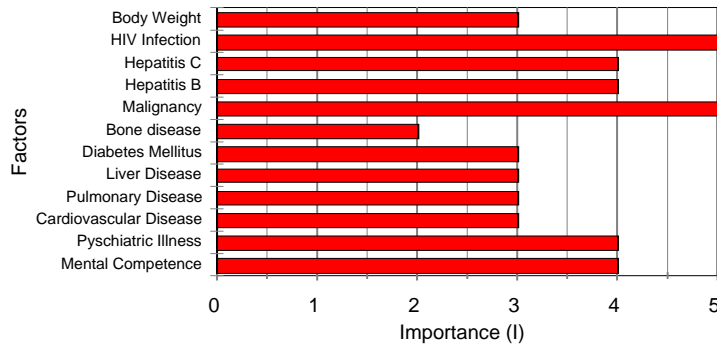
## 2. Comorbid Disease

In listing patients for heart transplantation, how important are the following factors in this decision:



**Figs. 3 & 4.** Bar graphs indicating the importance of comorbid disease factors in the decision to list patients for heart transplantation. Each bar in a row pertaining to a factor represents the percentage of heart transplantation centres (n=9) that rated the factor of no importance [I-0]; relative importance [I-1, I-2, I-3, I-4]; or of absolute importance [I-5] in the decision to list.

### Average Comorbid Factors in Heart Transplantation



**Fig. 5.** Bar graph illustrating the proportion each comorbid disease factor plays in the decision to list patients for heart transplantation. Each bar represents the average importance of a factor based on the response of nine transplant centres. The factor of bone disease was of relative importance [I-2]; cardiovascular disease, pulmonary disease, liver disease, diabetes mellitus, and body weight were of relative importance [I-3]; mental competence, psychiatric illness, hepatitis B and hepatitis C infection were of relative importance [I-4]; and malignancy and HIV infection were of absolute importance [I-5] in the decision to list patients for heart transplantation.

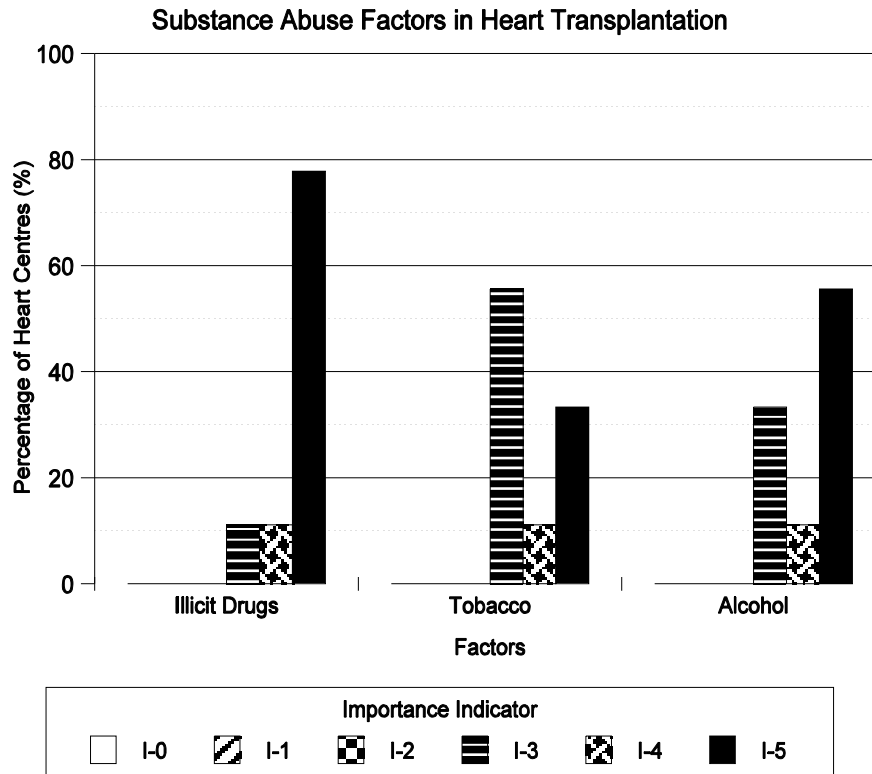
If applicable, please provide *details* on your requirements regarding the above categories.

- i. "Mental competence & psychiatric illness are not contraindications provided that a friend, loved one or 3<sup>rd</sup> party care-giver can ensure patient compliance"
  - ii. "DM with end organ damage/Malignancy/HIV/Acute Hepatitis- C/I"
  - iii. "We would not consider heart transplant in a patient who is HIV positive because their prognosis is already reduced and would be adversely affected by immunosuppression"
- Other:
- iv. "renal disease" [4], "vascular disease"[3]

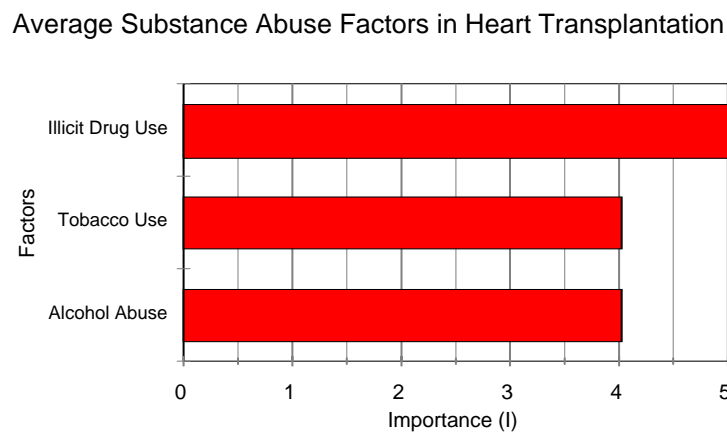


### 3. Substance Abuse

In listing patients for heart transplantation, how important are the following factors in this decision:



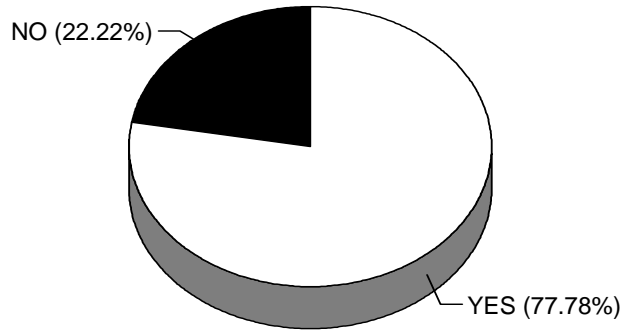
**Fig. 6.** Bar graph depicting the importance of substance abuse factors in the decision to list patients for heart transplantation. Each bar in a row pertaining to a factor represents the percentage of heart centres (n=9) that rated the factor of no importance [I-0]; relative importance [I-1, I-2, I-3, I-4]; or of absolute importance [I-5] in the decision to list.



**Fig. 7.** Bar graph illustrating the proportion each substance abuse factor plays in the decision to list patients for heart transplantation. Each bar represents the average importance of a factor based on the response of nine heart centres. The factors of illicit drug use, tobacco, and alcohol use were of absolute and relative importance [I-5, I-4, and I-4 respectively] in the decision to list.

If any of the above factors are of importance, do you require that the patient follow a formal treatment program prior to activation on the waiting list?

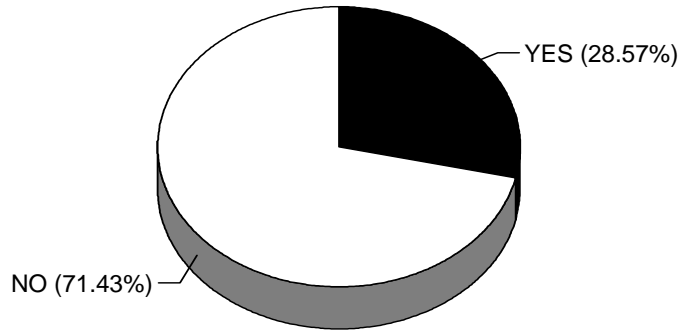
- Yes (7)
- No (2)



**Fig. 8.** Pie chart demonstrating the proportion of heart programs that require that a patient follows a formal treatment program prior to activation on the waiting list.

If the answer is yes, do you require that the patient sign a formal contract?

- Yes (2)
- No (5)



**Fig. 9.** Pie chart illustrating the proportion of heart programs that require that the patient sign a formal contract.

