FORUM LÉGISLATIF ET POLITIQUE INTERNATIONAL SUR LE DON ET LA TRANSPLANTATION

INTERNATIONAL DONATION AND TRANSPLANTATION LEGISLATIVE AND POLICY FORUM

STYLE & PUBLICATION GUIDE

The following should be considered when drafting the recommendations for the Forum publications.

Publication Strategy

There will be three types of primary outputs from the Forum:

1. Summary Publication: The major recommendations, which consider input from all the chapter groups. This publication will include all contributors as authors or group authors depending on journal restrictions. This will be submitted to Transplantation.

2. Chapter Articles: To be published in an academic manuscript format. These will be the chapter summaries formatted for peer-review publication.

   o The most likely target journal is Transplantation Direct. A link to their author instructions is included below. Most importantly for our project, the "overview articles" are limited to 6,000 words, and "articles" are limited to 4,000 words. We suggest 5,000 words or fewer if possible for these publications.

   o Publication in Transplantation Direct is open access, meaning our partners (TQ, TTS, CBS, etc.) can include the content freely on their websites. Content can also be reformatted into other reports.

   o Authorship for these manuscripts will be limited to chapter members and other participants from the Forum who meet authorship requirements.

3. Full Report: This will be made available on partner websites. The full reports would not be limited in terms of length and could include topics that had to be cut to respect manuscript length requirements.

4. Other formats: will be created by the knowledge translation group. This would include executive summaries for distribution to legislators and stakeholders, PowerPoint presentations, and other tools to increase the impact of this work. This will be made available in both English and French.

If you have suggestions for useful formats, please do not hesitate to share.

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Authorship

It is highly recommended that authorship roles be discussed and clarified prior to drafting recommendations. We recommend that groups consider these points when considering authorship:

1. Author order should correspond to the level of input. For instance, the person responsible for generating the first draft and collating the input from other authors should be listed as the first author. In medical publications of this type, the other positions for contributors who have contributed significantly would be:

    - The last listed author, or senior author. Often the senior member of the group who provided the most oversight to drafting.

    - The second and third listed authors. These are generally reserved for other group members who contributed more than the other co-authors.

    - Other authors who contributed equally are generally listed in alphabetical order in the middle after those positions are defined.

2. While it is likely that the chapter lead will be the first author for most groups, this recognition should be given to the person who actually drafts the document. This role and responsibility should be decided before drafting starts.

3. As mentioned above, other Forum participants who are not in the Chapter Group but contributed substantially to the content of a Chapter should be considered for authorship, but only if they meet the criteria as defined below.

4. Non-authorship acknowledgements should be given to any support staff or contributors who do not meet authorship requirements.

5. All authors should meet the criteria defined by the ICMJE, available at this site: http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html#two

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Level of Recommendations

There has been active discussion during the chapter group meetings regarding the level of the recommendations. By this, the question is often how detailed or specific we should make the recommendations. When drafting recommendations, authors should consider:

1. Recommendations should be targeted to multiple jurisdictions. In general, we should avoid overly prescriptive recommendations and instead focus on the general considerations for success.

    - An example from the consent model group might be that we do not recommend that opt-in vs opt-out consent is best. Instead, we recommend discussing the baseline aspects of a system that will create success no matter the consent model. (good public engagement and trust, defining and measuring success, etc.)

2. Despite generally not being overly prescriptive, there may be issues so widely accepted that they could be strongly recommended. Some of those examples would likely come from the ethics group – respect of the dead donor rule – or legal – need for mandatory referral legislation.

3. The recommendations should always be targeted as aspirational, meaning this is what we would do if we could overcome any political, social, or economic barriers. We can and should acknowledge why some of these issues might be difficult to implement in certain settings, but that should not keep us from making recommendations we think should be followed.

Literature Reviews

Each group should complete a review of the relevant published literature that informs their recommendations. It is not required that this be a structured review (e.g. a formal scoping or systematic review), but should be complete enough to link recommendations to published literature.

An output in each chapter could be a knowledge gaps section (see below) that could include topics that the group would think merit a more formal literature review.

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Connections to Other Chapters

As much as possible, reference should be made to other chapters. Nearly all of the groups will be referring back to the baseline ethics chapter, for instance, and we should not make duplicate recommendations on the same topic if avoidable.

We advise building on other chapter recommendations. So while the baseline ethical group will likely recommend something like preserving the primacy of the opportunity to donate, the innovation group will build on that by stating that participation in research should not interfere with the priority of clinical benefit of donation and transplant.

