



ORGAN AND TISSUE DONATION AND TRANSPLANTATION

Report on the Consultation “Donation Physicians in a Coordinated OTDT System”

**February 21 - 22, 2011
Whistler, British Columbia**

Acknowledgements

This consultation process was based on the collaborative wisdom of a broad range of stakeholders (See Appendix C: Participants), international experts and key leaders representing Canadian Blood Services and the Canadian Critical Care Society.

We collectively thank the Canadian Blood Services and the Canadian Critical Care Society for their support for this initiative as well as the Canadian and international expert participants who helped to create these recommendations.

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This report provides an overview of the consultation and a summary of participant recommendations in response to proscribed questions on the donation physician role. Consultation participants’ views represent a range of perspectives in the OTDT community.

In some cases, statements or recommendations may appear to conflict; these represent differences of opinion among respondents. In other cases, respondents may represent as factual, items that may not be entirely correct. In these cases, participants’ understandings are included as they were initially provided throughout the consultation.

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Executive Summary

Introduction

In August 2008, Canadian Blood Services was given a mandate by the Conference of Deputy Ministers of Health to lead the development of an inter-provincial /territorial strategy for organ and tissue donation and transplantation in Canada. As a result, Canadian Blood Services staff have been working in collaboration with the organ and tissue donation and transplantation (OTDT) community for the past two years to build an integrated strategy to deliver consistency, improve performance, and, most importantly, ensure more Canadians receive the organs and tissues they urgently need.

One of the final steps to inform development of this strategy was the co-hosting of an Organ and Tissue Donation and Transplantation Consultation on the role of “Donation Physicians in a Coordinated OTDT System” by Canadian Blood Services and the Canadian Critical Care Society. This consultation meeting was held on February 21 – 22, 2011.

The purpose of this meeting was to consult with international experts and key stakeholders regarding the proposed OTDT system design recommendation to formalize the donation physician role in health care centres in Canada. Objectives were to:

- Provide an overview of work to date on OTDT system design, ethical principles and strategy as a basis for informed discussions by consultation participants;
- Provide an overview of current policies and practices with respect to the role of donation physicians in Canada and internationally;
- Review and advise on the preliminary OTDT system design recommendation to formalize the role of donation physicians in clinical service, education, and research and innovation;
- Review the implications of Intensive Care Unit (ICU) bed and physician capacity with respect to the emerging recommendations;
- Provide information on current partners and explore potential partnerships in support of the development of the donation physician role;
- Explore sources of potential, real and perceived conflicts of interest in Canada and internationally, resulting from implementation of a donation physician role, and advise on mechanisms to explore strategies to mitigate conflicts that may arise.

The Meeting Terms of Reference outlined the scope for deliberations and the caveat that “Though specialization of donation care extends beyond the role of donation physicians to include nurse-based donor coordinators and other specialist or allied health roles, the scope of this initiative focuses primarily on the donation physician role in the system”. It was also noted that the Consultation Planning Committee had decided to focus on responding to the proposed OTDT system design recommendation to formalize donation physician roles in health care centres in Canada rather than to revisit the recommendation itself.

This report provides an overview of the consultation and a summary of participant conclusions developed in response to prescribed questions on the donation physician role. Consultation participants’ views represent a range of perspectives in the OTDT community.

In some cases, statements or recommendations may appear to conflict; these represent differences of opinion among participants. In other cases, participants may represent as factual, items that may not be entirely correct. In these cases, participants' understandings are included as they were initially provided throughout the consultation.

The Consultation Process

A Consultation Planning Committee (p 6) met several times throughout the process, providing oversight and insight with respect to this initiative. Eight priority areas were identified for the development of recommendations with respect to a coordinated system for OTDT in Canada:

- A. Donation Physician Model – Clinical Service and Professional Qualifications
- B. Education and Training
- C. Performance Management
- D. Remuneration
- E. System Capacity
- F. Research and Innovation
- G. Distribution of Physicians and Geographical Considerations
- H. Ethics

Planning Committee members also supported the development of a comprehensive background information package to support discussion of these priority areas, including:

- Meeting Terms of Reference
- Environmental Scan and Literature Review
- OTDT System Design: Progress to Date
- Summary of Public Opinion
- Survey of Donation Physicians Internationally (United Kingdom, Australia, Spain, Pittsburgh)
- Surveys of Health Professionals about OTDT (Canada)
- Royal College Training Requirements

The consultation was based on specific questions designed to stimulate discussion and conclusions related to the role of the donation physician in OTDT system design and implementation in Canada. Participants included intensive care physicians and ethicists as well as representatives from the Canadian Critical Care Society, Organ Procurement Organizations, the Canadian Neurosurgical Society and the Canadian Association of Emergency Physicians. An external process consultant and facilitator contributed an objective presence throughout the process.