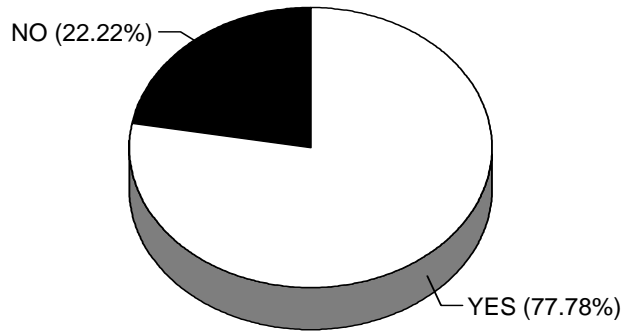
If a formal program is required, please provide *details* including the duration of abstinence.

- i. "3-6 months"
- ii. "6 months"
- iii. "[Tobacco less than 6 months: Alcohol: 1 yr]"
- iv. "[Alcohol/Drugs- abstinence  $\geq$ 6 months]"

#### 4. Social and Community Support

Do you require that the patient have established programs for social and community support prior to listing for heart transplantation?

- Yes (7)
- No (2)



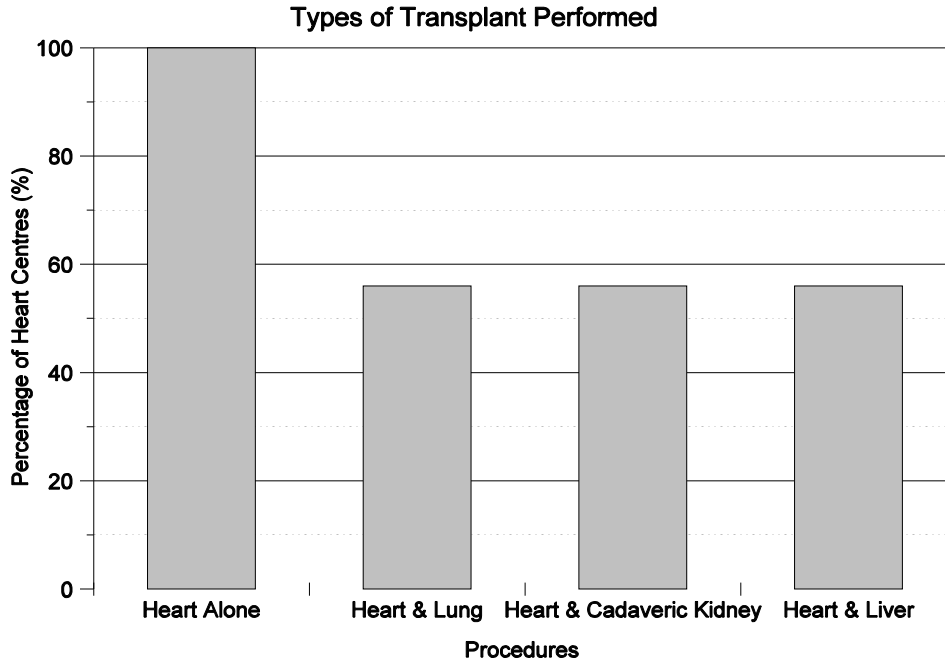
**Fig. 10.** Pie chart illustrating the proportion of heart programs that require that the patient have established programs for social and community support prior to listing for heart transplantation.

If the answer is *yes*, please provide the *details* of the system and your requirements.

- i. "social support more important than 'established' program"
- ii. "social support"
- iii. "all patients participate in an interview for a psychosocial assessment. The assessment includes a family and support system analysis, work on rehabilitation potential, alcohol/drug history, psychological, and financial assessment, medication and insurance coverage. Patients/families are referred to community agencies that could provide assistance to them. These agencies could include: Social Allowance, A.A., N.A., CPP, AISH, Blue Cross, or counselling services. If a language or cultural barrier is identified, interpretation services is made available. Assistance with transportation and accommodation is provided if patients are from outside the local area and need to remain in the city for an extended period of time"
- iv. "social service & psychology service carry out a full assessment of support system. Their reports are reviewed during the final committee meetings where decisions are made re: listing"
- v. "[to raise funds in their community: help through social programs]"
- vi. "[through social services]"

## 5. Types of Transplant Performed

Please indicate which of the following procedures are performed within your transplant program:



**Fig. 11.** Bar graph indicating the percentage of heart centres which perform heart alone, heart and lung, heart and cadaveric kidney, and heart and liver transplantation procedures.

In cases of double-organ procedures, please provide the impact this may have on your responses to questions 1 to 4 (demography and employment; comorbid disease; substance abuse; social and community support).

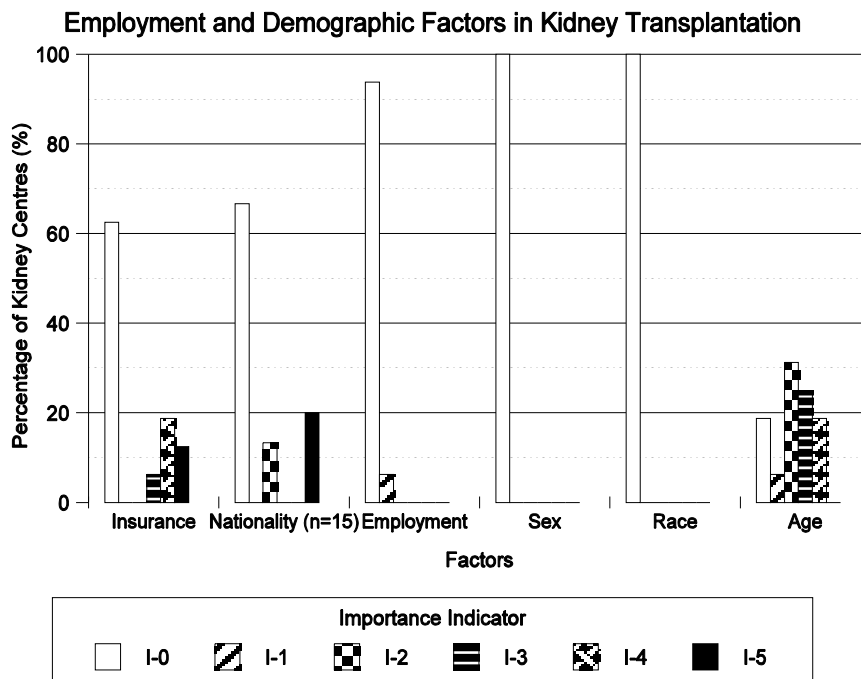
- i. "nil"
- ii. "with double organ procedures we tend to place greater emphasis on all other issues before accepting for transplant. We always consider the limited supply of organs and try to allocate to 'best' recipient. The decision is a group one where all opinions are heard & noted"
- iii. "[identical responses]"

# APPENDIX 2

## Criteria for Selection of Adult Recipients for Cadaveric Kidney Transplantation

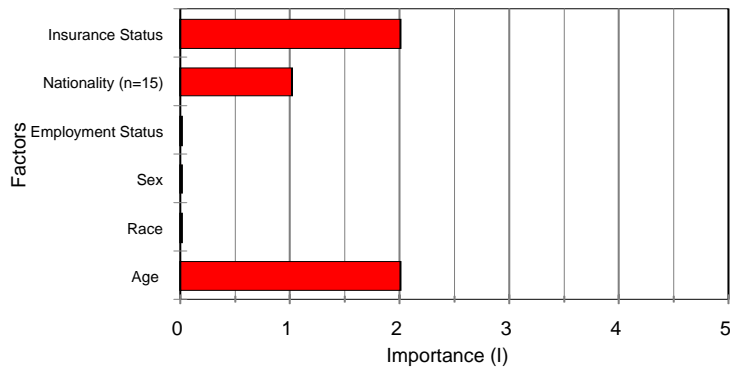
Below are the responses to our recent survey of 16 transplant centres in Canada. The numbers are based on the percentage of responses to each question.

### 1. Demography and Employment



**Fig. 1.** Bar graph depicting the importance of employment and demographic factors in the decision to list patients for kidney transplantation. Each bar in a row pertaining to a factor represents the percentage of kidney centres (n=16) that rated the factor of no importance [I-0]; relative importance [I-1, I-2, I-3, I-4]; or of absolute importance [I-5] in the decision to list patients for kidney transplantation. Fifteen of the sixteen transplant centres surveyed responded to the factor of nationality as a criterion for listing.

## Average Employment and Demographic Factors



**Fig. 2.** Bar graph illustrating the proportion each demographic factor and employment plays in the decision to list patients for kidney transplantation. Each bar represents the average importance of a factor based on the response of sixteen centres. In contrast to the factors of race, sex and employment status which were of no importance [I-0], the factors of age, insurance status and nationality were of relative importance [I-2, I-2, and I-1, respectively] in the decision to list. Fifteen of the sixteen kidney transplant centres surveyed responded to the factor of nationality as a criterion for listing patients.