Exchanges between chapter leads and members are encouraged. Discussions will occur in a live meeting later in June and throughout the writing process as issues arise.

Knowledge Gaps and Emerging Issues

Each group will likely identify areas that merit further study. Careful consideration should be placed to clearly enumerate those issues and recommend further study or attempts at an international consensus in the future.

For example, the Research and Innovation group may recommend the need for further qualitative and quantitative studies evaluating the impact of donation and transplant research on the lived experiences of families.

A table at the end of each chapter with priority knowledge gaps will provide guidance for future studies in the field to better inform future recommendations.

Language and Terminology

Please use the included acronym and glossary of terms. If you see a term with a definition that differs from your standard usage or you wish to add an acronym to the document, please contact me (matthew.weiss.med@ssss.gouv.qc.ca) & Manuel (mescoto@cdtrp.ca) to ensure standardization across the different chapters.

If nothing else, this will save me and the planning committee substantial editing work when we bring these together for publication!

Link to Transplantation Direct Author Instructions.
http://edmgr.ovid.com/txd/accounts/Transplantation_Direct_Instructions_for_Authors_2017.pdf

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SELECTED ACRONYMS

ABO	Blood group according to the ABO System
AE	Adverse Event
AR	Adverse Reaction
ARE	Adverse Reactions and Events
AST	American Society of Transplantation
BAL	Broncho-alveolar Lavage
BD	Brain Death (see NDD)
BDD	Brain Death Diagnosis
CA	Cardiac Arrest
CBF	Cerebral Blood Flow
CDC	Centers for Disease Control and Prevention (USA)
cDCDD	Controlled Donation after Circulatory Death or Donation after Circulatory Determination of Death
CIT	Cold Ischemic Time
CNS	Central Nervous System
CPR	Cardio-Pulmonary Resuscitation
CT	Computed Tomography
CTA	Computed Tomography Angiography
DBD	Donation after Brain Death
DBI	Devastating Brain Injury
DCDD	Donation after Circulatory Death or Donation after Circulatory Determination of Death
DD	Deceased Donor
DM	Donor Management
ECD	Expanded-Criteria Donor
ECG	Electrocardiogram
ECLS	Extracorporeal Life Support
ECMO	Extracorporeal Circulation with Membrane Oxygenation
ED	Emergency Department
EEG	Electroencephalogram
ENTV	Elective Non-Therapeutic Ventilation
EU	European Union

SELECTED ACRONYMS

FWIT	Functional Warm Ischemic Time
GCS	Glasgow Coma Scale
GODT	Global Observatory on Donation and Transplantation
HLA	Human Leukocyte Antigen
HMPAO	Hexamethylpropyleneaminoxime
ICOD	Intensive Care to Facilitate Organ Donation
ICU	Intensive Care Unit
IV	Intravenous
KPD	Kidney Paired Donation
LD	Living Donor
MPHO	Medical Products of Human Origin
MRI	Magnetic Resonance Imaging
NDD	Neurologic Determination Of Death (see brain death)
NRP	Normothermic Regional Perfusion
NTO	National Transplant Organization
ODO	Organ Donation Organization
ONT	Organización Nacional De Trasplantes (Spain)
PNF	Primary Non-Function
QA	Quality Assurance
SCD	Standard Criteria Donor
SOP	Standard Operating Procedure
SOT	Solid-Organ Transplantation
TA-NRP	Thoraco-Abdominal NRP
TCD	Transcranial Doppler
TTS	The Transplantation Society
uDCDD	Uncontrolled Donation after Circulatory Death or Donation after Circulatory Determination Of Death
UK	United Kingdom
VCA	Vascularised Composite Allograft
WHO	World Health Organization
WLST/M	Withdrawal Of Life-Sustaining Therapy/Measures