Canadian and International Perspectives

An international panel of four speakers provided their perspectives on the donation physician role in their national systems. The presence of donation physicians (generally critical care specialists) who are funded and have responsibility and accountability for organ and tissue donation in hospitals is one of the key contributors to increased and sustained donation

performance internationally. In Spain, for example, the donation physician role is credited with increasing that country's donation rate to more than 30 donors per million population—one of the highest in the world. In Australia and the United Kingdom, increases in donation performance (56 percent in Australia¹ and 28 percent in the United Kingdom²) have been attributed to recent reforms that included the introduction of donation physicians at local levels who have links to their respective national ODT coordinating bodies. International models range from direct clinical care to administration of donation programs.

Four additional presentations and related discussions at the beginning of the consultation provided an overview and update on the OTDT proposed system design process in Canada: one speaker focused on practices, preconceptions and barriers to change in the current OTDT system; a second outlined progress on the system design for organ donation and transplantation; another spoke about system design for tissue donation and transplantation; and a fourth described outcomes of a previous consultation on ethical issues related to role of donation physicians.

Additional speakers provided an overview of provincial perspectives with specific reference to Ontario, Manitoba, Alberta, Québec, Nova Scotia, and other Atlantic provinces. Currently in Canada, the responsibility for donation in hospitals is generally left to physicians in ICUs. There is variability in time, training or commitment to make donation a standard part of end-of-life care. Accountability for donation at the system, hospital, senior leader and individual levels is lacking. Consequences for missing potential donors are minimal and as a result, donation opportunities are missed. It is important to note that Manitoba and Ontario have established or are in the process of establishing donation physician roles, with greatly differing models. The leadership and experiences of these provinces should be leveraged during the development phase of Canada's OTDT system design.

Consultation Results

A majority of consultation participants agreed that the integration of donation physicians with donor coordinators and hospital donation teams has the potential to drive increases in all forms of deceased donation in Canada. It was generally agreed that donation physicians should assume a leadership role in donation care, administration, education, quality assurance and performance management that is separate and distinct from attending physicians providing care in intensive care units. Specifically, the role of the donation physician (in collaboration with other donation team members) was seen to include:

- promoting culture of organ and tissue donation,
- providing clinical leadership within the hospital and broader community on organ and tissue donation,

¹DonateLife Australia, News Release, January 18, 2011 www.donatelife.gov.au/News-and-Events/News/Media-Releases/2010-Organ-donation-figures-show-record-high.html

² NHS Blood and Transplant News Release, January 23, 2011. <http://www.nhsbt.nhs.uk/news/2011/newsrelease210111.html>

- serving as a clinical resource, educator and champion to improve all aspects of deceased donation (e.g., identification, referral, ICU access, consent, donor management, recovery and utilization),
- providing consultation and support to ICU teams and assist in bedside donor care as required,
- leading performance management, quality improvement and quality-assurance activities for donation,
- facilitating donation opportunities in regions that are challenged by geographic disparities through telephone consultations, advocacy for transport and ICU access, facilitation of operational issues and web-based education,
- providing consultation to referral hospitals in the identification, management and transfer of potential donors through use of technology (such as telemedicine and remote monitoring) and existing infrastructure (such as ICU bed-allocation systems),
- facilitating or providing education and training to physician colleagues, physician trainees, and other health care professionals on organ and tissue donation and ensure the development of local educational and training opportunities in collaboration with Canadian Critical Care Society, the Royal College of Physicians and Surgeons, universities and other professional societies, and
- serving as a source of knowledge and advice regarding the ethical and legal aspects of organ and tissue donation and manage disagreements that may arise,
- facilitating research on organ and tissue donation.