If applicable, please provide *details* on your requirements regarding the above categories.

### Age:

- i. ">75 absolute cut off- 70-74 only under exceptional circumstances"
- ii. "age is physical and chronological. Early 70's and good health- we will transplant"
- iii. "once on the waiting list, age is not a factor, although it could be a factor in deciding whether or not a patient is an appropriate candidate and should go on the list"
- iv. "age is not an obstacle to kidney tx but pts over age 70 are usually in exceptionally good health. We transplanted 3 pts in their 70's in 1998 (Pts with IV drug abuse or alcoholism which is current are offered treatment in order to make them eligible for txn)"
- v. "over 70 we get concerned about latent malignancy. Few have lived >5yr"

### Nationality:

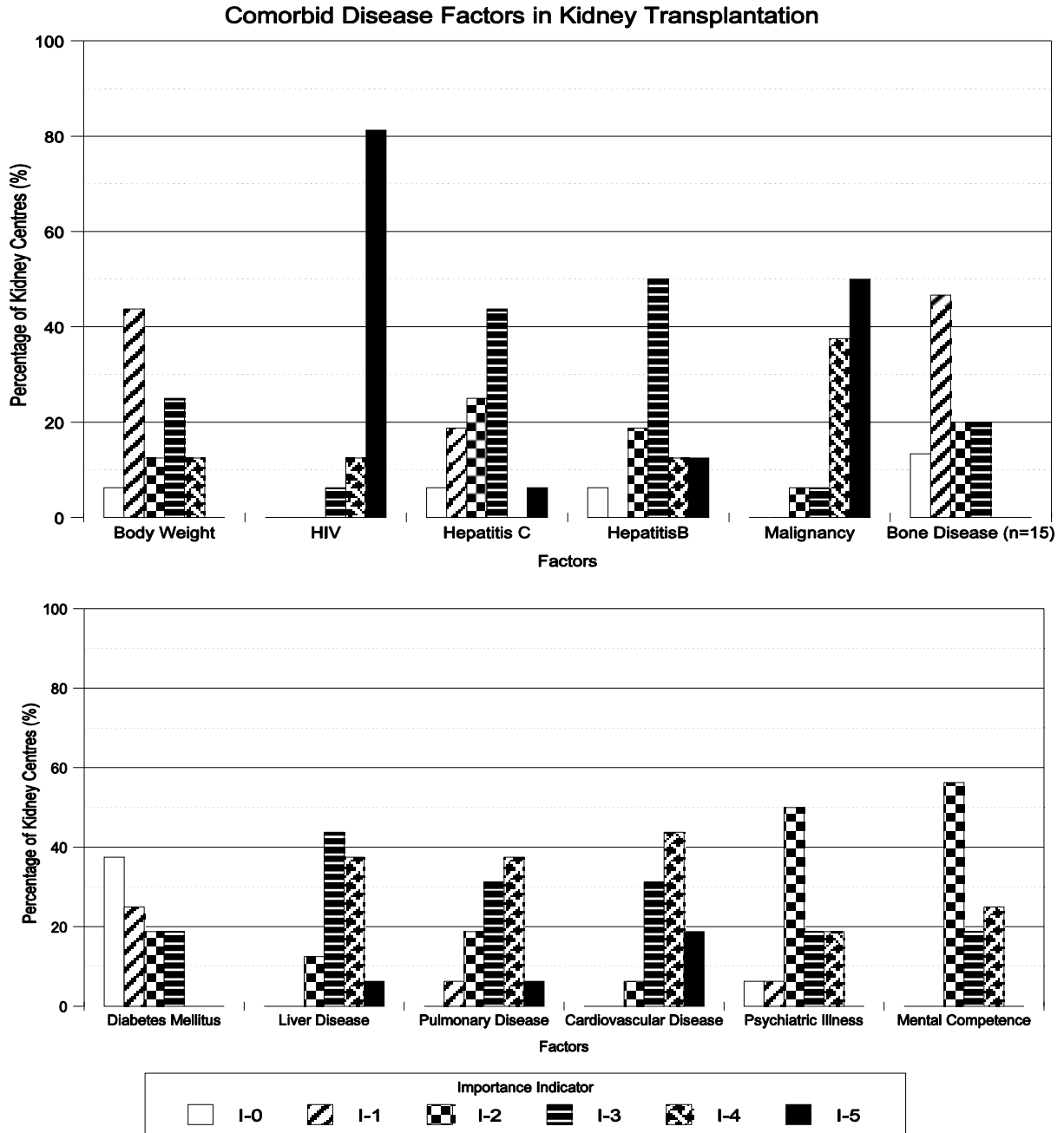
- vi. "PT must be [provincial] resident"
- vii. "we do not list non Canadians in [province] for cadaveric Tx. We will provide LD support however, at hospital cost, for certain cases"
- viii. "we will list patients who have either Canadian citizenship or landed immigrant"

### Insurance Status:

- ix. "[Pt must] be eligible for medical coverage in [province]"
- x. "need to have [provincial health insurance] plan or have another resource to pay for meds"
- xi. "we want to insure that patients are able to be able to obtain the medication post-transplant. That they require private insurance or eligibility for provincial drug funding"
- xii. "absolute requirement of [#] number for cadaver kidneys"
- xiii. "[physiological age is more important than chronological age]"

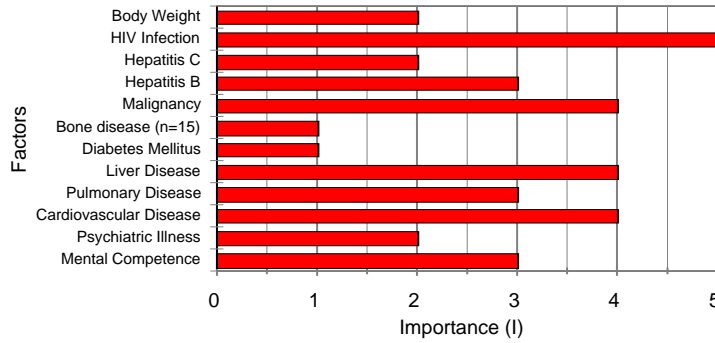
## 2. Comorbid Disease

In listing patients for cadaveric kidney transplantation, how important are the following factors in this decision:



**Figs. 3 & 4.** Bar graphs indicating the importance of comorbid disease factors in the decision to list patients for kidney transplantation. Each bar in a row pertaining to a factor represents the percentage of kidney transplant centres (n=16) that rated the factor of no importance [I-0]; relative importance [I-1, I-2, I-3, I-4]; or of absolute importance [I-5] in the decision to list. Fifteen of the sixteen transplant centres surveyed responded to the factor of bone disease as a criterion for listing.

### Average Comorbid Factors in Kidney Transplantation



**Fig. 5.** Bar graph illustrating the proportion each comorbid disease factor plays in the decision to list patients for kidney transplantation. Each bar represents the average importance of a factor based on the response of sixteen transplant centres. The factors of diabetes mellitus and bone disease were of relative importance [I-1]; psychiatric illness, hepatitis C and body weight were of relative importance [I-2]; mental competence, pulmonary disease, liver disease, and hepatitis B infection were of relative importance [I-3]; cardiovascular disease and malignancy were of relative importance [I-4]; and HIV infection was of absolute importance [I-5] in the decision to list patients for kidney transplantation. Fifteen of the sixteen kidney centres surveyed responded to the factor of bone disease as a criterion for listing patients.



If applicable, please provide *details* on your requirements regarding the above categories.

