

The Canadian Council for Donation and Transplantation

Kidney Allocation in Canada:

A Canadian Forum

October 25-27, 2006

Toronto, Ontario

Report and Recommendations

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Foreword

The Canadian Council for Donation and Transplantation (CCDT) was established in October 2001 to improve organ and tissue donation and transplantation in Canada. The CCDT is an independent, not-for-profit corporation mandated to provide advice to the Conference of Federal/Provincial/Territorial Deputy Ministers of Health in support of its efforts to coordinate federal, provincial, and territorial activities relating to organ donation and transplantation.

The CCDT Transplantation Committee is developing a framework for action at local, provincial, territorial, and national levels that will result in a sustainable, systematic approach to organ transplantation. This framework will be based on evidence gathered through a review of existing national and international practices, policies, or guidelines, a review of peer-reviewed scientific literature, and expert consensus.

The Canadian forum, *Kidney Allocation in Canada*, brought together stakeholders responsible for kidney allocation in their jurisdictions to discuss and develop consensus recommendations for allocation. The aim of the forum was to develop a step-by-step decision-making model that is acceptable, useful, and adaptable within unique regions across the country. This aim was successfully achieved by interactive group work at the forum. The participants acknowledged that acceptance and implementation of a kidney allocation model would require thoughtful implementation strategies and must recognize the unique needs of regions, programs and health-care professionals.

We believe that the recommendations from this forum will make a vital contribution to transparent and equitable kidney allocation practices in Canada.



Dr. David Hollomby
Chair, CCDT Transplantation Committee

Preface

The *Kidney Allocation in Canada* forum was conceived to address how deceased and non-directed living donor kidneys are allocated to adult and pediatric patients on wait-lists. Sponsored by the Canadian Council for Donation and Transplantation in collaboration with the Canadian Society of Transplantation, it was held in Toronto from October 25 to 27, 2006.

The goal of the forum was to develop recommendations on best practices for practitioners and health-care providers related to the allocation of kidneys for transplantation. Underpinning the forum were the following key premises:

- Optimal organ allocation is the process by which kidneys are allocated in an equitable and transparent way to patients who are waiting for transplantation.
- Patient need for deceased donor organs outstrips supply and, as a result, decisions must be made about which patient among the many waiting will receive a kidney for transplantation.
- The gap between the supply of and demand for organs makes equity and transparency in the allocation process essential.
- The allocation of a scarce resource (e.g., transplantable organs) must be done fairly, considering both equitable access and optimal outcomes for transplantation.
- Developing an organ allocation model does not dictate medical practice, but provides a framework for operations. Individual physicians will continue to make decisions regarding individual patients.
- The model will focus on the allocation of deceased and non-directed living donor organs.
- The kidney allocation initiative will incorporate organ sharing for sensitized patients, as previously recommended (see *Assessment and Management of Immunologic Risk in Transplantation: A CCDT Consensus Forum*, 2005), but will not otherwise include organ-sharing across jurisdictions.
- Policies and approaches specific to the Canadian health-care system are necessary for accountability.

Fifty-eight participants from across Canada and the United States attended the forum, including leading experts in kidney transplantation, health-care administration, bioethics, and health law. Presentations supported by extensive background research were followed by facilitated group discussion aimed at exploring issues and achieving consensus.

It is hoped that this report on the forum proceedings and recommendations will serve as an instrument for change and improvement by laying a foundation for effective local/regional practices and national strategies for kidney allocation in Canada.



Dr. Greg Knoll
Forum Chair

Acknowledgements

Forums of this type would have no hope of success without the work of the people who organize them. To this end, we would like to thank Tracy Brand, Dorothy Strachan, Nancy Greene, and Leslie Ebbs. Their efforts throughout the forum process are deeply appreciated.

A special note of appreciation goes to the Steering Committee and the Forum Recommendations Group for their committed participation in the process that has led to the recommendations in this report.

To David Hollomby, thank you for your long-standing belief in the importance of this project. To all of the participants, thank you for giving of your expertise and time to ensure the success of this process.

The support and guidance of the Chief Executive Officer of the CCDT, Kimberly Young, was integral to the success of the *Kidney Allocation in Canada* project.

In closing, we would like to acknowledge the support of the CCDT Council and the Chair of Council, Leah Hollins – thank you.

Executive Summary

Kidney Allocation in Canada was the first in a series of fora dedicated to the area of organ allocation. It was sponsored by the Canadian Council for Donation and Transplantation (CCDT) in collaboration with the Canadian Society of Transplantation (CST). Fifty-eight participants and speakers from across Canada and the United States attended the event in Toronto, Ontario, from October 25 to 27, 2006.

The aim of this forum was to develop a step-by-step decision-making model that would be acceptable, useful, and adaptable within unique regions across the country. It provided an opportunity for discussion and agreement on the key components of a deceased donor kidney allocation model.

The forum had the following objectives:

1. To identify factors (e.g., medical, legal, ethical, logistical, and administrative) that contribute to transparent and equitable kidney allocation practice;
2. To develop a kidney allocation model that incorporates the factors in objective 1 and that is sufficiently flexible to adapt to regional applications;
3. To enhance transparency and improve public confidence in the Canadian transplantation system; and
4. To identify important areas of research related to kidney allocation.

The scope of the kidney allocation initiative was to address how deceased and non-directed living donor kidneys are allocated to adult and pediatric patients on wait-lists. The resultant model will include kidney and kidney/pancreas allocation only.

Forum participants participated both as experts in their fields and as agents of change. A multi-disciplinary group that represented all regions of Canada and parts of the United States, they included health professionals, representatives of various government and non-government health organizations, health administrators, and policy makers. Forum discussions focused on building consensus on key challenges and were both lively and reflective, resulting in practical and thoughtful recommendations.

The Steering Committee provided substantive background documents in advance of the forum, which were enriched by presentations by national and international experts at the forum. To develop recommendations, participants worked in small groups to address key challenge questions related to kidney allocation. Following these deliberations, the Forum Recommendations Group (FRG), a multidisciplinary group representative of forum stakeholders, met to review the results and develop consensus recommendations. These were then returned to plenary for further clarification and discussion.

The forum process resulted in recommendations on the following aspects of kidney allocation:

- The inclusion of human leukocyte antigen (HLA) matching, sensitization, and wait-time in the kidney allocation model;
- The start of wait-time and wait-time accrual in certain circumstances;

- Medical issues related to donor-recipient age matching, priority consideration for certain patient groups and circumstances, and expanded criteria donor kidneys;
- Legal and ethical issues regarding the kidney allocation process; and
- Ranking of various factors for consideration in local/regional algorithms for the allocation of standard criteria donor and expanded criteria donor kidneys.

Participants' suggestions for relevant research questions were also gathered.

Next Steps

These recommendations will be forwarded to the CCDT for consideration regarding advice to the Conference of Federal/Provincial/Territorial Deputy Ministers of Health. The CCDT will also distribute the report to other stakeholders with responsibilities for implementation in the field. Specifically, the recommendations will be presented and discussed at the Canadian Society of Transplantation Kidney Working Group meeting in March 2007. In addition, further discussions will be held with key stakeholder groups, such as provincial/local transplant organizations, to support collaboration for knowledge translation and implementation.

Outcomes

Immediate outcomes of the forum will be to provide recommendations for the transplant community on the allocation of deceased and non-directed living donor kidneys and to provide advice on the recommended components and practices for improved kidney allocation in Canada to the Conference of Federal/Provincial/Territorial Deputy Ministers of Health.

Over the intermediate and long term, the kidney allocation initiative will result in the following:

- Consistent and transparent kidney allocation in Canada;
- Recommendations for a kidney allocation model to contribute to the development of government policy and appropriate funding for the allocation of kidneys and transplant patient care in Canada;
- Enhanced confidence in the Canadian transplantation system by members of the public and health-care professionals;
- Increased health services research opportunities in kidney allocation; and
- Recommendations to address gaps in infrastructure support.

Forum Committees

Greg Knoll, MD Forum Chair	Division of Nephrology, The Ottawa Hospital	Steering Committee Planning Committee
Edward Cole, MD	Division of Nephrology, University Health Network	Steering Committee Planning Committee
Peter Nickerson, MD	Division of Nephrology, University of Manitoba	Steering Committee Planning Committee
Dana Baran, MD	Medical Director, Québec-Transplant	Steering Committee
Sandra M. Cockfield, MD	Division of Nephrology, University of Alberta	Steering Committee
John Dossetor, MD	Bioethics	Steering Committee
Beryl Ferguson	National Program Director, Kidney Foundation of Canada	Steering Committee
John Gill, MD	Division of Nephrology, University of British Columbia	Steering Committee
Diane Hébert, MD	Division of Nephrology, Hospital for Sick Children	Steering Committee
Bjorn Nashan, MD	Multi-Organ Transplant Program, Queen Elizabeth II—Health Science Centre	Steering Committee
Tracy Brand, RN, BSN	Director of Initiatives, Canadian Council for Donation and Transplantation	Steering Committee Planning Committee
Kimberly Young	Chief Executive Officer, Canadian Council for Donation and Transplantation	Steering Committee
Dorothy Strachan	Strachan-Tomlinson Consulting	Forum Facilitation

Sponsored by:

Canadian Council for Donation and Transplantation

In collaboration with:

Canadian Society of Transplantation

Participating Organizations

- British Columbia Transplant Society
- Canadian Association of Transplantation
- Canadian Bioethics Society
- Canadian Council for Donation and Transplantation
- Canadian Society of Nephrology
- Canadian Society of Transplantation
- Kidney Foundation of Canada
- Multi-Organ Transplant Program – Atlantic Canada
- New Brunswick Department of Health
- Québec-Transplant
- Saskatchewan Transplant Program
- Transplant Manitoba – Gift of Life
- Trillium Gift of Life Network



Part I:

Forum Overview

Part I: Forum Overview

The aim of this forum was to develop a step-by-step decision-making model for the allocation of kidneys that is acceptable, useful, and adaptable within unique regions across the country. The forum provided an opportunity for discussion and agreement on the key components of this model.