Participants concluded that the domain of donation physicians should encompass the entire hospital and extend to the pre-hospital and emergency medical services environment. It is recognized that factors such as geography, system capacity and the availability of qualified physicians would impact how the role could be implemented across the country.

Internationally, donor coordinators work in close collaboration with donation physicians. In Canada, donor coordinators are integral members of donation teams. Collaboration among donation physicians and coordinators must continue if Canada is to realize improvements in organ and tissue donation activities and develop a 'donation culture'.

If these steps are taken, potential benefits for the system would include:

- clear leadership and advocacy for organ and tissue donation processes and practices,
- recognized oversight of, and responsibility for, donation performance measurement and quality assurance,
- access to trained physicians who are knowledgeable about, and capable of supporting potential donation opportunities for attending ICU physicians, ICU teams and donor coordinators,
- access to expert consultation, support and education and training on organ and tissue donation for hospital and OPO staff,
- access to physicians who can advise hospitals and OPOs in the implementation of donation leading practices,
- availability of knowledgeable physicians who can support or discuss donation with the families of potential donors or otherwise support consent conversations as needed,
- a resource to support the discussion of ethical issues and manage potential conflicts,

- a resource to facilitate research on organ and tissue donation,
- an increase in the number of organ and tissue donors,
- hospital donation practices that are informed by death-related data from the emergency department to the intensive care unit including clinical triggers, all of which should translate into improved transplant outcomes, and
- death related data and transplant outcomes to inform critical care decisions on resource allocation.

Closing Remarks and Next Steps

The consultation concluded with Dr. John Granton, President of the Canadian Critical Care Society, thanking Canadian Blood Services staff for all their hard work on the proposed system design and the opportunity for the CCCS to be a partner in improving the Canadian OTDT system through co-hosting the consultation. He commented that while many critical care physicians see donation services as being something that is already a part of their job, having a system in which the role is recognized nationally, clearly defined, and supported with resources, standards and research, would provide an opportunity that can't be missed.

Planning Committee Chair Dr. Sam Shemie thanked participants, international and national guest speakers and planning committee members for their hard work and rich input before and during the consultation. He closed the meeting by commenting on next steps: the purpose of the consultation is to inform system design recommendations to be presented to FPT DMs in June 2011; throughout the coming months, Canadian Blood Services will also be in communication with the CCCS and the larger OTDT community to keep everyone apprised of developments as they occur. Once approved, implementation of the donation physician role will require time and resources to establish the roles and responsibilities and align with, and support, existing donation personnel and practices across the country. Building on the Donation Physician Consultation, further work will be required (with the Canadian Critical Care Society, the organ and tissue donation community and governments) to develop all aspects of the role, including structure, aspects of donor care, experience and qualifications, number and distribution, reporting relationships, accountability and performance requirements, and remuneration.

Inter-provincial coordination and leadership through a national donation physicians' network is expected to be essential to support development of this role. Such a network would enable planning and development as well as ongoing sharing of leading practices, addressing system-level issues of accountability and performance, and further work to support creation of a culture of organ and tissue donation. Canadian Blood Services is positioned to lead this network in partnership with the CCCS, OPOs and OTDT stakeholders.

Introduction

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On February 21-22, 2011 at Whistler BC, Canadian Blood Services and the Canadian Critical Care Society (CCCS) co-hosted an OTDT Consultation on Donation Physicians in a Coordinated OTDT system. This meeting was one part of a comprehensive and inclusive consultation process leading to the development of an integrated system strategy for OTDT which will be presented to the Federal, Provincial, Territorial Deputy Ministers of Health later this year.

The purpose of this meeting was to consult with key stakeholders regarding the proposed OTDT system design recommendation to inform and formalize the donation physician role in health care centres in Canada. Objectives were:

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Opening Remarks

Kimberly Young, Executive Director, Organs and Tissues, Canadian Blood Services, welcomed participants and thanked them for taking the time to contribute their expertise to the consultation. She highlighted the significant opportunities available throughout the two days for learning from national and international speakers and engaging in discussions with colleagues about how to tailor leading practice for OTDT to the Canadian situation. Ms Young confirmed the commitment of Canadian Blood Services to consulting in depth with the OTDT community and integrating the results of this meeting in the final stages of system design.