SELECTED GLOSSARY

Actual Organ Donor	A person from whom at least one organ or tissue has been recovered for transplant purposes.
Agonal Phase	The period in a donation after circulatory determination of death process from the withdrawal of life sustaining therapies or measures until circulatory arrest.
Allocation	The process for the assignment and distribution of organs or tissues.
Ancillary Tests	Auxiliary or supplementary tests beyond the bedside clinical exam and apnea test used for the determination of death by neurologic criteria.
Apnea Test	Procedure to evaluate the cessation of the spontaneous breathing reflex regulated by the respiratory centers located in the brainstem.
Asystolic Time	See 'Primary warm ischemic time'
Audit	Periodic, independent, documented examination and verification of activities, records, processes, and other elements of a quality system to determine their conformity with specific internal or external requirements. Audits may be conducted by professional peers, internal quality system auditors, or auditors from certification bodies.
Authorization	Legally valid permission from a person or their surrogate decision maker to recover an organ or perform procedures on a deceased person to facilitate organ recovery for transplantation. Some jurisdictions use the word consent instead of authorization. Both are distinct from informed consent as used in the context of medical treatment because the person is deceased, and thus concepts such as medical risk and benefit cannot apply. See also consent, informed consent.
Best Practices	See good practices.
Brain Death	The complete and permanent loss of brain function as defined by an unresponsive coma with loss of capacity for consciousness, brainstem reflexes, and the ability to breathe independently. This may result from the permanent cessation of oxygenated circulation to the brain and/or after devastating brain injury. See also neurologic determination of death and death.
Clinical Practice Guidelines	Systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.
Clinical Triggers	Specific medical criteria that, when met, should result in the referral of a patient who is a possible deceased organ donor to the corresponding organ donation organization by the treating medical team or organ donor coordinator (consistent with local practices).
Cold Ischemic Time	The elapsed time between the cooling of an organ after its blood supply has been cut off and the time when the organ is reperfused by circulation in the recipient. This interval can occur while the organ is still in the body or after it is removed from the body and applies only to organs stored by static cold storage. In cases of machine perfusion, the details of temperature, oxygenation, perfusate (blood vs other) should be provided.
Compensation	Reimbursement limited to recovering the expenses and inconvenience related to living or deceased donation.
Consent	Legally valid permission from a person or a surrogate decision maker to perform an intervention or procedure related to organ donation. In cases of living donation or premortem interventions, informed consent as required in the context of medical treatment is required (see below). Some jurisdictions prefer the term authorization in interventions after death determination (see above).
Consented Organ Donor	An eligible organ donor who has given legally valid consent either themselves or confirmed by their surrogate decision maker for donation whether or not an organ was actually recovered.

SELECTED GLOSSARY

Controlled Donation After the Determination of Death By Circulatory Criteria (cDCDD)	Donation from a person whose death has been established by circulatory criteria, following an expected circulatory arrest after either withdrawal of life-sustaining therapies/measures or, where permitted, voluntary euthanasia or medical assistance in dying.
Death	For the purposes of this document, death is defined as a physiologic phenomenon consistent with the above definition of brain death. We recognize that legal definitions of death vary throughout the world and that this physiologic definition does not address the diverse social, cultural, and religious implications of the dying process.
Death By Neurologic Criteria	See brain death.
Death Determined By Circulatory Criteria	Death is determined by evidence of permanent cessation of circulation to the brain.
Deemed Consent	See opt-out consent.
Delayed Graft Function (DGF)	Manifestation of acute graft injury, in which the graft functions after a period of time post-implantation.
Devastating Brain Injury (DBI)	A neurological injury where there is an immediate threat to life from a neurologic cause and where limitation of therapies intended to prolong the patient's life is being considered in favor of comfort and end-of-life care.
Devastating Brain Injury (DBI) Care Pathway	A care pathway or protocol that recommends therapies, including observation in an intensive care setting, after a DBI irrespective of initial estimation of prognosis. These protocols are deployed with the primary goal of allowing further time for neuroprognostication and also allow for the possibility of deceased donation if active treatment is unsuccessful.
Distribution	The process of transport and delivery of organs after they have been allocated.
Donation After The Circulatory Determination of Death (DCDD)	Donation from a person who has been declared dead on the basis of circulatory criteria. Depending on the clinical scenario in which cardiac arrest occurs, it can be classified as controlled or uncontrolled and in one of the four Maastricht categories. See also 'Controlled donation after circulatory death' and 'Uncontrolled donation after circulatory death'.
Donation After The Neurologic Determination of Death (DNDD) or Donation After Brain Death (DBD)	Donation from a person who has been declared dead on the basis of the complete and permanent loss of brain function as stated in "brain death" above.
Donor	A person, living or deceased, from whom one or several organs or tissues could be or has been recovered for transplantation. See also possible, potential, eligible, and actual donor.
Donor Assessment Or Selection	The process of determining the suitability of a potential donor, living or deceased, to donate. This process allows a prediction of whether the transplantation of one or several of his/her organs will be safe for the recipient(s), and in the case of living donation, that the recovery procedure will be well tolerated.