Mental Competence/Psychiatric Illness:

- i. "we have used surrogate decision makers for mentally incompetent"
- ii. "mental competence and psych. problems are absolutes if the patient cannot comply with therapy"

Cardiovascular Disease/Pulmonary Disease:

- iii. "severe cardiac disease or EF <30% usually rule out Tx"
- iv. "some forms of heart disease (eg, inoperable 3 vessel disease, esp with [decreased] liver function are discouraged from being txed"
- v. "we exclude patients at very high perioperative risk re: cardiac + pulmonary disease"

Liver Disease:

- vi. "absence of cirrhosis"

Malignancy:

- vii. "is relative [depending on site]"
- viii. "must be a cure"
- ix. "malignancy is absolute for defined periods if > basal skin cancer"
- x. "we follow tx guidelines around common malignancies (eg breast, renal cell, lymphoma) (in general we try to offer txn as widely as possible but do discourage pts with severe co-morbidity)"
- xi. "depends on TYPE and time from diagnosis"
- xii. "malignancy varies skin or not skin (except melanoma/ and duration of follow-up 2yrs w/or..."
- xiii. "freedom of cancer for 2-5 yrs depending on type of malignancy"

Hepatitis B/C Infection:

- xiv. "we will Tx Hep B+C pts without cirrhosis"[ 'with respect to hepatitis, it depends on severity of the disease"]
- xv. "Hep B by careful detailed informed consent"
- xvi. "we tx hep C+ve pts who don't have cirrhosis"
- xvii. "we will do Hep B+C without serious liver disease"
- xviii. "absence of HBV DNA replication"

HIV Infection:

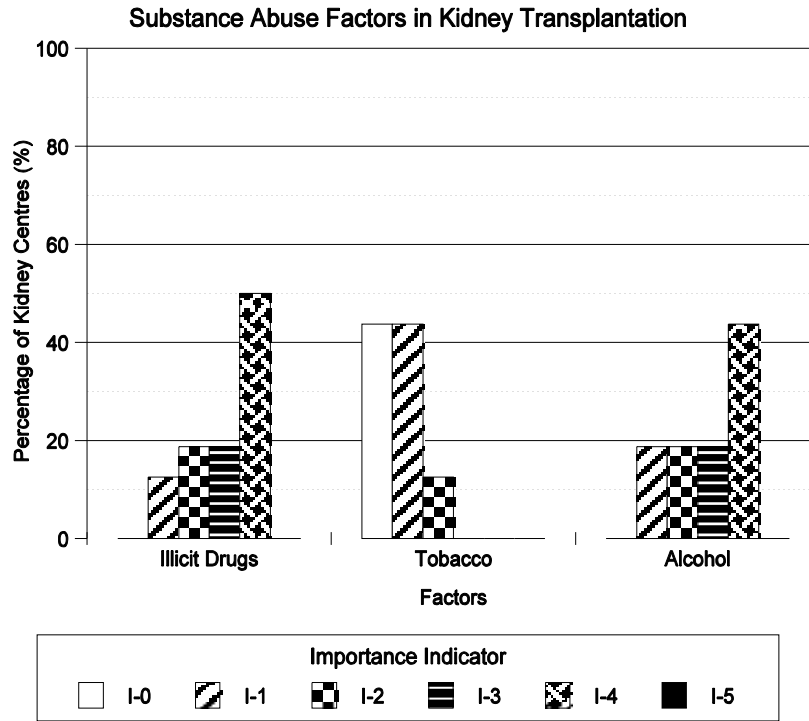
- xix. "never have had an asymptomatic HIV infected patient. I suspect if challenged we would transplant (significant vital organ disease a rel. contraindication. mild disease is not a contraindication)

Other:

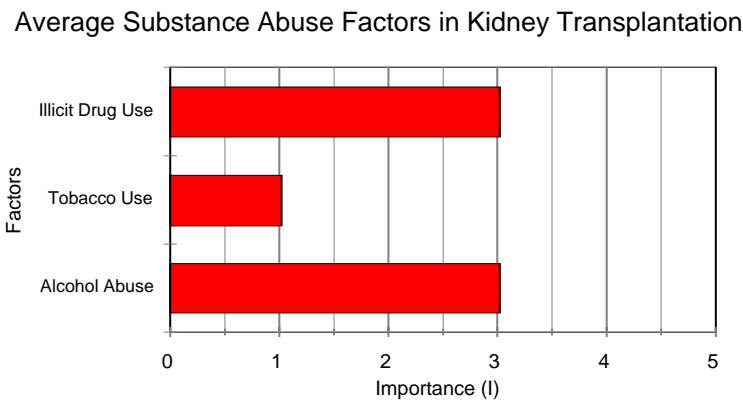
- xx. "[diabetic complications]"[5]

### 3. Substance Abuse

In listing patients for cadaveric kidney transplantation, how important are the following factors in this decision:



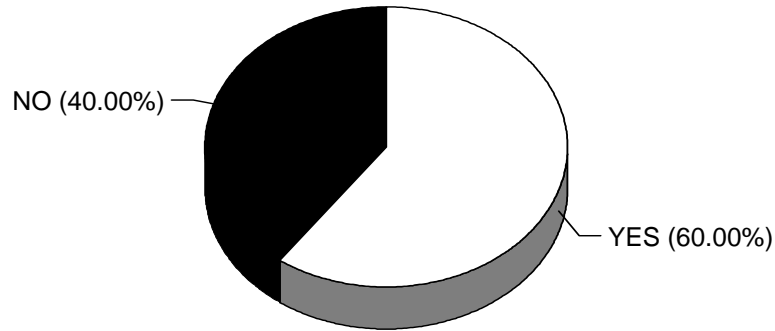
**Fig. 6.** Bar graph depicting the importance of substance abuse factors in the decision to list patients for kidney transplantation. Each bar in a row pertaining to a factor represents the percentage of kidney centres (n=16) that rated the factor of no importance [I-0]; relative importance [I-1, I-2, I-3, I-4]; or of absolute importance [I-5] in the decision to list.



**Fig. 7.** Bar graph illustrating the proportion each substance abuse factor plays in the decision to list patients for kidney transplantation. Each bar represents the average importance of a factor based on the response of sixteen kidney centres. The factors of illicit drug use, tobacco, and alcohol use were of relative importance [I-3, I-1, and I-3 respectively] in the decision to list.

If any of the above factors are of importance, do you require that the patient follow a formal treatment program prior to activation on the waiting list?

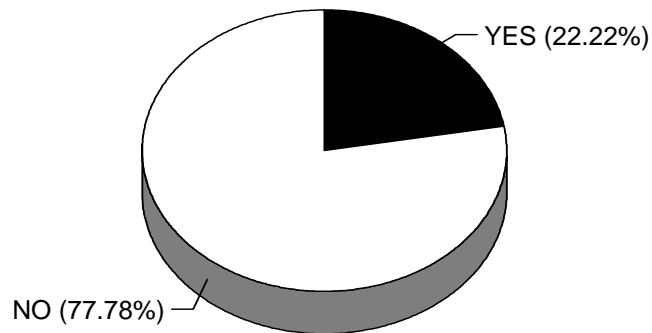
- Yes (9)
- No (6)



**Fig. 8.** Pie chart demonstrating the proportion of kidney programs that require that a patient follows a formal treatment program prior to activation on the waiting list.

If the answer is yes, do you require that the patient sign a formal contract?

- Yes (2)
- No (7)



**Fig. 9.** Pie chart illustrating the proportion of kidney programs that require that the patient sign a formal contract.

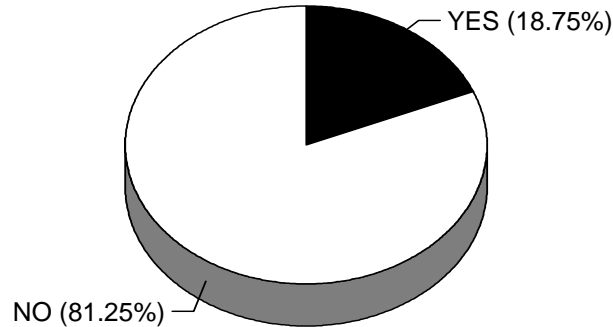
If a formal program is required, please provide *details* including the duration of abstinence.

- i. "For drugs+alcohol with require some active involvement in a recovery program with monitoring. We have only rarely used a contract. We would like to impose smoking cessation but have not done so yet"
- ii. "For severe alcoholism/drug abuse at least 6 months of abstinence"
- iii. "Individualized, but at least 6 months"
- iv. "We don't come across this very often and use local expertise to advise us about the best program of treatment for each individual" [formal treatment program "for current alcoholism or IV drug abuse; formal contract "not a requirement, but is recommended"]
- v. "We exclude most alcoholics or those with current drug abuse problems"
- vi. "12 months of abstinence"
- vii. "6-12 [months of abstinence]"
- viii. "We have transplanted active drinkers who have had problems in past"
- ix. "6 [months]"

#### 4. Social and Community Support

Do you require that the patient have established programs for social and community support prior to listing for cadaveric kidney transplantation?