Objectives

The forum had the following objectives:

1. To identify factors (e.g., medical, legal, ethical, logistical, and administrative) that contribute to transparent and equitable kidney allocation practice;
2. To develop a kidney allocation model that incorporates the factors in objective 1 and that is sufficiently flexible to adapt to regional applications;
3. To enhance transparency and improve public confidence in the Canadian transplantation system; and
4. To identify important areas of research related to kidney allocation.

Scope

The scope of the kidney allocation initiative is to address how deceased and non-directed living donor kidneys are allocated to adult and pediatric patients on wait-lists. The model will include kidney and kidney/pancreas allocation only and, therefore, it will not include the following:

- Allocation of organs from directed living donors;
- Allocation of deceased donor islet cells;
- Allocation of List Exchange kidneys;
- Paired or living-donor exchange models (addressed within another CCDT transplantation initiative); or
- Tissue allocation (addressed within a CCDT tissue initiative).

Assumptions

Core assumptions were the agreed-upon “givens” that provided a common starting point for reflection, discussion, and decision making at this forum. They outlined the perspective within which the process unfolded and helped ensure that everyone involved was focused on a common purpose and objectives. The key assumptions underlying this forum were as follows:

1. Optimal organ allocation is the process by which kidneys are allocated in an equitable and transparent way to patients who are waiting for transplantation.
2. Patient need for deceased donor organs outstrips supply and, as a result, decisions must be made about which patient among the many waiting will receive a kidney for transplantation.
3. The gap between the supply of and demand for organs makes equity and transparency in the allocation process essential.

4. The allocation of a scarce resource (e.g., transplantable organs) must be done fairly, considering both equitable access and optimal outcomes for transplantation.
5. Developing an organ allocation model does not dictate medical practice, but provides a framework for operations. Individual physicians will continue to make decisions regarding individual patients.
6. The model will focus on the allocation of deceased and non-directed living donor organs.
7. The kidney allocation initiative will incorporate organ sharing for sensitized patients, as previously recommended (see *Assessment and Management of Immunologic Risk in Transplantation: A CCDT Consensus Forum*, 2005), but will not otherwise include organ-sharing across jurisdictions.
8. Policies and approaches specific to the Canadian health-care system are necessary for accountability.

Key Considerations

The following important circumstances, facts, data, and concerns will be taken into account due to their potential impact on the success of the kidney allocation initiative:

1. There is regional variability in Canada with regard to wait-times for deceased donor kidney transplants. Differences in current organ allocation practices in part reflect differences in deceased donor rates within regions of Canada.
2. Consensus guidelines on eligibility criteria for kidney transplantation have been developed by the CST Kidney Working Group and have been published in the *Canadian Medical Association Journal*.
3. The applicability of kidney allocation models utilized by other countries [e.g., United Network for Organ Sharing (UNOS), UK Transplant, Australia] will inform the project.
4. Increased incidence of end-stage renal disease will escalate the need for donor organs. Paradigms for kidney allocation will need to evolve as need escalates.
5. Prolonged exposure to dialysis while on the wait-list for transplantation is associated with increased mortality.
6. Transplantation is more beneficial to children and adolescents (e.g., growth, education, quality of life) and, consequently, prioritization of children should be considered.
7. The acceptance and implementation of a kidney allocation model will require thoughtful implementation strategies that recognize the unique needs of regions, programs, and health-care professionals.
8. The CCDT sponsored a related project in 2005/06, a report to consider the feasibility of a national paired-donor exchange registry.

Process

Substantive background documents were provided by the Steering Committee in advance of the forum, including comprehensive literature reviews and related practice surveys. Each topic area was addressed during the forum using the following process:

1. Presentations by experts from national and international jurisdictions were followed by a question-and-answer period. Participants then worked in small groups to address key challenge questions. Each group selected a facilitator to keep people on track and a recorder to reflect agreement by group members and prepare a brief plenary report.
2. Small group discussions focused on specific questions related to kidney allocation. The following five challenge areas and questions were addressed:

Human Leukocyte Antigen Matching and Sensitization

Questions explored the following:

- Inclusion of HLA matching in the algorithm.
- Inclusion of sensitization in the algorithm.

Wait-Time

Questions explored the following:

- Inclusion of wait-time in the algorithm.
- Wait-time accrual prior to dialysis.
- Start of wait-time for patients on dialysis.
- Start of wait-time for re-transplants.
- Wait-time accrual for patients with early graft failure.
- Deceased or non-directed living-donor transplants for patients not on dialysis.
- Wait-time accrual for patients who move to another jurisdiction.

Medical Issues

Questions explored the following:

- Priority consideration for children.
- Donor-recipient age matching.
- Priority consideration for young adults.
- United Network for Organ Sharing (UNOS) definition of extended criteria donor (ECD) kidney.
- Allocation of ECD kidneys.
- Separate wait-list for recipients of ECD kidneys.
- Criteria for recipients of ECD kidneys.
- Allocation of ECD kidneys as doubles.

- Priority consideration for kidney/pancreas transplant recipients.
- Consideration for other combined-organ transplant recipients.
- Consideration of medical urgency.

Legal and Ethical Issues

Questions explored the following:

- Allocation based on factors other than wait-time.
- Disclosure of donor information to recipients.
- Transparency and accountability in kidney allocation process.

Ranking

This exercise involved ranking, in order of priority, various factors for consideration in a local/regional algorithm for the allocation of standard criteria donor (SCD) kidneys.

3. After each round of group discussions was completed, the FRG met to review results and develop consensus recommendations, which were later returned to the plenary for further clarification and discussion.
4. Participants' suggestions for relevant research questions were gathered and summarized.

Forum participants represented a broad range of disciplines, ensuring that discussions were inclusive and involved multiple perspectives. Forum deliberations were thoughtful, dynamic, and collegial as participants focused on building agreement on key challenge questions.

Members of the FRG panel came to unanimous agreement on recommendations to inform current and future practice and ranked factors for consideration in a local/regional algorithm for the allocation of SCD kidneys according to five levels of priority.

The FRG also recommended factors for consideration in a local/regional algorithm for the allocation of ECD kidneys, areas that should be addressed in order to improve the current information system, and areas requiring further research.

Outcomes

Results of the deceased donor kidney allocation initiative will help to achieve the following overarching outcomes:

Immediate

- Recommendations for the transplant community on the allocation of deceased donor and non-directed living donor kidneys.
- Advice on the recommended components and practices for improved kidney allocation in Canada to the Conference of Federal/Provincial/Territorial Deputy Ministers of Health.

Intermediate and Long-Term

- Consistent and transparent kidney allocation in Canada.
- Recommendations for a kidney allocation model to contribute to the development of government policy and appropriate funding for the allocation of kidneys and transplant patient care in Canada.
- Enhanced confidence in the Canadian transplantation system by members of the public and health-care professionals.
- Increased health services research opportunities in kidney allocation.
- Recommendations to address gaps in infrastructure support.