Ms. Young introduced Dr. John Granton, President of the CCCS, the partner and co-host with Canadian Blood Services for the consultation. Dr. Granton expressed the commitment of the CCCS to exploring system recommendations during the consultation and reminded participants of the CCCS position paper published in 2001 that confirmed the integral role for the CCCS in donation and transplantation. He expressed his hope that this initiative would drive improvement in the day-to-day practice of physicians, thus also having a positive impact on patients. Dr. Granton concluded by thanking Dr. Sam Shemie and Dr. Giuseppe Pagliarello for their collaborative efforts as planning committee members in representing the consultation partners.

The consultation facilitator, Dorothy Strachan, reviewed the agenda and projected outcomes for the meeting. She referred participants to the Meeting Terms of Reference (Appendix B) which outlined the scope for deliberations and the caveat that “Though specialization of donation care extends beyond the role of donation physicians to include nurse-based donor coordinators and other specialist or allied health roles, the scope of this initiative focuses primarily on the donation physician role in the system”.

Ms Strachan also commented that the planning committee had decided to focus on responding to the proposed OTDT system design recommendation to formalize donation physician roles in health care centres in Canada rather than to revisit the recommendation itself.

Participant Introductions

These focused on "What is one question or comment you have coming into this consultation?" The following is a synthesis of responses.

- How can we build a simple, comprehensive and accessible national system that:
 - accounts for provincial mandates and resources for healthcare and related inter- and intra-provincial issues in donation?
 - assures a consistent and pan-Canadian approach while taking into consideration the diversity of geographical and regional considerations and perspectives in the country?
 - ensures provincial counterparts are on side with respect to the underlying philosophy?
 - identifies, understands and addresses the barriers to donation in order to create effective solutions?
 - includes a strong focus on both high performance and accountability?
 - links transplant outcomes with donor management?
- What needs to be done to support enhanced inter- and intra-professional relationships?
 - Given human resources and geographic realities, are we going to frame a solution that is specialty-based, or are we going to advocate for a skills-based solution that would have non-intensivists engaged in this work?
 - How can the process and strategies engage the neurosurgeons and neurologists who see themselves as primary caregivers for brain injured patients? Recognition of potential donors in the Emergency Department (ED) by neurosurgeons has been cited as an issue and a potential barrier to donation.

- How will we define the donation physician's role?
- There is a need to clarify the relationship between the physician and the nurse coordinator.
- What can we do to support the ICU and intensivists at a practical level?
- Where do responsibilities for the donation physician overlap with the ICU attending physician and how can we address this without alienating health professionals?
- How can this meeting be a catalyst for developing a set of moral commitments for an integrated strategy?
 - A frank (and difficult) discussion is required about our role: we need to recognize our commitment to patients, and at the same time our commitment to OTDT best practices.
 - Critical care specialists should see part of their role as donor identification in order to fulfill the ethic of recognizing the wishes of the dead or dying patient to donate.
 - How can Canada address the ethical and legal challenges that relate to DCD and share the best of approaches in other countries?
 - What are our values with respect to treating organ donors coming in with a critical illness when they could save six lives? What is the value of the potential donor relative to other critically ill patients?
- How can we improve the number of organs donated?
 - How can we enhance the role of intensivists and critical care specialists with respect to the identification of potential donors in the ICU? One key to the success of the Spanish model is that intensivists understand that one part of their mission is donation.
 - How do we increase enthusiasm for transplant in general at non-transplant centres?
 - There is a need for increased public and professional awareness, e.g., education and awareness of donation to a diverse population and developing strategies to support conversion of potential donors.
 - Will the system enable the sharing of best practices from high performing centres?
- How can we allocate resources appropriately between (i) identifying and managing donors in the ICU, and (ii) raising public awareness around the need for increased donation?
- How will, or should we, move forward with a specialist model and how will this improve care?
- Will the donation physician specialist embrace the tissue side?
- How do we best train our specialists in critical care for this future role?
- In the short term and with current resources, what can we do now with the resources we have, to achieve gains and improvements in the system?

Ms Strachan posted these responses and asked participants to keep them in mind throughout the consultation.