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Donor Characterization	The process of collecting the relevant information on the characteristics of the donor needed to evaluate their suitability for organ donation in order to undertake a proper risk assessment, minimize the risks for the recipient and donor while optimizing organ allocation.
Donor Coordinator	The person responsible for coordinating and supporting all the subsequent steps supporting organ donation, including organ procurement and distribution. Often responsible for either performing or ensuring the proactive identification of potential donors at the hospital level. They may also be called 'transplant coordinator', 'key donation person' or other names.
Elective Non-Therapeutic Ventilation	The initiation of mechanical ventilation, in patients with a devastating brain injury in whom further treatment is deemed futile, with the aim of incorporating the option of organ donation into their end-of-life care. See also intensive care for organ donation and premortem interventions.
Eligible Organ Donor	A potential donor (see below) who has been determined to be medically suitable to become a deceased donor and 1) has undergone evaluation and meets criteria for DBD/DNC or 2) has a planned WLST and is expected to die within accepted limits of warm ischemic time or 3) has a planned voluntary euthanasia or medical assistance in dying or 4) has been determined dead by circulatory criteria in an uncontrolled DCDD pathway.
Expanded-Criteria Donor	A donor in whom co-morbidities exist that may compromise organ function. This concept should not be confused with the non-standard-risk donor. See also 'Non-standard-criteria donor.'
Export	The process of transporting human organs, tissues or cells intended for human application to another country where they are to be processed further or used.
Follow Up	Subsequent evaluation of the health of a patient, living donor or recipient, for the purposes of monitoring the results of the donation or transplantation, maintenance of care and initiation of post-donation or post-transplant interventions.
Functional Warm Ischemic Time	The period in a DCDD process between the first episode of significant hypoperfusion or hypoxia as defined by local criteria and the start of in situ preservation (either cold or through normothermic regional perfusion).
Good Practice	A method or technique that has consistently shown results superior to those achieved by other means and which is currently used as a benchmark. This could take the form of clinical, administrative, policy, or legislative practices.
Graft	Part of the human body that is transplanted in the same person or another person to replace a damaged part or to compensate for a defect.
Grafting	See transplantation.
Implantation	See transplantation.
Import	The process of transporting human organs, tissues or cells into one country from another.
Informed Consent	A person's or a surrogate decision maker's voluntary agreement, based upon adequate knowledge and understanding of relevant information (e.g. the nature, material risks, potential benefits and side effects of the intervention, alternatives to the intervention, and the consequences of foregoing the intervention), to donate an organ or to undergo a diagnostic, therapeutic or preventive procedure. See also authorization and consent.
Intensive Care To Facilitate Organ Donation (ICOD)	The initiation or continuation of intensive care measures in patients with a devastating brain injury, in whom further treatment is deemed futile, with the aim of incorporating the option of organ donation into their end-of-life care.

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Intent To Donate Registry	A repository where a person can record their desire to donate organs in the eventual possibility of their death in circumstances that could permit organ recovery.
Ischemic Time	The period during which an organ is deprived of oxygenated circulation. See also 'Cold ischemic time', 'Warm ischemic time', 'Functional warm ischemic time', 'Primary warm ischemic time' "Secondary Warm Ischemic Time" and 'Total ischemic time'.
Living Donor	A living person from whom organs, tissues or cells have been removed for transplantation. A living donor has one of these possible relationships with the recipient: A. Related A1. Genetically related: First-degree genetic relative: parent, sibling, offspring. Second-degree genetic relative: grandparent, grandchild, aunt, uncle, niece, nephew. Other than first or second degree genetically related, e.g. cousin. A2. Emotionally related: Spouse (if not genetically related), in law, adopted, friend. B. Unrelated: Non-related, not genetically or emotionally related.
Neurologic Determination of Death	The process of establishing, through neurologic criteria (clinical examination with or without ancillary testing) that a person is dead.
Non-Resident	A person donating an organ or receiving a transplant who does not have legal permission to reside permanently in the country where donation or transplantation takes place.
Non-Standard-Criteria Donor	Donor in whom evidence of disease-transmission risk exists. The risk can be graded according to risk levels (which differ for infectious diseases and malignancies). This concept should not be confused with the expanded-criteria donor concept.
Normothermic Regional Perfusion (NRP)	*In situ* (in the body of the patient who is a potential donor) perfusion of organs with oxygenated blood using a device applied at normal body temperature.
Opt-In Consent Model	A system where consent to donation is given explicitly from the donor (prior to losing capacity) or from the surrogate decision maker. Also called 'explicit consent' or 'informed consent' models.
Opt-Out Consent Model	A system where legally competent residents in a jurisdiction are assumed to have consented for donation unless they have registered an objection. Also referred to as 'presumed' or 'deemed' consent systems.
Organ	A differentiated part of the human body, formed by different tissues, that maintains its structure, vascularization, and capacity to develop physiological functions with a significant level of autonomy. A part of an organ is also considered to be an organ if its function is to be used for the same purpose as the entire organ in the human body, maintaining the requirements of structure and vascularization.
Organ Donation Organization	A healthcare establishment, a person, a team or a unit of a hospital, or any other body which undertakes or coordinates the recovery of organs and is authorized to do so under the regulatory framework in the member state concerned.
Outcome Registry	A repository of data collected on organ donors and/or transplant recipients for the purpose of outcome assessment, quality assurance, healthcare organization, research and surveillance. Not to be confused with intent to donate registries.