Expert Speakers

Given the complexity of the social, medical, ethical, and legal challenges related to kidney allocation, the following presentations were made to enhance participant learning and understanding in advance of discussions:

Challenge Address

Greg Knoll, MD, Chair Challenge Address

Part A: HLA Matching and Sensitization

Peter Nickerson, MD HLA Matching and Sensitization

Part B: Wait-Time

John Gill, MD Wait-Time

Part C: Medical Issues

Bertram Kasiske, MD Donor Recipient Age

Edward Cole, MD Expanded Criteria Donors

Bryce Kiberd, MD Kidney/Pancreas Allocation

Sandra M. Cockfield, MD Medical Urgencies

Part D: Current and Future Allocation Issues in North America

John Gill, MD Canada/USA Comparison

Mark Stegall, MD US/Kidney Allocation Review Subcommittee Overview

Alan Leichtman, MD Net Benefits Model

Part E: Legal and Ethical Issues

Timothy Caulfield, LL.M. Legal and Ethical Principles in Allocation

Part F: Ranking

Greg Knoll, MD Ranking Overview

Part G: Forum Recommendations Group and Plenary Discussion

Forum Recommendations FRG Recommendations
Group

Closing Remarks

David Hollomby, MD Closing Remarks

Forum Recommendations Group Members

Dana Baran, MD	Medical Director, Québec-Transplant, Montréal QC
Brendan Barrett, MD	Division of Nephrology, Health Sciences Centre, St. John's NL
Tim Caulfield, LL.M.	Health Law Institute, University of Alberta, Edmonton AB
Sandra M. Cockfield, MD	Division of Nephrology, University of Alberta Hospital, Edmonton AB
Edward Cole, MD	Division of Nephrology, University Health Network, Toronto ON
John Gill, MD	Division of Nephrology, University of British Columbia, Vancouver BC
Greg Knoll, MD	Division of Nephrology, The Ottawa Hospital, Ottawa ON
Bjorn Nashan, MD	Multi-Organ Transplant Program, Queen Elizabeth II—Health Science Centre, Halifax NS
Peter Nickerson, MD	Medical Director, Transplant Manitoba—Gift of Life, Winnipeg MB
Steven Paraskevas, MD, PhD	Department of Surgery, McGill University Health Centre, Montréal QC
Linda Wright, MHSC	Bioethicist, University Health Network, Toronto ON

Advisory to the Forum Recommendations Group

Tracy Brand, RN, BSN	Director of Initiatives, Canadian Council for Donation and Transplantation Forum Project Manager, Kidney Allocation in Canada
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Part II:

**Recommendations Related
to Kidney Allocation**

Part II: Recommendations Related to Kidney Allocation

The recommendations and kidney allocation algorithms presented in this report may be customized based on local/regional conditions. Each jurisdiction is encouraged to adapt them to suit its particular needs and circumstances, and to implement them in a way that maximizes the use of deceased donor kidneys and minimizes wastage.

In discussions related to legal and ethical issues surrounding kidney allocation, FRG members identified the following overarching recommendations that apply to all challenges.

Overarching Recommendations

We recommend that the kidney allocation process reflect a thoughtful and transparent balance of utility and justice, grounded in the best available evidence.

We recommend that all material information be provided to transplant recipients in a manner that is understandable and that respects existing legal requirements for both consent and donor privacy. This includes information on the potential for transmissible disease and any other relevant information related to the consequences of accepting or declining the organ.

We recommend that members of the public be consulted when reviewing and developing kidney allocation algorithms. In addition, algorithms should be available for public scrutiny; for example, in hospital clinics, in dialysis units, and on appropriate websites.

Key Considerations

- Justice in organ allocation involves a number of factors that are not necessarily restricted to wait-time.
- Allocation criteria should be careful to avoid discrimination on the basis of medically irrelevant factors.

A. Human Leukocyte Antigen Matching and Sensitization

A1: Inclusion of Human Leukocyte Antigen Matching in Algorithm

We recommend that human leukocyte antigen matching be included in a local/regional algorithm. We recognize the major advantage of a zero ABDR mismatch. The additional benefit of lesser matches, including zero BDR or zero DR mismatch, is much less and therefore their inclusion needs to be balanced against competing issues.

Key Considerations

- Other biological factors should be able to override HLA matching.
- Medical judgment should be used in situations where the benefit of HLA matching may not be realized.
- Including HLA matching makes allocation less predictable and therefore complicates wait-list management.

A2: Inclusion of Sensitization in Algorithm

We recommend that highly sensitized patients (e.g., panel reactive antibody greater than or equal to 80 per cent*) be given priority in a local/regional algorithm. Lesser degrees of sensitization will have less impact on transplantability and, therefore, need to be balanced against competing issues.

- * This threshold could change based on the deliberations of the highly sensitized registry's Laboratory Oversight Committee.

Key Considerations

- Canadian stakeholders have confirmed in a previous CCDT forum that one of two kidneys should be preferentially offered to highly sensitized patients [panel reactive antibody (PRA) \geq 80%] on a national basis. It is anticipated, however, that only 10 per cent of such offers would find suitable recipients due to the difficulty of finding acceptably matched kidneys for these highly sensitized patients.
- All programs should be standardized to flow-based technology for PRA measurement.
- The method of calculating PRA should be standardized in reference to the local donor pool.

B. Wait-Time

B1: Inclusion of Wait-Time in Algorithm

We recommend that wait-time be included in a local/regional algorithm.

Key Considerations

- Increased time on dialysis is associated with decreased survival, both before and after transplantation.
- Increased time on dialysis prior to transplantation is associated with decreased graft survival after transplantation.
- Justice in organ allocation involves a number of factors that are not restricted to wait-time.

B2: Start of Wait-Time for Patients on Dialysis

We recommend that wait-time be calculated from the start of chronic dialysis.

B3: Wait-Time Accrual Prior to Dialysis

We recommend that patients may be listed prior to dialysis if their measured or estimated glomerular filtration rate is less than or equal to 15 ml/min/1.73m²; however, credit for wait-time should not accrue until dialysis begins.

We recommend that patients not on dialysis be allowed to receive a deceased or non-directed living donor kidney transplant.

Key Considerations

- Glomerular filtration rate is measured differently in various centres and should be standardized locally/regionally.
- While pre-emptive transplantation may be the desired renal replacement therapy, the scarcity of deceased donor kidneys makes the accumulation of wait-time prior to the start of dialysis problematic.
- Allowing patients to receive pre-emptive transplants based on factors other than wait-time provides an opportunity to maximize utility and attempt to achieve fairness in organ allocation. Pre-emptive listing also encourages early transplant referral and assessment, which may have indirect benefits.

B4: Start of Wait-Time for Re-Transplants

We recommend that the start of wait-time for re-transplant be the date of the initiation of dialysis after graft failure.

B5: Wait-Time Accrual for Patients with Early Graft Failure

We recommend that patients with early graft failure (less than or equal to 90 days) retain credit for previously accrued wait-time.

B6: Wait-Time Accrual for Patients Who Move to Another Jurisdiction

We recommend that patients who move from one jurisdiction to another be allowed to maintain credit for wait-time accrued since the start of dialysis.

We recommend that patients be active on only one local/regional kidney wait-list at a time.

C. Medical Issues

C1: Priority Consideration for Children

We recommend that children (18 and under) receive priority consideration in a local/regional allocation scheme.

C2: Donor-Recipient Age Matching

We recommend that young donor kidneys be given to pediatric recipients (18 and under).

C3: Priority Consideration for Young Adults

We recommend that young adults be given priority in a local/regional allocation scheme in order to facilitate their access to young standard criteria donor kidneys.

Note: The intent is to facilitate access to younger kidneys by younger recipients; not necessarily to reduce wait-time for younger recipients (see Appendix 2, Section 3, for supporting evidence).

Key Considerations

- It is recognized that age matching is already a part of Canadian transplant practice.
- The availability of young standard criteria donor kidneys is limited.
- Evidence shows that transplanting young donor kidneys to young recipients maximizes graft survival and reduces the need for re-transplantation.

C4: Definition of Expanded Criteria Donor Kidneys

We recommend that an expanded criteria donor, for the purposes of kidney transplantation, be defined as a donor aged 60 and over.

Key Considerations

- The UNOS definition used for this forum needs to be validated in a Canadian setting and periodically re-evaluated.
- ECD kidneys, as defined by UNOS criteria, are currently being used at most Canadian transplant centres.
- The current UNOS definition of an ECD kidney may account for too large a proportion of the donor pool. Use of this definition may restrict the number of kidneys available to all patients on the waiting list.
- In certain circumstances, local/regional programs may choose to consider other factors in defining an ECD kidney.

C5: Allocation of Expanded Criteria Donor Kidneys

We recommend that expanded criteria donor kidneys be allocated based on medical urgency and wait-time in order to minimize cold ischemic time and maximize outcome.

Key Considerations

- Other factors may also be taken into consideration, such as known zero ABDR mismatch.
- To reduce perioperative morbidity and mortality, a system that facilitates pre-identification and preparation for intended recipients is desirable.
- In certain circumstances, an ECD kidney may be offered to a recipient who is not on the ECD list—with informed consent.

C6: Placement on Wait-List for Expanded Criteria Donor Kidneys

We recommend that patients who have given informed consent to receive an expanded criteria donor kidney be clearly identified on the transplant wait-list. We recommend that these patients be eligible to receive either a standard or expanded criteria donor kidney.

Key Considerations

- All patients on the ECD list should still be on the standard list and will be placed on the ECD list with informed consent.

C7: Criteria for Expanded Criteria Donor Kidney Recipients

We recommend that consenting patients aged 60 and over and younger patients with significant comorbidities be listed for expanded criteria donor kidneys.

Key Considerations

- Preference for an ECD kidney should be given to recipients who will benefit from shorter wait-times, the trade-off being the acceptance of a kidney of potentially inferior donor quality.
- For transplantation of an ECD kidney to be of benefit, the wait-time for recipients of ECD kidneys must be significantly shorter than the wait-time for SCD kidneys.
- The utilization of ECD kidneys should be encouraged in order to reduce discard rates and optimize outcome.

C8: Allocation of Expanded Criteria Donor Kidneys as Dual Kidneys

We recommend that expanded criteria donor kidneys be utilized as dual kidneys in a setting where they would not be accepted as single transplants within the local/regional area.