- Yes (3)
- No (13)



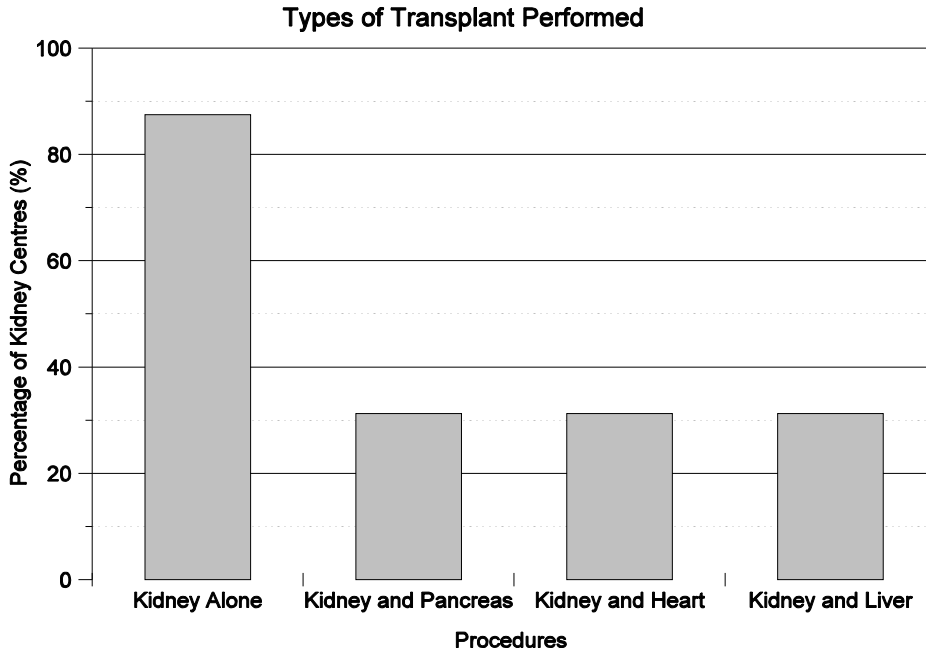
**Fig. 10.** Pie chart illustrating the proportion of programs that require that the patient have established programs for social and community support prior to listing for kidney transplantation.

If the answer is *yes*, please provide the *details* of the system and your requirements.

- i. "All patients are assessed by a transplant social worker and a plan is put in place"
- ii. "patients needs are assessed and an implementation plan is created for if and when the patient gets a kidney"
- iii. "evidence of enrollment in private or provincial drug plan for immunosuppressants"
- iv. "we never withhold kidney tx from patients because they are socially disadvantaged. Our biggest problem is ensuring that pts have adequate drug coverage before they are transplanted and we have a vigorous, systematic program for encouraging that each pt has drug coverage at the time of listing"
- v. "only support is for payment of medications"
- vi. "we don't have a system to assess support"

## 5. Types of Transplant Performed

Please indicate which of the following procedures are performed within your transplant program:



**Fig. 11.** Bar graph indicating the percentage of kidney centres which perform kidney alone, kidney and pancreas, kidney and heart, and kidney and liver transplantation procedures.

In cases of double-organ procedures, please provide the impact this may have on your responses to questions 1 to 4 (demography and employment; comorbid disease; substance abuse; social and community support).

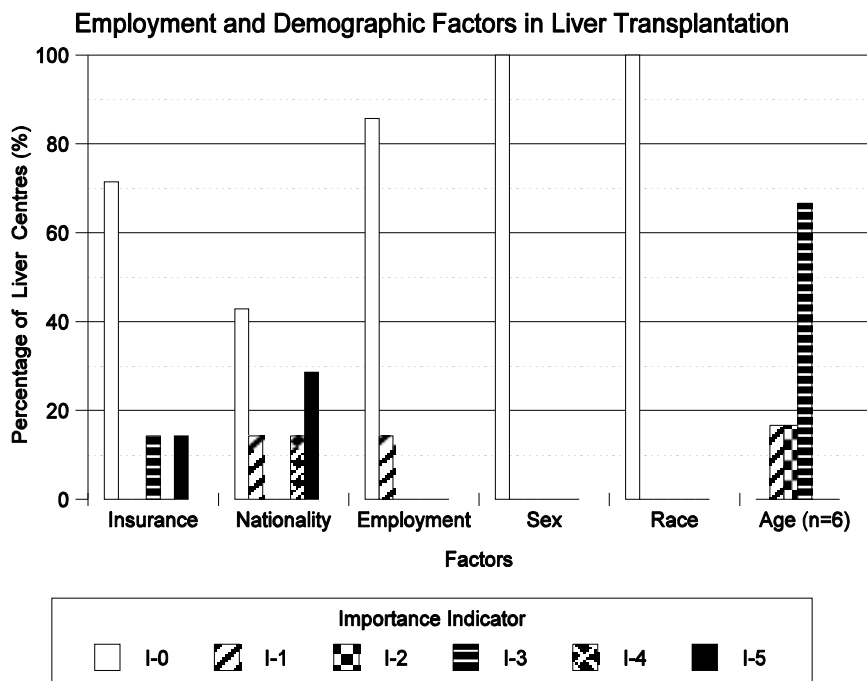
- i. "For a pancreatic transplant they need to have an extensive cardiovascular workup"
  - ii. "combined liver-kidney problematic without data to support most current usage. We will perform with high sensitized patient, and [primary] hyperoxalate patients. Others, case by case"
  - iii. "combined transplants infrequent except kidney-pancreas. For that, there are more rigorous acceptance criteria re: age + cardiovascular disease"
  - iv. "Except K-P to have little or no IHD (more restricted than K alone)"
  - v. "Criteria of vital organ transplant are of primary concern. Each case is discussed individually since these are always complex"
- Other:
- vi. "Bone Marrow"[ 1 centre] "Living Kidney"[3 centres]
  - vii. "In case of heart or liver or lung transplant, substance abuse and community support may have an impact"

# APPENDIX 3

## Criteria for Selection of Adult Recipients for Liver Transplantation

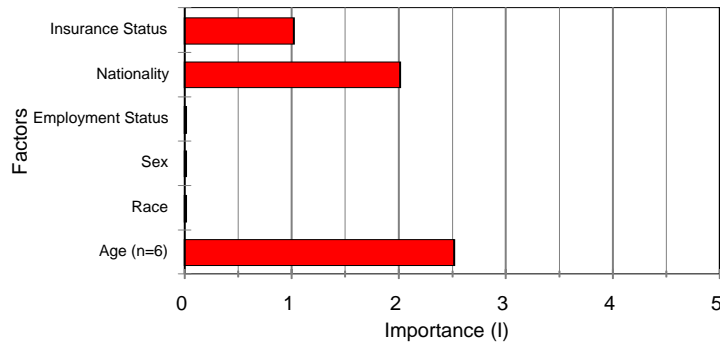
Below are the responses to our recent survey of 7 transplant centres in Canada. The numbers are based on the percentage of responses to each question.

### 1. Demography and Employment



**Fig. 1.** Bar graph depicting the importance of employment and demographic factors in the decision to list patients for liver transplantation. Each bar in a row pertaining to a factor represents the percentage of liver centres (n=7) that rated the factor of no importance [I-0]; relative importance [I-1, I-2, I-3, I-4]; or of absolute importance [I-5] in the decision to list patients for liver transplants. Six of the seven transplant centres surveyed responded to the factor of age as a criterion for listing.

## Average Employment and Demographic Factors



**Fig. 2.** Bar graph illustrating the proportion each demographic factor and employment plays in the decision to list patients for liver transplantation. Each bar represents the average importance of a factor based on the response of seven liver centres. In contrast to the factors of race, sex and employment, which were of no importance [I-0], the factors of nationality, insurance and age were of relative importance [I-2, I-1, and I-2.5 respectively] in the decision to list. Six of the seven liver transplant centres surveyed responded to the factor of age as a criterion for listing patients.

If applicable, please provide *details* on your requirements regarding the above categories.