SELECTED GLOSSARY

Possible Organ Donor	A patient who is apparently medically suitable for donation with either: 1) a devastating brain injury or 2) consideration of withdrawal of life-sustaining therapies/measures (e.g. mechanical ventilatory or circulatory support). Jurisdictions generally have defined clinical triggers that determine when these patients should be referred to the ODO. Of note, some jurisdictions combine possible and potential organ donors into a single group for auditing and reporting purposes.
Potential Organ Donor	A possible organ donor (see above) who either: 1) is suspected, but not confirmed, to fulfill DBD/DNC criteria or 2) has planned discussions to consider WLST and is and is expected to die within accepted limits of warm ischemic time or 3) has been evaluated and approved to receive voluntary euthanasia or medical assistance in dying or 4) meets established criteria for uncontrolled DCDD. Of note, some jurisdictions combine possible and potential organ donors into a single group for auditing and reporting purposes.
Premortem Intervention	Interventions undertaken prior to the determination of death with the goal of enhancing the likelihood of success of organ or tissue donation.
Presumed Consent	See 'Opt-out donation system'.
Primary Non-Function	A situation when a graft never functions following transplantation.
Primary Warm Ischemic Time	In a DCDD process, the period between circulatory arrest and the start of in situ preservation.
Procedure	Description of the operation(s) or process(es) to be carried out, the precautions to be taken and measures to be applied that relate directly and indirectly to the transplant process from donation to transplantation.
Recipient	A person who receives transplanted organs, tissues and/or cells.
Recovery	The removal of organs, tissues or cells from a donor for the purpose of transplantation. The term 'procurement' has been used in the past with equivalent meaning.
Secondary Warm Ischemic Time	The time between the transfer of a recovered organ from cold storage or machine perfusion and the re-establishment of circulation in the recipient.
Standard Criteria Donor	A donor manifesting no evidence of disease-transmission risk and no co-morbidities compromising organ function.
Surveillance	The systematic and ongoing collection, collation and analysis of data for public health purposes, and the timely dissemination of public health information for assessment and public health response, as necessary. See also 'Follow-up' (which includes surveillance).
Tissue	An aggregate of cells joined together by, for example, connective structures and performing a particular function.
Total Ischemic Time	The time from cessation of adequate circulation to an organ in the donor to the establishment of adequate perfusion in the recipient. This would include (if applicable) functional warm ischemic time, primary warm ischemia, cold ischemic time, machine perfusion time, and secondary warm ischemic time. During this period, multiple organ-preservation technologies can be applied.

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Traceability	Ability to locate and identify an organ at each stage in the chain from donation to transplantation/disposal, including the ability to identify the donor, the donor hospital and the recipient(s) at the transplant centre(s), and to locate and identify all relevant non-personal information relating to products and materials coming into contact with that organ.
Transplant Center	A healthcare establishment which undertakes the transplantation of organs.
Transplantation	The surgical procedure in which an organ (or organs) from a donor is (are) inserted into a recipient with the aim of restoring function(s) in the body. Also referred to as implantation or grafting.
Uncontrolled Donation After The Circulatory Determination of Death (uDCDD)	Donation from persons whose death has been established by circulatory criteria following an unexpected circulatory arrest and resuscitation that failed to reestablish spontaneous circulation in the patient.
Utilized Organ Donor	An actual donor from whom at least one organ has been transplanted in a recipient.
Warm Ischemic Time (WIT)	The time an organ remains at body temperature after its blood supply has been reduced or cut off but before it is cooled or reconnected to a blood supply. See also functional warm ischemic time