C9: Priority Consideration for Kidney/Pancreas Transplant Recipients

When a suitable pancreas donor becomes available, we recommend that the allocation of the kidney follow that of the pancreas, when required.

Key Considerations

- The aim of kidney/pancreas allocation should be to optimize the use of eligible pancreata.
- Centres should place all patients waiting for a pancreas (e.g., those waiting for a pancreas alone as well as those waiting for a combined kidney/pancreas transplant) on a common waiting list.

C10: Consideration for Other Combined Organ Transplant Recipients

We recommend that other combined organ transplants be considered in a local/regional algorithm.

Key Considerations

- Suitability for combined organ transplants requires full discussion at a subsequent forum that includes other organ experts.

C11: Consideration of Medical Urgency

We recommend that in exceptional circumstances a kidney may be preferentially allocated to a patient who is deemed medically urgent due to, for example, lack of dialysis access, severe uremic neuropathy, or severe uremic cardiomyopathy.

Key Considerations

- Other indications may be considered at the discretion of the program.
- Patients deemed medically urgent must be otherwise suitable for kidney transplantation.
- Consensus should be achieved to approve medically urgent status.
- Appropriate documentation should be provided to justify medical urgency. If access is an issue, the patient should be referred to a centre with expertise in vascular surgery and interventional radiology.
- Documentation should be provided that other therapy, including dialysis, has been optimized.
- Periodic review of this status is recommended.

D. Ranking

D1: Allocation of Standard Criteria Donor Kidneys in a Local/Regional Algorithm

We recommend that the following factors should be taken into consideration in a local/regional algorithm on kidney allocation. The factors listed in each of the five categories of priority are not ranked in comparison to others within the same category; ranking within these categories is to be determined at the local/regional level.

- Overriding priority:
 - Medical urgency.
- High priority (listed in alphabetical order):
 - Age: pediatric recipient.
 - Age: young donor to pediatric recipient.
 - Combined transplant: kidney/pancreas transplantation.
 - Matching: zero ABDR mismatch.
 - Sensitization: sensitized patient with panel reactive antibody greater than or equal to 80 per cent.
- Medium priority (listed in alphabetical order):
 - Age: young donor to young adult recipient.
 - Sensitization: sensitized patient with panel reactive antibody between 50 and 79 per cent.
 - Wait-time.
- Low priority:
 - Matching: lesser degree of human leukocyte antigen matching below zero ABDR mismatch.
- No priority:
 - Pre-emptive transplantation.

The following areas were not fully discussed at the forum:

- Priority ranking for potential transplant recipients who were previous living donors. This is an important issue that was not completely reviewed at the forum. Decisions regarding this should be made at the at local/regional level.
- Priority ranking of patients listed for combined transplants (other than kidney/pancreas). This is an important issue that needs to be clarified through further discussion with other organ-specific groups.

E. Information Systems and Research

These recommendations are based on input from group and plenary discussions, as well as expert opinion from FRG members.

E1: Information Systems

We recommend that a comprehensive end-stage renal disease database management strategy be created that incorporates elements of existing databases and those under development. We also recommend that the current national database of dialysis and transplant patients be expanded to include characteristics of donors and wait-listed patients. This is essential to develop allocation algorithms, monitor compliance, ensure quality improvement, and evaluate patient outcomes.

E2: Research in the Canadian Context

We recommend that the following areas of research be carried out related to kidney allocation:

- Impact of donor demographics on recipient outcomes.
- Identification of factors that predict the advantage of receiving a transplant compared to remaining on dialysis.
- Validation and/or refinement of the expanded criteria donor definition.
- Determination of which expanded criteria donor kidneys should be allocated as single vs. dual transplants.
- Legal and ethical issues related to kidney allocation.

Conclusion

Members of the FRG panel came to unanimous agreement on recommendations to inform current and future practices and drafted generally applicable algorithms for the allocation of ECD and SCD kidneys that provide room for local/regional adaptation.



Appendices

Appendix 1: Key Terms and Acronyms

0-antigen mismatch	Occurs when none of the donor A, B, or DR antigens is different from the recipient. Also known as: zero-antigen mismatch 0 HLA mismatch zero HLA-mismatch zero 6 antigen HLA mismatch HLA 6 Antigen zero mismatch zero-mismatch.
6-antigen match	Occurs when a donor and recipient both have all six of the HLA-A, B, and DR antigens in common.
ABDR	A, B and DR antigens
BDR	B and DR antigens
BMI	Body Mass Index
CCDT	Canadian Council for Donation and Transplantation
Cerebrovascular accident	Also known as a stroke, occurring when there is an occlusion of an arterial vessel going to the brain or when there is bleeding into the brain. (source: UNOS)
Clinical Practice Guidelines	In 1994, the Canadian Medical Association (CMA) adopted the definition of clinical practice guidelines (CPGs) as "... systematically developed statements to help practitioner and patient decisions about appropriate health care for specific clinical circumstances." CPGs help physicians decide what is the most effective and appropriate intervention, while care maps help the health-care team organize the delivery of the interventions. Good clinical guidelines have three properties: They define practice questions and explicitly identify all their decision options and outcomes; They explicitly identify, appraise and summarize, in ways that are most relevant to decision-makers, the best evidence about prevention, diagnosis, prognosis, therapy, harm, and cost-effectiveness; and They explicitly identify the decision points at which this valid evidence needs to be integrated with individual clinical experience in deciding on a course of action.
Comorbidities	Coexisting medical problems that are listed as secondary diagnoses (not principal diagnoses).
Cold ischemia time	The amount of time an organ spends being preserved in a cold perfusion solution after organ procurement surgery.

Creatinine clearance	A measure of the amount of creatinine that the kidneys are able to remove from the blood over a 24-hour period. It is one method to measure kidney function.
CST	Canadian Society of Transplantation
Delayed graft function	Delayed graft function: a condition in which a transplanted organ does not function as it should after a transplant.
Diabetes mellitus	A disease that occurs when the body is not able to use blood glucose (sugar). A group of metabolic diseases characterized by high blood sugar (glucose) levels, which result from defects in insulin secretion, action, or both.
DR	DR antigen
ECD	Expanded or extended criteria donor: A donor whose characteristics may include general or organ specific factors such as advanced donor age, prior infection with hepatitis B or hepatitis C, a history of hypertension or diabetes mellitus, abnormal donor organ function, or non-heartbeating status of a deceased donor. The term "expanded" is used because an expansion of the donor pool is considered to increase transplantation and is preferred over the term "marginal donor." (source: UNOS)
ECD kidney	A kidney donated for transplantation from any brain dead donor over the age of 60 years; or from a donor over the age of 50 years with two of the following: a history of hypertension, a terminal serum creatinine greater than or equal to 1.5 mg/dl, or death resulting from a cerebral vascular accident (stroke). (source: UNOS)
Equitable	Implying justice dictated by reason, conscience, and a natural sense of what is fair to all; "equitable treatment of all citizens"; "an equitable distribution of gifts among the children." (www.wordnet.princeton.edu/perl/webwn)
ESRD	End-stage renal disease: Irreversible kidney failure.
European Kidney Allocation System	System based on a consensus among the participating countries Austria, Belgium, Germany, Luxembourg, the Netherlands, and Slovenia.
Evidence-Based Medicine	Good clinical practice guidelines come from evidence-based medicine (EBM), ¹ which is the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients.

¹ An excellent resource for EBM is the Users' Guides to the Medical Literature by the Evidence Based Medicine Working Group. The series was published in JAMA 1993-2000 (bibliography) and is available from Centres of Health Evidence (CHE) at <http://www.cche.net/usersguides/main.asp>.

Evidence-Based Medicine (cont'd)	<p>The five steps of EBM are as follows:</p> <ul style="list-style-type: none"> Convert clinical information needs into answerable questions. Track down the best evidence with which to answer them. Critically appraise that evidence for its validity (closeness to the truth) and usefulness (clinical applicability). Apply the results of this appraisal in clinical practice. Evaluate your clinical performance. <p>EBM can address each of the following five clinical objectives:</p> <ul style="list-style-type: none"> Achieving a diagnosis Estimating a prognosis Deciding on the best therapy Determining harm Providing care of the highest quality.
Flow crossmatch	An HLA crossmatch performed using cell surface fluorescence as the readout to indicate a positive test result. It is considered the most sensitive crossmatch text.
FRG	Forum Recommendations Group
GFR	Glomerular filtration rate: A measure used to determine kidney function, GFR indicates the kidney's ability to filter and remove waste products. (source: UNOS)
Glomerulosclerosis	Scarring of the glomeruli (tiny blood vessels in the kidney).
HLA	Human leukocyte antigen: differences between donor and recipient HLA molecules stimulate the recipient immune system to reject the graft. This can be overcome with immunosuppressive medications (i.e., anti-rejection drugs).
HLA crossmatch (or T cell crossmatch or B cell crossmatch)	An evaluation for the presence of HLA Ab in the recipient's serum that is directed against the HLA molecules of the donor. The presence of donor-specific HLA Ab is an immunologic risk factor for early rejection or graft loss. T cells are generally used as targets for Class I IgG donor-specific antibodies, while B cells can be used to detect both Class I and Class II IgG donor-specific antibodies.
KARS	Kidney Allocation Review Subcommittee
MM	Mismatch
PAK	Pancreas after kidney transplant
Performance Measures	Performance measures are methods or instruments to estimate or monitor the extent to which the actions of a health-care practitioner or provider conform to practice guidelines, medical review criteria, or standards of quality. (Institute of Medicine, 1990)