### Age:

- i. "with increasing age, particular attention is paid to the existence of co-morbidity - esp., cardiopulmonary"
- ii. "as related to the physiological condition of the candidate (as an example: cardiovascular condition)"

### Nationality:

- iii. "no more than 5% of recipients for liver transplant can be non-Canadian"
- iv. "Foreign National- TX is offered only under exceptional compassionate circumstances in view of the severe shortage of Cdn donors for Cdn recipients"
- v. "but has to be a resident of the province, save for cases of vital emergency"
- vi. "Canadian Citizenship: This last category was 'imposed' on us by the 'ethics committee' of [provincial] Transplant but is not in accordance of the Canadian Transplant Society agreement which allows for 5% of Liver Transplant recipients to be from countries that do not have Liver Transplant programs"

### Insurance:

- vii. "all pts covered by [province of residence] or other provincial health insurance, Drug coverage is ensured through preop assessment"
- viii. "health care coverage is required of the program by hospital administration in all but Emergency situations - i.e., the program would assist the patient to obtain appropriate coverage"
- ix. "uninsured patients must have adequate resources before OLTx approved (hospital policy)"

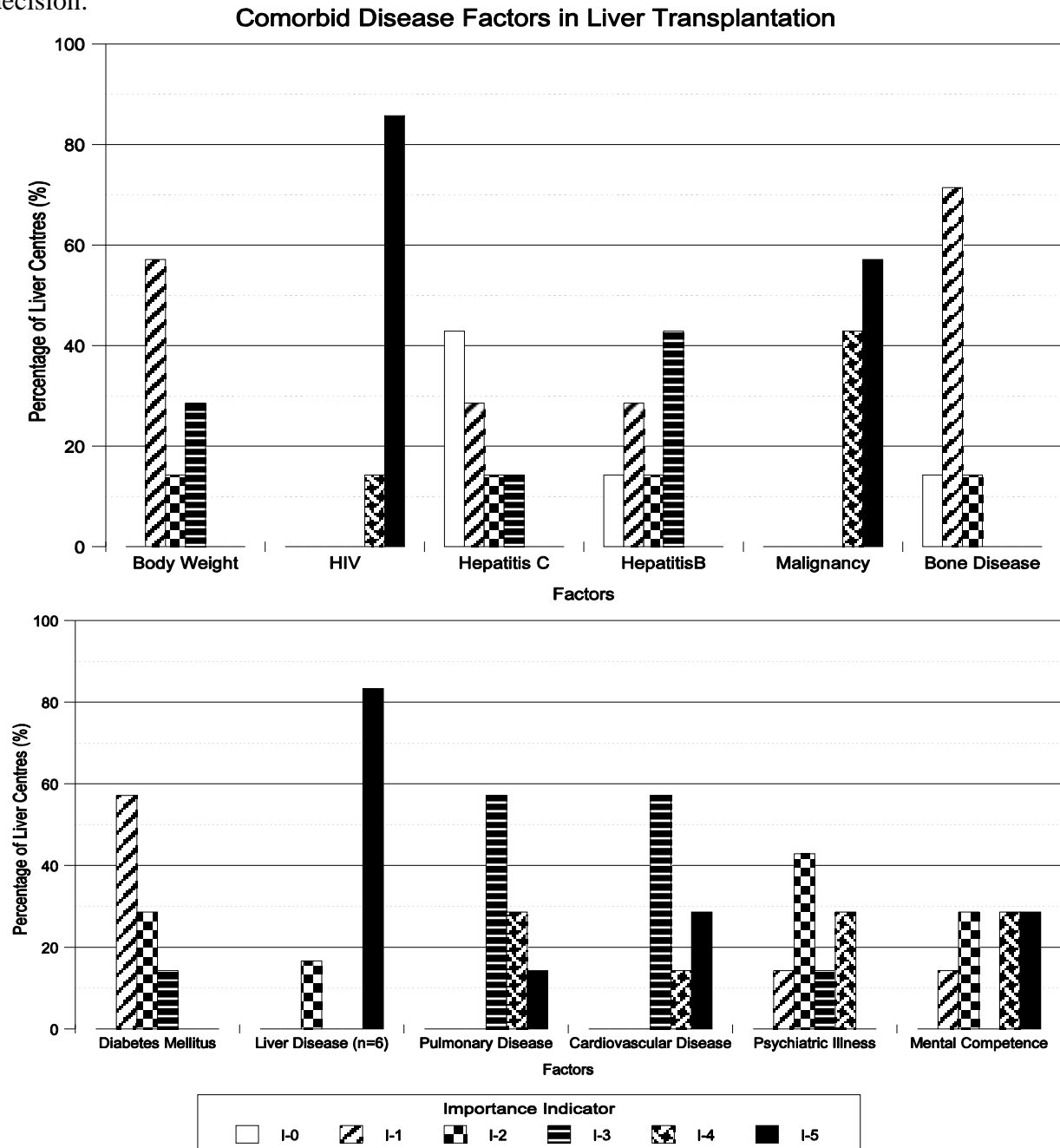
### Other:

- x. "existence of support person"[2]



## 2. Comorbid Disease

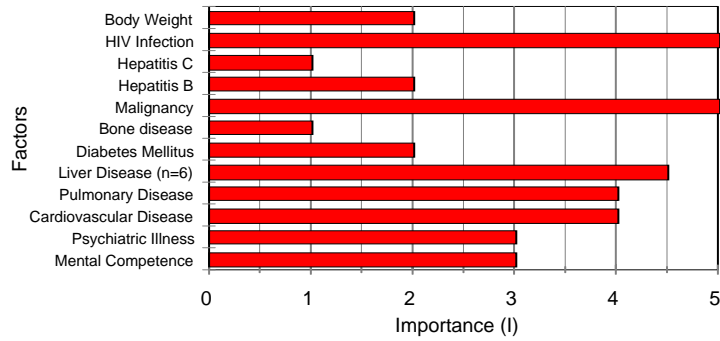
In listing patients for liver transplantation, how important are the following factors in this decision:



**Figs. 3 & 4.** Bar graphs indicating the importance of comorbid disease factors in the decision to list patients for liver transplantation. Each bar in a row pertaining to a factor represents the percentage of liver centres (n=7) that rated the factor of no importance [I-0]; relative importance [I-1, I-2, I-3, I-4]; or of absolute importance [I-5] in the decision to list. One of the seven

centres rated 0-1 for each of the factors of diabetes mellitus and bone disease; for purposes of this report, each of these factors was given a rating of I-1. Six of the seven transplant centres surveyed responded to the factor of liver disease as a criterion for listing.

### Average Comorbid Factors in Liver Transplantation



**Fig. 5.** Bar graph illustrating the proportion each comorbid disease factor plays in the decision to list patients for liver transplantation. Each bar represents the average importance of a factor based on the response of seven transplant centres. The factors of bone disease and hepatitis C were of relative importance [I-1]; diabetes mellitus, hepatitis B, and body weight were of relative importance [I-2]; mental competence and psychiatric illness were of relative importance [I-3]; cardiovascular disease and pulmonary disease were of relative importance [I-4]; liver disease, malignancy and HIV infection were of absolute importance [I-4.5; I-5; I-5] in the decision to list patients for liver transplantation. Six of the seven liver transplant centres surveyed responded to the factor of liver disease as a criterion for listing patients.

If applicable, please provide *details* on your requirements regarding the above categories.

Mental Competence:

- i. "patient or caregiver must be capable of complying with medication regimen"
- ii. "with the exception if patient comatosed with acute fulminant hepatic failure, pts or their guardian must understand the risk + benefits"
- iii. "unless correlated with liver disease (eg., encephalopathy)"

Psychiatric Illness:

- iv. "most controlled [psychiatric] illness is compatible with TX (we have Tx'd a number of pts diagnosed with chronic schizophrenia)"

Cardiovascular/Pulmonary Disease:

- v. "detailed cardiopulmonary asst essential post TX investigation- ..."

Liver disease:

- vi. "presence of hepatocellular carcinoma assessment + Tx'd only according to CLTSG [Canadian Liver Transplant Study Group] guidelines"

Malignancy:

- vii. "apart from small hepatocellular CA"
- viii. "unless limited to primary small size hepatoma"

Hepatitis B Infection:

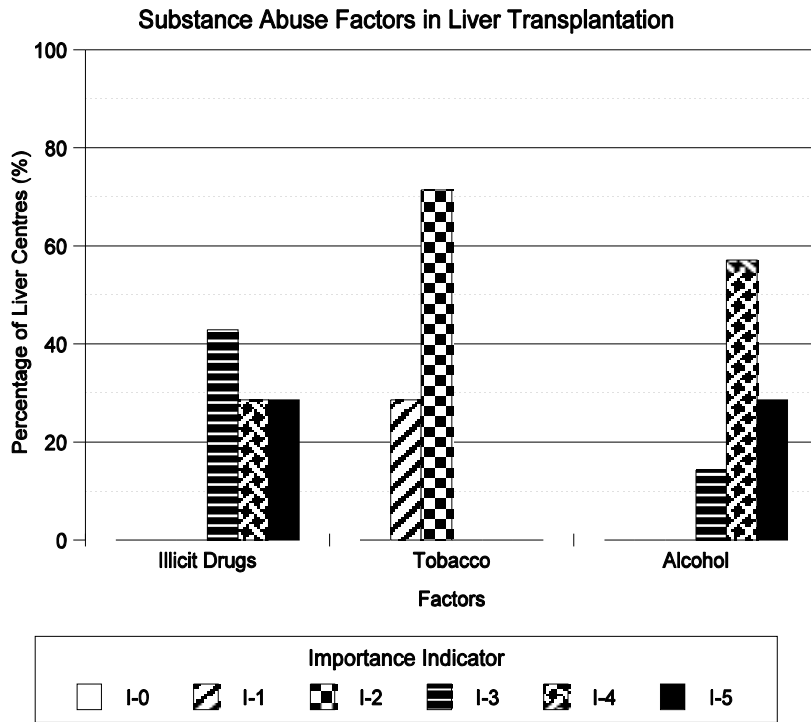
- ix. "must be DNA negative on lamivudine"
- x. "in the past we would not list HepB patients who maintain HBV DNA+"