PRA	Panel reactive antibody: A measure of the degree to which a person has been sensitized (i.e., exposed and developed antibodies to foreign HLA molecules usually via blood transfusion, pregnancy or prior organ transplant) to the different HLA molecules that exist in the general population. The higher the % PRA the greater the degree of sensitization which is associated with a decreased likelihood that a deceased donor organ will be acceptable (i.e., a negative HLA crossmatch).
Review Criteria	Review criteria seek “to enable clinicians and others to assess care.” More specifically, the Institute of Medicine (IOM) suggests that they are “systematically developed statements that can be used to assess the appropriateness of specific health-care decisions, services and outcomes.” To permit such assessments, the statements must usually be “suitable for retrospective medical record review of clinical practice” and capable of evaluating key pathways of past care, including guideline implementation. Although clinicians and others may aim for excellence, review criteria frequently emphasize minimum thresholds of care. Moreover, they should be “based on mandatory or, at worst, near mandatory elements.” Despite the IOM definition of review criteria, it is therefore important that these criteria assess appropriateness and necessity in order to show whether inappropriate and necessary care have taken place. Criteria describing appropriate care and unnecessary care are irrelevant to assessing minimum care and identifying service under use and overuse.
RR	Relative risk
SCD	Standard criteria donor
SCD kidney	A kidney donated for transplantation from any standard criteria donor.
SPK	Simultaneous pancreas/kidney transplant
Standards of quality	Standards of quality are authoritative statements of: 1) minimum levels of acceptable performance or results, 2) excellent levels of performance or results, or 3) the range of acceptable performance or results. (Institute of Medicine, 1990)
UNOS	United Network for Organ Sharing (United States)
Uremic	Pertaining to or caused by a toxic condition associated with renal insufficiency produced by the retention in the blood of nitrogenous substances normally excreted by the kidney.

Appendix 2: Summaries of Evidence

1. Human Leukocyte Antigen Matching and Sensitization

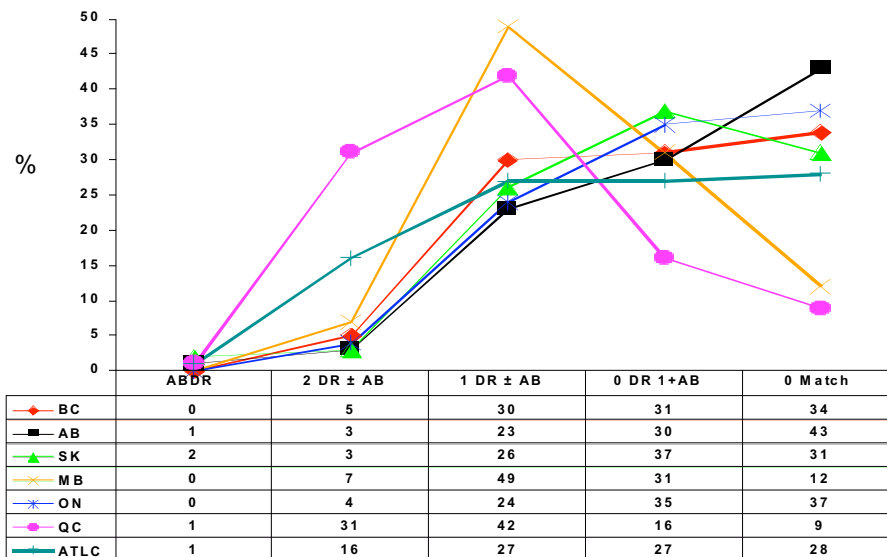
Worldwide there is clear evidence for the benefit of 0 ABDR HLA mismatches being associated with superior long-term graft survival (1-4). For lesser degrees of matching there is clear benefit in terms of early events (i.e., diminished acute rejection) especially for 0 DR HLA mismatches.

Canadian practice:

[1] HLA matching

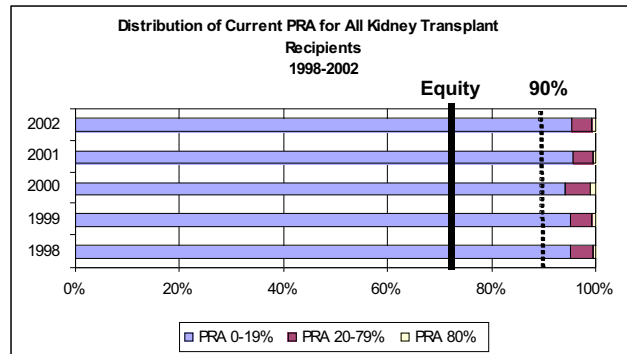
At present there is no consistent practice in Canada, some provinces and/or programs give priority to HLA matching whereas others do not (see figure below).

**Deceased Donor HLA Matching in Canada
(CORR 1999 -2003)**



[2] HLA Sensitization

Sensitized patients (PRA > 20%) make up 30% of the waitlist and yet receive < 5% of the kidney transplants. In the figure below the percentage of sensitized patients receiving a kidney transplant are represented. As can be seen very few sensitized patients are transplanted in Canada.



Canadian Organ Replacement Registry Jan 2005

International practice:

USA:

- There is mandatory sharing of 0 ABDR MM kidneys at a national level.
- Points are awarded for PRA > 80%.

Eurotransplant:

- Points are awarded for HLA matching.
- Highly sensitized patients (PRA > 85%) are given top priority for kidneys via an acceptable mismatch program.

Existing recommendations:

- At present, there are no consensus recommendations for HLA matching in Canada. Indeed, there is large disparity worldwide as to the priority given to HLA matching (i.e., the United Kingdom is moving toward giving more priority while the United States is moving toward giving less priority).
- Most countries have in place a mechanism to give priority to sensitized patients. Indeed, stakeholders in Canada have agreed to share organs for the highly sensitized patient (i.e., PRA > 80%) via a highly sensitized patient registry. However, to date there has been no consensus regarding lesser degrees of HLA sensitization.

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2. Wait-Time

Should wait-time be included in a Canadian algorithm?

The longer patients wait on dialysis before transplantation, the worse their post-transplant outcomes. Patients who wait for a transplant for prolonged periods on dialysis may develop comorbid conditions that were not present at the time of initial activation to the waiting list but which could have a major impact on their post-transplant course. The best outcomes are achieved when dialysis is avoided entirely (pre-emptive transplantation). The unfavorable relationship between time spent on dialysis and outcome is progressive up to four years, which confers about a 70% additional risk of mortality and graft loss compared with pre-emptive transplantation.

Should patients be allowed to accrue wait-time prior to dialysis?

The practice in Canada is variable.

In order to encourage pre-emptive transplantation, UNOS permits patients to be wait-listed at a GFR of 20 ml/min. This policy has the potential to further disadvantage patients who may have presented late in their course of native kidney disease due to a variety of socioeconomic or geographic factors or due to rapid progression to ESRD. This policy also may inadvertently disadvantage patients who require a lengthy transplant evaluation because of the need for additional specialized investigations or interventions that are either not readily available or best delayed until after dialysis is initiated (i.e., coronary angiography). Additional considerations include the facts that it may be difficult to precisely estimate GFR in patients with advanced kidney function impairment, that renal function may vary dramatically in patients with advanced kidney disease, and that some patients may develop significant symptoms at a GFR > 20 ml/min. As a result of these considerations, standardization of the start of wait-time (i.e., date of first chronic dialysis therapy) may be preferable and has been proposed in the United States. Standardization of transplantation from the date of dialysis initiation may also facilitate the completion of a more thorough assessment of patient suitability prior to active wait-listing.

There are some potential drawbacks to standardizing the onset of wait-time to the dialysis start date. One is that because wait-time would be determined independently of the behavior of the patient, there may be a disincentive for some to initiate and complete the evaluation process expeditiously. To prevent this possibility it would need to be made clear to all patients that they must complete the work-up and be listed in order to be offered a kidney, and that delays in listing might lead them to miss an opportunity to receive a kidney. Children in a critical growth phase could be potentially disadvantaged by not permitting pre-dialysis accrual of wait-time; therefore, it may be wise to continue to allow children to be wait-listed pre-emptively.

When should wait-time start for patients on dialysis?

The practice in Canada is variable.

In the United States, time is accrued after the patient is ready for listing.

As above, a non-standardized start time for accrual of wait-time could disadvantage some patients.

All patients will already be treated with dialysis, so there is no consideration of pre-emptive transplantation.

Removing the time pressure to complete the transplant evaluation will likely help manage the patient load in large programs (opinion). However, opportunities to educate patients and families about living-donor transplantation may be delayed, and patients may feel disconnected from the transplant process if the need to list patients as quickly as possible is removed (opinion).

Should the start of wait-time for re-transplant be different than for first transplant?

The issue of when patients should be listed for repeat transplantation has received little attention in the literature. Patients with failing transplants can have a very slow decline in kidney function and may be able to maintain low levels of allograft function and avoid dialysis for prolonged periods of time. Few analyses have examined the effect of wait-time on repeat transplant outcomes. UNOS does not have a separate policy for wait-listing patients for repeat transplantation.

Should patients with early graft failure (i.e., < 90 days) retain previously accrued wait-time?

The UNOS policy (<http://www.unos.org/policiesandbylaws/policies.asp>) regarding immediate and permanent non-functioning transplant kidneys appears below:

3.2.4.2 Waiting Time Reinstatement for Kidney Recipients. In those instances where there is immediate and permanent non-function of a transplanted deceased or living donor kidney, the candidate may be reinstated to the Waiting List and retain the previously accumulated waiting time without interruption for that transplant only. For purposes of this policy, immediate and permanent non-function shall be defined as: (1) kidney graft removal within the first ninety (90) days of transplant evidenced by a report of the nephrectomy for the transplanted kidney or (2) kidney graft failure within the first ninety (90) days of transplant evidenced by documentation that the candidate is either: (a) on dialysis, or (b) has measured creatinine clearance/calculated GFR less than or equal to 20 ml/min on the date that is ninety (90) days following the candidate's kidney transplant. Waiting time will be reinstated upon receipt by the Organ Center of a completed Renal Waiting Time Reinstatement Form and the documentation described above. The Organ Procurement and Transplantation Network contractor will notify the organ procurement organization serving the recipient transplant center of the relisting and forward a copy of the relisting form to that organ procurement organization.

Should patients not yet on dialysis be allowed to receive a deceased or non-directed living donor kidney transplant?

Pre-emptive deceased donor transplantation is not uncommon in the United States, where 39% of all pre-emptive transplants between 1995 and 1998 were from deceased donors.

Non-directed living-donor kidney transplants have been allocated to wait-listed patients pre-emptively.

3. Donor-Recipient Age

There is clear evidence that increasing recipient and donor age are associated with poorer outcomes. Specifically, older donor and recipient age are associated with an increased risk of graft failure (Table 1) and an increased risk of death (Table 2).

It has been suggested that graft survival might be better if older donor kidneys were transplanted into older recipients, rather than into younger recipients. However, the results of registry analyses have failed to support this hypothesis. In an analysis of the United States Renal Data System, Kasiske and Snyder found that donor kidneys ≥ 55 years old were 78% more likely to fail compared with kidneys 18-29 years old. However, giving older kidneys to older recipients had little additional effect on graft survival once the effects of recipient and donor age were taken into account. For example, transplanting donor kidneys ≥ 55 years old into recipients ≥ 55 years old reduced the risk of graft failure only 6% (95% confidence interval, -18 to 8%, $P = 0.3923$) after the effects of donor and recipient age *per se* were taken into account (1). In another US study, Keith and others found that patient survival was affected by donor age for all recipient age groups, including recipients older than 55 years (2). For recipients 0-40 years old, 10-year patient survival for donors 0-17 was 84% compared to 76% for donors ≥ 55 years old (i.e., a difference of 8%). For recipients ≥ 55 years old, 10-year patient survival for donors 0-17 was 48% compared to 35% for donors ≥ 55 years old (i.e., a difference of 13%). Based on this, it appeared that the effects of donor age were similar for young and old recipients, and that donor-recipient age matching would improve survival in younger recipients but adversely affect survival in older patients by reducing the availability of younger donor kidneys for this group (2). In summary, registry analyses confirm that older donor kidneys are equally poor for young and old recipients and vice versa.

Canadian practice:

From the *Kidney Allocation in Canada Survey* (3), there was evidence of age matching in some programs, with seven of nine program respondents indicating that pediatric recipients are given priority for pediatric donations. The following answers were given to the question “Do you attempt age-matching?”:

- 1/12 – Yes; if 20% age difference or less between donor and recipient.
- 4/12 – Loosely (i.e., ‘old for old’ and/or ‘young for young’ policy).
- 4/12 – No age matching.
- 1/12 – ‘Old for old’ used for ECD kidneys only.

International practice:

USA:

- Among other criteria, donor age > 60 years is part of the ECD definition.
- The option of *voluntary* allocation of old kidneys to older recipients with informed consent is allowed.

Eurotransplant:

- Eurotransplant Senior Program allocates donors > 65 years to recipients > 65 years.
- It is a voluntary system requiring informed patient consent.

UK Transplant:

- Allocation points for mismatch between donor and recipient age are reduced according to the following equation: age difference points = $-\frac{1}{2}$ (donor-recipient age difference)².
- Allocation according to age comes after points are given for wait-time and HLA match.

Existing recommendations:

At present, there are no Canadian consensus guidelines on how to allocate kidneys based on donor and recipient age. From the Canadian survey there appears to be strong support for prioritizing pediatric age donors to pediatric recipients.

Table 1. Effects of recipient and donor age on Graft Failure after deceased donor kidney transplantations in 1998-2003 (N=42,979).

Characteristic	Percent of Population	Relative Risk (95% C.I.)	P-Value
Recipient age (years)			
0-17	3.7	1.27 (1.11-1.46)	0.0006
18-34 (reference)	13.7	1.00 (-----)	-----
35-49	30.8	0.87 (0.81-0.94)	0.0001
50-64	39.7	1.05 (0.98-1.13)	0.1334
≥ 65	12.1	1.42 (1.31-1.55)	<0.0001
Donor age (years)			
0-17	14.7	1.03 (0.95-1.12)	0.4507
18-34 (reference)	25.7	1.00 (-----)	-----
35-49	26.0	1.18 (1.11-1.26)	< 0.0001
50-64	20.5	1.43 (1.32-1.55)	< 0.0001
≥ 65	3.8	1.78 (1.57-2.01)	< 0.0001
Unknown	9.4	1.44 (1.14-1.82)	0.0020

Adjusted for transplant era, recipient gender, recipient race, recipient ethnicity, primary cause of end-stage renal disease, pre-transplant hepatitis B & C serologies, education level, employment status, primary payor, prior time on dialysis, donor gender, donor race, donor ethnicity, and donor cause of death. Data are from the U.S. Renal Data System, USRDS 2005 Annual Data Report.

Table 2. Effects of recipient and donor age on Death after deceased donor kidney transplantations in 1998-2003 (N=42,979).

Characteristic	Percent of Population	Relative Risk (95% C.I.)	P-Value
Recipient age (years)			
0-17	3.7	1.06 (0.75-1.51)	0.7272
18-34 (reference)	13.7	1.00 (-----)	-----
35-49	30.8	1.90 (1.62-2.24)	< 0.0001
50-64	39.7	3.72 (3.18-4.35)	< 0.0001
≥ 65	12.1	6.21 (5.26-7.83)	< 0.0001
Donor age (years)			
0-17	14.7	0.93 (0.83-1.05)	0.2685
18-34 (reference)	25.7	1.00 (-----)	-----
35-49	26.0	1.16 (1.05-1.27)	0.0029
50-64	20.5	1.37 (1.22-1.54)	< 0.0001
≥ 65	3.8	1.62 (1.34-1.95)	< 0.0001
Unknown	9.4	1.56 (1.09-2.24)	0.0160

Adjusted for transplant era, recipient gender, recipient race, recipient ethnicity, primary cause of end-stage renal disease, pre-transplant hepatitis B & C serologies, education level, employment status, primary payor, prior time on dialysis, donor gender, donor race, donor ethnicity, and donor cause of death. Data are from the U.S. Renal Data System, USRDS 2005 Annual Data Report.

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4. Expanded Criteria Donors

Kidney transplants from older donors are associated with worse graft survival than those from younger donors; however, there is still a reduced risk of long-term mortality compared to remaining on the waiting list (Ojo, 2001).

The mortality benefit associated with renal transplantation is reduced with increased wait-time on dialysis (Meier-Kriesche, 2004). This effect is most significant for older recipients, such that all benefit may be lost with wait-times of four to six years for older recipients (Jassal, 2003; Schnitzler, 2003). However, it is much less important for those with longer expected survival (e.g., younger patients with fewer comorbidities).

The best evidence-based definition of ECDs is from UNOS (Port, 2002), which defines those criteria associated with relative risk of graft loss ≥ 1.7 compared to ideal donors. These are age ≥ 60 or age 50-59, with 2 of hypertension, cerebrovascular accident as cause of death and donor creatinine $> 132.6 \mu\text{mol/L}$.

Merion and others (Merion, 2005) in a retrospective analysis of US data, showed that three-year mortality was reduced by accepting an ECD kidney vs. waiting for an ideal kidney for those ≥ 40 years old or diabetics in programs with an average wait-time of more than 1,350 days. This is based on the premise that there will be fewer patients waiting for ECD kidneys and, thus, significantly shorter wait-time. If wait-time was close or equal to that for an ideal donor, ECD recipients would have a worse outcome.

Another issue emphasized by Meier-Kriesche (2004) is that giving younger donor kidneys to older recipients does not allow the full survival benefit of these organs, as recipient lifespan is often less than donor-organ expected survival.