Other:

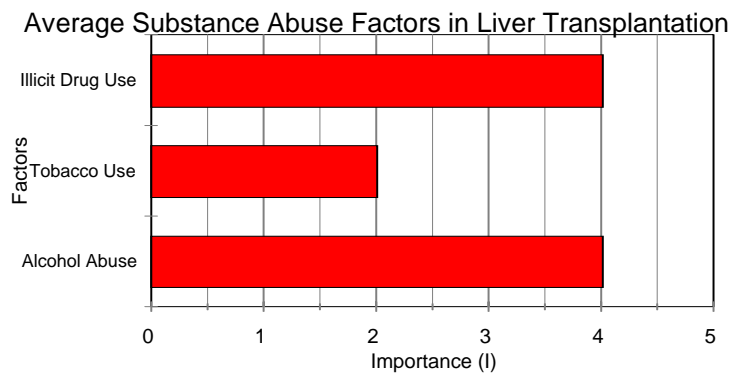
- xi. "active sepsis outside of liver"[5] "extra-hepatic malignancy"[5]

### 3. Substance Abuse

In listing patients for liver transplantation, how important are the following factors in this decision:



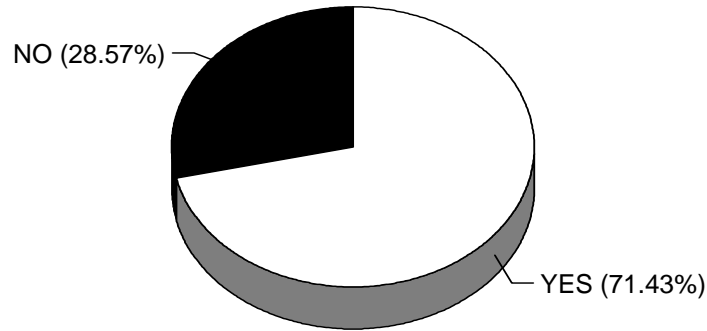
**Fig. 6.** Bar graph depicting the importance of substance abuse factors in the decision to list patients for liver transplantation. Each bar in a row pertaining to a factor represents the percentage of liver centres (n=7) that rated the factor of no importance [I-0]; relative importance [I-1, I-2, I-3, I-4]; or of absolute importance [I-5] in the decision to list. One of the seven centres rated 0-1 for the factor of tobacco use; for purposes of this report, this factor was given a rating of I-1.



**Fig. 7.** Bar graph illustrating the proportion each substance abuse factor plays in the decision to list patients for liver transplantation. Each bar represents the average importance of a factor based on the response of seven liver centres. The factors of illicit drug use, tobacco, and alcohol use were of relative importance [I-4, I-2, and I-4 respectively] in the decision to list

If any of the above factors are of importance, do you require that the patient follow a formal treatment program prior to activation on the waiting list?

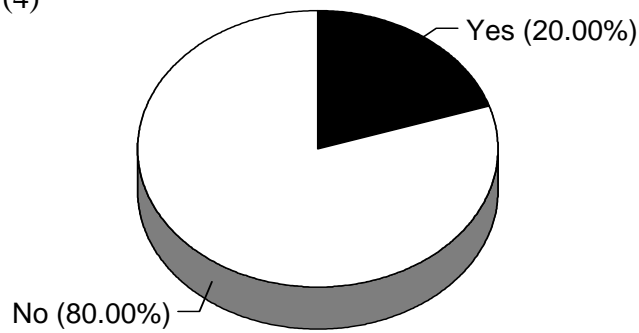
- Yes (5)
- No (2)



**Fig. 8.** Pie chart demonstrating the proportion of liver programs that require that a patient follows a formal treatment program prior to activation on the waiting list.

If the answer is yes, do you require that the patient sign a formal contract?

- Yes (1)
- No (4)



**Fig. 9.** Pie chart demonstrating the proportion of liver programs that require that the patient sign a formal contract.

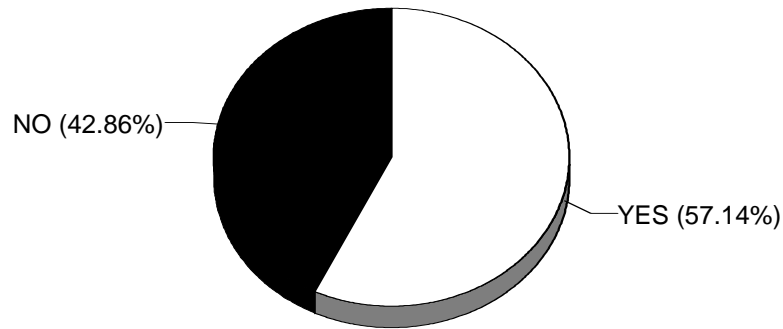
If a formal program is required, please provide *details* including the duration of abstinence.

- i. "a contract is under development for any prospective candidate with recent alcohol abuse or IV drug abuse- assessment in a residential treatment program is mandatory as is a 6 month period free of alcohol/injection drug use"
- ii. "alcohol important if the patient has alcoholic liver disease [Province guidelines keeping with CLTSG- 6 month period of abstinence"
- iii. "[Individualized]- min: 6 months [alcohol] abstinence, may require assessment/treatment by addiction expert if our team deems them 'mod/high' risk of recidivism"
- iv. "for alcoholic abstinence of  $\geq$  6 months generally required"
- v. "a formal consultation with a "Transplant psychiatrist" to evaluate substance abuse personality is requested before listing. Also AA is strongly encouraged and a family meeting & social work evaluation is requested. A minimum of 6 months Abstinence is required in nearly all cases"

#### 4. Social and Community Support

Do you require that the patient have established programs for social and community support prior to listing for liver transplantation?

- Yes (4)
- No (3)



**Fig. 10.** Pie chart illustrating the proportion of programs that require that the patient have established programs for social and community support prior to listing for liver transplantation.

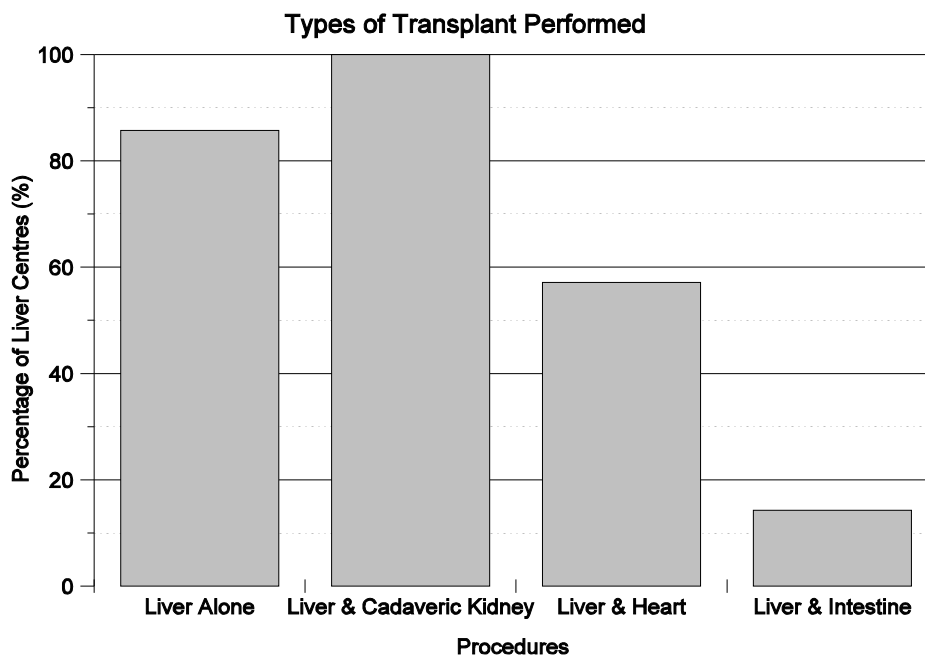
If the answer is *yes*, please provide the *details* of the system and your requirements.