An important issue that has not been sorted out is how to select which ECD kidneys to use and when to perform dual vs. single kidney transplants. Three methodologies have been suggested: donor creatinine clearance (based on data from retrospective UNOS review showing reduced two-year graft survival with donor creatinine clearance of $< 80 \text{ ml/min}$), donor pathology (conflicting data from studies as to appropriate criteria and no good validation studies) and scoring systems (Nyberg's system has been validated but age has such a large number of points vs. other criteria that it is unclear if this scoring system is of much practical benefit) (Nyberg, 2003).

It should be appreciated that as more patients go on the ECD list the benefit of this strategy will fall, as wait-time increases.

Canadian practice:

There is no current uniform practice.

In Toronto, older patients and diabetics are asked if they wish to go on the ECD list. All on the ECD list are also on the regular list and get whichever comes up first. Entry to the ECD list involves signed informed consent. Criteria defining ECD are based on UNOS criteria. For ECDs, single transplants are done if Cockcroft Gault creatinine clearance is $\geq 70 \text{ ml/min}$ and duals if less. If creatinine clearance is $< 50 \text{ ml/min}$, the kidneys are not used.

This is based on consensus rather than ideal evidence, although Toronto General Hospital data were used in deriving this information.

International practice:

UNOS:

ECD definition as above for Toronto. All on ECD list go on regular list. Consent required for ECD list.

Allocation based on wait-time only unless zero HLA mismatch.

Double Kidney Allocation

Kidneys from adult donors must be offered singly unless the donor meets at least two of the following conditions and the organ procurement organization would not otherwise use the kidneys singly:

- Donor age greater than 60 years.
- Estimated donor creatinine clearance less than 65 ml/min based upon serum creatinine upon admission.
- Rising serum creatinine [greater than 2.5 mg/dl (220 μ mol/L)] at time of retrieval.
- History of medical disease in donor (defined as either longstanding hypertension or diabetes mellitus).
- Adverse donor kidney histology [defined as moderate to severe glomerulosclerosis (greater than 15% and less than 50%)].

Eurotransplant:

Eurotransplant Seniors Programme

- Kidneys from donors ≥ 65 allocated to recipients ≥ 65 .
- Only for recipients with PRA $< 5\%$ and first transplants.
- Dual transplants only if donor's creatinine clearance is < 70 ml/min.

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5. Kidney/Pancreas Allocation

Canadian practice:

Variable across country.

International practice:

UNOS:(<http://www.unos.org/contact.asp>) When a pancreas becomes available and there is a zero 6 antigen HLA mismatch candidate, that candidate receives the pancreas. If that recipient also needs a kidney, that recipient also receives the kidney. When a pancreas organ becomes available, the organ is offered first locally, then within the region, and then nationally. Priority is generally by wait-time. Blood group O goes to blood group O. There are separate lists for SPK, PAK, pancreas alone, and islet cells. If the highest ranked recipient also needs a kidney, then the kidney is allocated along with the pancreas. Pancreata from donors >50 years or BMI >30 go to islet programs. Kidneys that are shipped are paid back.

Australia: (Jeremy Chapman, MD, Clinical Stream Director of Renal, Urology, and Transplantation at the Centre for Transplant and Renal Research, Westmead Hospital, Australia tsanz@racp.edu.au) Whole pancreas has precedence over islet. SPK overrides kidney allocation (kidney follows pancreas). Pancreas allocation goes to patient with longest time on the list (So PAK may be transplanted ahead of SPK). Preference is wait-time based within blood group.

UK Transplant: (<http://www.uktransplant.org.uk/ukt/default.jsp>). Similar allocation to Australia. Country divided into pancreas retrieval zones, with a pancreas transplant center in each zone. Local use first, then by rotation to other zones. Centre determines priority and use of kidney. In general kidney follows pancreas. Local center decides whether PAK or SPK (however, scheme suggests SPK priority). However if there is a pediatric HLA 6 Antigen zero mismatch then the kidney is offered first to the child. Payback in effect.

Scandinavia: (Niels Grunnet, Medical Director at Scandiatransplant, Department of Clinical Immunology, Aarhus University Hospital, Denmark at grunnet@scandiatransplant.org) Kidney follows pancreas. Payback of kidney within six months.

Eurotransplant: (Mayer G, Persijn GG. NDT 2006;21:2-3 and personal communication with Bjorn Nashan, MD, Director of the Multi-Organ Transplant Program at Queen Elizabeth II Health Sciences Centre in Halifax NS) Combined have priority over kidney alone. Payback in effect.

Existing recommendations:

No specific allocation recommendations, only that pancreas transplantation should be an option for uremic patients with diabetes mellitus.(1-3) The American Diabetes Association's most recent position statement is as follows(1):

Pancreas transplantation should be considered an acceptable therapeutic alternative to continued insulin therapy in diabetic patients with imminent or established end-stage renal disease who have had or plan to have a kidney transplant, since the successful addition of a pancreas does not jeopardize patient survival, may improve kidney survival, and will restore normal glycemia. Such patients also must meet the medical indications and criteria for kidney transplantation and not

have excessive surgical risk for the dual-transplant procedure. The pancreas transplant may be done simultaneous to, or subsequent to, a kidney transplant. Pancreas graft survival is better when done simultaneous to a kidney transplant.

In the absence of indications for kidney transplantation, pancreas-alone transplantation should only be considered a therapy in patients who exhibit these three criteria: 1) a history of frequent, acute, and severe metabolic complications (hypoglycemia, marked hyperglycemia, keto-acidosis) requiring medical attention; 2) clinical and emotional problems with exogenous insulin therapy that are so severe as to be incapacitating; and 3) consistent failure of insulin-based management to prevent acute complications. Program guidelines for ensuring an objective multidisciplinary evaluation of the patient's condition and eligibility for transplantation should be established and followed.

Pancreatic islet transplants hold significant potential advantages over whole-gland transplants. Recent strides have been made in improving the success rates of this procedure. However, at this time, islet transplantation should be performed only within the setting of controlled research studies.

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3. Steinman T.I., B.N. Becker, A.E. Frost, K.M. Olthoff, F.W. Smart, W.N. Suki, A.H. Wilkinson; Clinical Practice Committee, American Society of Transplantation. (2001). Guidelines for the referral and management of patients eligible for solid organ transplantation. *Transplantation*. 71:1189. Sponsored by the American Society of Transplantation (Dated).

6. Medical Urgencies

Canadian practice:

Most but not all regions surveyed have the ability to list patients based on medical urgency. In all jurisdictions a consensus decision is reached by transplant programs and in a single centre (Hamilton), the consensus group includes the non-transplant nephrologists. Most centres do not have formal policies outlining a review process. However, in Québec, failure to accept the first kidney offered for a patient listed as a medical priority would result in the status being reviewed with the listing centre. In programs with the medically urgent category, such patients are allocated kidneys ahead of the usual dominant criteria of wait-time and HLA match (with some exceptions for zero HLA-mismatched recipients). In all programs, it was felt that kidney allocation on this basis occurred rarely over recent years, if at all.

International practice:

France: “Super-urgent” patients as defined by a national group of experts have priority at a national level as do the highly sensitized with ≤ 1 ABDR mismatch, and fully HLA-matched unsensitized patients.

Eurotransplant: Patients are considered medically urgent when they meet one of the following criteria:

- Imminent lack of access for either hemodialysis or peritoneal dialysis
- Severe uremic polyneuropathy
- Inability to cope with dialysis with a high risk for suicide
- Severe bladder problems (hematuria, cystitis, etc.) due to kidney graft failure after SPK, provided that the pancreas graft is bladder-drained and functioning adequately

The request for medical urgency must be made in writing and is reviewed by Eurotransplant medical staff. Under the Eurotransplant kidney allocation system, the allocation of kidneys from deceased donors < 65 yrs, priority is given to sensitized (historical or current PRA $\geq 85\%$) patients based on acceptable mismatches, followed by zero HLA-mismatched recipients. Medically urgent patients “compete” for the remaining kidneys based on point score. The relatively high number of points awarded for medically urgent listing would favour allocation to these patients after reasonably well-matched pediatric recipients.

Scandiatransplant: Not stated in allocation policy.

UK Transplant (excludes Ireland): The points scoring system guiding kidney allocation does not include national points for medical urgency. It appears that medically urgent patients would be allocated kidneys retained for local use (i.e., kidneys where there is no zero-mismatched adult recipient nationally or locally, or no favorably matched pediatric recipient nationally or locally) but how this proceeds to include such prioritized patients is unclear.

Australia and New Zealand: Not stated in allocation policy.

United States: No points are awarded to patients based upon medical urgency for regional or national allocation of kidneys. Locally, the physician has the authority to use medical judgment in assignment of medical urgency points if there is only one renal transplant centre (within the organ procurement organization). When there is more than one local renal transplant center, a cooperative medical decision is required prior to assignment of medical urgency points.

7. Legal and Ethical Principles in Allocation

Ethics

Most allocation policies are built on two fundamental principles: justice and utility (Veatch, 2004). Justice requires that we should strive to treat individuals equally and that unequal treatment is only justified when “resources are allocated in light of morally relevant differences, such as those pertaining to need or likely benefit” (McNeally et al., 1997; Shevory, 1986).

The principle of utility requires that we “make optimal use of the resources, so that the greatest total benefit is obtained” (Hackler & Hester, 2005). In other words, in the context of organ donation, this principle would encourage the allocation of resources in a manner that would ensure that the individuals who would benefit the most receive the organs.

There is a natural tension created by the interplay between justice and utility. This is reflected in the changing approaches to transplantation allocation strategies. In the past, queuing has often been a favored approach to rationing because it appears to be objective and impersonal (Childress, 1996). More recently, however, evidence-based predictions of outcome and need have played an increasingly prominent role in allocation policies.

Law

The *Canadian Charter of Rights and Freedoms* has been used with mixed success to challenge governmental resource allocation decisions in health care. The *Charter* requires that individuals enjoy equal access to benefits provided by law (including public health-care services under Canada’s Medicare system) and prohibits discrimination on grounds such as physical/mental disability, sex, religion and race. While some *Charter* cases have succeeded, the Supreme Court of Canada has ruled that courts should not interfere with government resource allocation decisions in regard to services that are beyond the core programs covered under the Medicare system (*Auton v. British Columbia*, 2004). That said, in *Eldridge v. British Columbia* (1999), the court ruled that a hospital and the provincial Ministry of Health discriminated against deaf patients by refusing to provide sign language interpreters as an insured health-care benefit.

Malpractice law is also relevant to resource allocation policies. In general, the legal standard of care in Canada is determined by examining what “could reasonably be expected of a normal, prudent practitioner” (*Crits v. Sylvester* 1956, 508; *ter Neuzen v. Korn* 1995, 588). Though clinical practice guidelines are becoming increasingly common, especially in areas such as transplantation, practice guidelines remain only one piece of evidence in the formulation of the legal standard of care. A case-by-case analysis remains the norm and, as such, the standard of care is re-examined in each lawsuit.

There are no reported Canadian court decisions involving the alleged negligent allocation of organs. However, there are a variety of negligence cases that are relevant to allocation decisions more broadly. For example, in the well-known case of *Law Estate v. Simice* (1994) the court had to consider the impact of cost containment pressure on a physician’s clinical decision. The court held that: “[I]f it comes to a choice between a physician’s responsibility to his or her individual patient and his or her responsibility to the Medicare system overall, the former must take precedence in a case such as this.”

Fiduciary law is another area that has tremendous significance in this context. It requires physicians to act with the utmost good faith and loyalty toward their patients (*McInerney v. MacDonald*, 1992). For transplant physicians, this legal duty creates a dilemma. How can a physician focus on the best interests of his/her patient, which would undoubtedly include receiving an organ as soon as possible, when the needs of other patients must also be considered?

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1. Childress J. (1996). Ethics and the Allocation of Organs for Transplantation *Kennedy Institute of Ethics Journal* 6: 397-401.
2. Hackler C. and D. Hester. (2005). Age and the Allocation of Organs for Transplantation: A Case Study. *Health Care Analysis* 13: 129-136.
3. McKneally M., B. Dickens, E. Meslin, P. Singer. (1997). Bioethics for Clinicians: Resource Allocation.” *Canadian Medical Association Journal* 157:163-7.
4. Shevory T. (1986). Applying Rawls to medical cases: an investigation into the usages of analytical philosophy. *Journal of Health Politics, Policy and Law* 10(4):749-64.

Appendix 3: Forum Agenda

Wednesday, October 25, 2006

16:00 *Forum Opening*

- *Welcome and Opening Remarks*

Kimberly Young, Chief Executive Officer, Canadian Council for Donation and Transplantation

- *Challenge Address*

Greg Knoll MD, Forum Chair, Medical Director, Renal Transplant Program, The Ottawa Hospital

- *Forum Process and Procedures*

Dorothy Strachan, Strachan-Tomlinson

17:00 *Part A – HLA Matching and Sensitization*

- Peter Nickerson MD, Manitoba Transplant

17:30 **Challenge Questions & Table Discussion**

18:00 *Part B – Wait-Time*

John Gill MD, University of British Columbia

18:30 **Challenge Questions & Table Discussion**

Thursday, October 26, 2006

08:00 *Part C – Medical Issues*

- *Donor Recipient Age*

Bert Kasiske MD, University of Minnesota

- *Expanded Criteria Donors*

Edward Cole MD, Toronto General Hospital

- *Kidney/Pancreas Allocation*

Bryce Kiberd MD, Dalhousie University

- *Medical Urgencies*

Sandra M. Cockfield MD, University of Alberta Hospital

09:40 **Challenge Questions & Table Discussion**

11:30 **Forum Recommendations Group Meeting**

13:30 ***Part D – Current Situation***

- *Canada/USA Comparison*

John Gill MD
University of British Columbia

- *US/KARS Overview*

Mark Stegall MD
Mayo Clinic - College of Medicine

- *Net Benefits Model*

Alan B. Leichtman MD
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14:40 **Plenary Questions and Answers**

15:00 ***Part E – Legal and Ethical Issues***

- *Legal and Ethical Principles in Allocation*

Timothy Caulfield LLM

15:30 **Challenge Questions & Table Discussion**

16:00 ***Part F – Ranking***

- *Overview*

Greg Knoll MD

16:15 **Challenge Questions & Table Discussion**

16:45 **Closing**

17:00 **Forum Recommendations Group Meeting**

Friday, October 27, 2006

08:00 ***Part G – Report: Forum Recommendations Group and Plenary Discussion***

11:45 **Plenary Wrap-up**

12:00 ***Forum Closing***

- *Closing Remarks*

David Hollomby MD, CCDT Council Member Chair, Organ Transplantation
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12:30 – 15:30 **Forum Recommendations Group Meeting**

Appendix 4: List of Participants

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Appendix 5: Forum Background Documents

The following documents can be downloaded from the CCDT website at www.ccdt.ca:

1. Baran, D. (2006). *Deceased Donor Kidney Allocation in the US, Europe, Australia, and New Zealand*. Canadian Council for Donation and Transplantation: Edmonton.
2. Caulfield, T. (2006). *The Allocation of Organs: Emerging Legal Issues*. Canadian Council for Donation and Transplantation: Edmonton.
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4. Cole, E. (2006). *Extended Criteria Kidney Donors: Benefits, Risks, and Optimal Use*. Canadian Council for Donation and Transplantation: Edmonton.
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6. Kasiske, B. (2006). *Donor and Recipient Age and the Allocation of Deceased Donor Kidneys for Transplantation*. Canadian Council for Donation and Transplantation: Edmonton.
7. Kiberd, B. (2006). *Kidney Pancreas Allocation*. Canadian Council for Donation and Transplantation: Edmonton.
8. Nickerson, P. (2006). *HLA Matching and Sensitization in Kidney Transplantation*. Canadian Council for Donation and Transplantation: Edmonton.

Appendix 6: CCDT Fora and Reports

The following reports from CCDT fora are posted on the CCDT website (www.ccdt.ca):

Severe Brain Injury to Neurological Determination of Death (April 2003)

The report was endorsed by the CCDT, Canadian Critical Care Society, Conference of Chief Coroners and Medical Examiners of Canada, Canadian Association of Emergency Physicians, Canadian Neurological Society, Canadian Neurosurgical Society, Canadian Neurocritical Care Group, Canadian Association of Transplantation, Canadian Society of Transplantation, Québec-Transplant, Trillium Gift of Life Network and its ICU Advisory Group, Alberta Health and Wellness, and British Columbia Transplant Society.

Medical Management to Optimize Donor Organ Potential (February 2004)

The report was endorsed by the CCDT, Canadian Critical Care Society, Canadian Association of Transplantation, and Canadian Society of Transplantation. Guidelines were published (CMAJ, CJA).

Assessment and Management of Immunologic Risk in Transplantation (January 2005)

Clinical and laboratory specialists from transplant programs across Canada convened to examine current practices, literature and new technologies for the assessment of human leukocyte antibodies pre-transplant with the goal of being able to develop recommendations on best practices. Consensus recommendations will be used to improve immunologic risk assessment and management in transplantation with the goals: to improve solid organ transplant outcomes; improve equity of access to organ transplants for highly sensitized patients; reduce the wait-list time for highly sensitized patients; and increase the number of organ donors.

Donation after Cardiocirculatory Death (February 2005)

Post-forum public survey showed substantial support for proceeding with this type of donation in Canada. Guidelines were published (CMAJ).

Enhancing Living Donation (March 2006)

The purpose of this forum was to build national agreement on strategies to enhance living organ donation within a safe and ethical environment, and to overcome the barriers that are current disincentives to live organ donation in Canada. The forum process resulted in recommendations on the following aspects of living donation: risks and benefits of living donation related to informing the donor and to organ-specific medical/surgical risks for kidney, liver and lung transplantation; psychosocial considerations affecting living donors; long-term follow-up of living organ donors; legal and ethical challenges related to consent; and economic implications of living donation related to out-of-pocket expenses and loss of income.