- i. "[No] Although a strong positive, if none are available, the program (esp. social worker) will work to establish such a system"
- ii. "careful psychosocial assessment to ensure adequate support for pt postop. We have a preop/postop support group - voluntary"
- iii. "comprehensive social evaluation prior to listing - and provision of support for the post-operative phase"
- iv. "we require that the family is involved and that social services will see the pt before in order to initiate adequate return to pts usual environment"
- v. "Multi-disciplinary support: family, friend, social,...psych. Etc."



## 5. Types of Transplant Performed

Please indicate which of the following procedures are performed within your transplant program:



**Fig. 11.** Bar graphs indicating the percentage of liver centres which perform liver alone, liver and cadaveric kidney, liver and heart, and liver and intestine transplantation procedures.

In cases of double-organ procedures, please provide the impact this may have on your responses to questions 1 to 4 (demography and employment; comorbid disease; substance abuse; social and community support).

- i. "none";
  - ii. "no fundamental differences";
  - iii. "much more emphasis on co-morbid disease (diabetes, respiratory status, social supports)";
  - iv. "only medical factors considered";
  - v. "none different from liver alone";
  - vi. "none"
  - vii. [Procedures] "although not performed, recipients have been evaluated for combined liver-heart transplant and a patient is currently listed for liver-lung"
- Other:
- viii. Lung [3 centres], pancreas [2 centres], living donor kidney [1 centre].



**Appendix 4**  
**Sample Mail Outs**



October 2, 1998

Dr. John Doe  
Director of Heart Transplant  
Your Hospital  
1 Avenue  
City, Prov. A1A 2B2

Dear Dr. Doe:

I am writing to ask of your program's willingness to participate in a mail survey designed to review current criteria for adult recipient selection for heart (cadaveric kidney, liver) transplantation from both ethical and social viewpoints. This survey is part of a larger study to assess current Canadian and international criteria for adult recipient selection for heart, cadaveric kidney and liver transplantation from ethical and social viewpoints based on survey results and a review of published literature.

Following this letter, you will receive a fax on October 16 to confirm receipt of the mail survey and to determine your willingness to participate in this study. If wishing to participate, please respond to the attached questionnaire and return it with a signed consent form using the enclosed stamped self-addressed envelope by Friday, November 13. If you do not wish to take part in this study, please return the enclosures after October 16.

Should you have further questions, please contact me by email [husseinn@ccohta.ca] or telephone us at (613) 226-2553.

Yours sincerely,

Hussein Z. Noorani, MSc  
*Project Director and Research Associate*

c.c. Dr. Jill Sanders, President, CCOHTA  
encls.



Identifiant:OH

CONSENT FORM

**Title of Project:** Criteria for Selection of Adult Recipients for Heart, Cadaveric Kidney and Liver Transplantation

**Project Team:** Mr. Hussein Noorani                      Ms. Lynda McGahan                      Ms. Annie Hall  
Director    Assistant    Librarian

**Board Representative:** Dr. Renaldo Battista, Conseil d'évaluation des technologies de la santé du Québec

**Clinical Advisory Panel:** Dr. Bernard Dickens                      Dr. Paul Keown                      Dr. William Wall  
University of Toronto                      Vancouver General Hospital                      London Health Sciences Centre

**Scientific Advisory Panel:** Dr. Murray Krahn                      Dr. Andreas Laupacis \*                      Dr. Bernie O'Brien \*  
The Toronto Hospital University of Ottawa                      McMaster University

**Objective of the Project:** To assess current Canadian and international criteria for adult recipient selection for heart, cadaveric kidney and liver transplantation from ethical and social viewpoints

**Description of the Project:** Your transplant program has been identified for this study from the "Directory of Participating Dialysis Centres, Transplant Centres and Organ Procurement Organizations in Canada, 1998," published by the Canadian Institute for Health Information.

This study involves completion of a 30 to 45 minutes mail questionnaire tailored for transplantation by organ type. Each survey will be sent to the director of the relevant program with a request that all members of the transplant team who could provide information to complete the questionnaire be consulted. This study is designed to review current listing practices for heart, cadaveric kidney and liver transplantation from ethical and social viewpoints.

Your program's participation in this study will assist us in preparing a document to benefit participants in transplantation including individuals responsible for public policy, healthcare professionals in the field, and potential organ recipients. Upon completion of the project, you will be provided with a copy of the report, including survey results describing current listing practices at the national level.

**Confidentiality:** Your responses to the survey will be held in strictest confidence; only members of the project team identified above will have access to them. Each survey contains a unique identification number that ensures respondents' anonymity. No information that discloses your name or your program's identity will be released or published without your additional consent.

**Consent:**

\_\_\_\_\_  
Name of participating transplant program  
\*Members until October, 1998.

\_\_\_\_\_  
Signature of program director

\_\_\_\_\_  
Date

## Criteria for Selection of Adult Recipients for Heart (Cadaveric Kidney, Liver) Transplantation

### 1. Demography and Employment

In listing patients for heart transplantation, how important are the following factors in this decision: (Please *circle* the appropriate degree of importance for each category)

	<u>None</u>		<u>Relative</u>				<u>Absolute</u>
Age:	0	1	2	3	4	5	
Race:	0	1	2	3	4	5	
Sex:	0	1	2	3	4	5	
Employment status:	0	1	2	3	4	5	
Nationality:	0	1	2	3	4	5	
Insurance status:	0	1	2	3	4	5	
Other: _____	0	1	2	3	4	5	
_____	0	1	2	3	4	5	

If applicable, please provide *details* on your requirements regarding the above categories.

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**2. Comorbid Disease**

In listing patients for heart transplantation, how important are the following factors in this decision: (Please *circle* the appropriate degree of importance for each category)

	<u>None</u>		<u>Relative</u>			<u>Absolute</u>
Mental competence:	0	1	2	3	4	5
Psychiatric illness:	0	1	2	3	4	5
Cardiovascular disease:	0	1	2	3	4	5
Pulmonary disease:	0	1	2	3	4	5
Liver disease:	0	1	2	3	4	5
Diabetes mellitus:	0	1	2	3	4	5
Bone disease:	0	1	2	3	4	5
Malignancy:	0	1	2	3	4	5
Hepatitis B infection:	0	1	2	3	4	5
Hepatitis C infection:	0	1	2	3	4	5
HIV infection:	0	1	2	3	4	5
Body weight:	0	1	2	3	4	5
Other:	0	1	2	3	4	5
_____	0	1	2	3	4	5
_____	0	1	2	3	4	5

If applicable, please provide *details* on your requirements regarding the above categories.

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### 3. Substance Abuse

In listing patients for heart transplantation, how important are the following factors in this decision: (Please *circle* the appropriate degree of importance for each category)

	<u>None</u>		<u>Relative</u>		<u>Absolute</u>	
Alcohol abuse:	0	1	2	3	4	5
Tobacco use:	0	1	2	3	4	5
Illicit drug use:	0	1	2	3	4	5
Other:	0	1	2	3	4	5
_____	0	1	2	3	4	5
_____	0	1	2	3	4	5

If any of the above factors are of importance, do you require that the patient follow a formal treatment program prior to activation on the waiting list?

- Yes
- No

If the answer is *yes*, do you require that the patient sign a formal contract?

- Yes
- No

If a formal program is required, please provide *details* including the duration of abstinence.

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**4. Social and Community Support**

Do you require that the patient have established programs for social and community support prior to listing for heart transplantation?

- Yes
- No

If the answer is *yes*, please provide the *details* of the system and your requirements.

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**5. Types of Transplant Performed\***

Please indicate which of the following procedures are performed within your transplant program:

- Heart alone
- Heart and Lung
- Heart and Cadaveric Kidney
- Heart and Liver
- Other:

\_\_\_\_\_  
\_\_\_\_\_

In cases of double-organ procedures, please provide the impact this may have on your responses to questions 1 to 4 (demography and employment; comorbid disease; substance abuse; social and community support).

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

\*For cadaveric kidney transplantation, the listed procedures were: cadaveric kidney alone; cadaveric kidney and pancreas; cadaveric kidney and heart; cadaveric kidney and liver; other.  
For liver transplantation, the listed procedures were: liver alone; liver and kidney; liver and heart; liver and intestine; other.