OTDT System Design in Canada

Dr. Sam Shemie, Medical Director (Donation), Canadian Blood Services, and Planning Committee Chair, discussed practices, preconceptions, and barriers to change in the current OTDT system. He emphasized that given the current fragmented state of the Canadian system, the opportunity for positive change is immense, whether in terms of improved patient outcomes, cost savings, efficiencies or the opportunity to build a centralized database for tracking, quality assurance (QA), and research on outcomes. Canada is in need of a system to ethically serve the needs of potential transplant recipients as well as donors and their families. The current approach has made some improvements in best practices, but clarification is needed in order to empower the practice of physicians and increase the willingness and responsibility to act within the system itself.

Kimberly Young, Executive Director, Canadian Blood Services, gave an overview of the proposed OTDT system design for organs, calling attention to the history of poor organ donation performance in Canada. Based on a vision for 2017 in which Canadian patients would have a trusted, integrated transplant system that performs well among international leaders, Ms Young described the breakthrough performance potential of an integrated system based on accountability, increased organ donation and improved access to transplantation which is expected to translate into a 50% increase in donation.

Mathias Haun, Director, Strategic Planning for Tissues, Canadian Blood Services, outlined the proposed system design for tissues, emphasizing that this approach had been developed based on expressed needs in previous consultations with the tissue community. A goal of the integrated system is to raise the bar on safety and security. Given the lack of organization and documentation in the current Canadian tissue system, Mr. Haun commented on the considerable potential for significant improvement in the tissue area.

After these initial presentations on the current system in Canada, participants engaged these two speakers with questions and comments.

Discussion

- Measurement and accountability are cornerstones of the proposed system design. Every feature on the organs and tissues strategy maps will have deliverables and metrics to assess performance. The donation physician could be involved in this data collection and management.
- Although current consent levels may be too low, placing a target on consent rates may be potentially problematic, as it will fluctuate across diverse populations.
- The distinction between targets and measurements is an important one. Measuring everyone in the system is different than targeting everyone. Targets will differ depending on the population served; measurement will be key for accountability.
- While tissue may often seem like a secondary focus, about 40% of organ donors also donate tissue. In Spain and other high performing systems, the rates of tissue donation are much higher. There are missed opportunities in Canada for tissue donation originating outside of the ICU.

- Supporting donor families should be a priority, e.g., through measuring aspects of the donor family relationship. The resulting data could be very valuable if it confirms that we are meeting the needs of donor families through the role of the donation physician.
- From the perspective of the Spanish system, tissue donation has a positive effect on organ donation in general. Society becomes more aware of the necessity of donation because unlike organ donation, tissue donation is a daily activity. As a result, the donation physician has an opportunity to speak with donor families every day — an important contributor to system improvement and professional development.
- Low donor volume, especially for Donation after Cardiac Death (DCD), can be a challenge. Regionalizing care in higher volume centres is one option to consider.
- One of the greatest challenges will be in raising the importance and relevance of donation to families. We need to advocate for donors to do more than sign the donor card. A national level campaign (leveraging the work already being done in blood) would be an important part of any new strategy. How can we get community messaging on the tips of tongues?
- Ontario families tell us they feel no differently about donating organs or tissues. Therefore the discrepancy between organ and tissue donation rates need to be explained and gaps addressed.
- Having daily rounds, a donation physician, data collection, an information management system – all these would help build a better understanding of the donation process.
- Patients have the right to donate and we need to convey this to them. We need a dynamic way to promote access to donation, e.g., through visuals on Canadian Blood Services trucks.
- We underestimate the value of donation to families – there is evidence to suggest it helps with the grieving process.

Ethics Consultation Report

Dr. Franco Carnevale gave a presentation on the Ethics Consultation, hosted by CBS on January 20-21 2011, which asked for ethical perspectives in three key areas of the proposed system design: Opportunity to Donate, Financial Transactions in the Tissue System, and Potential Conflicts of Interest.

Participants were asked to keep the results of the ethical consultation in mind as they would have two further opportunities to bring their questions forward throughout the consultation: after the international ethics panel discussion, and again during the last part of the consultation.

Provincial and International Perspectives on Donation Physicians

Several brief presentations brought provincial perspectives on donation physicians to the front of participants' minds. Brief summaries of these presentations are outlined in Appendix C. To provide insight into international models for donation physicians, international experts from Australia, Spain, the United Kingdom and the United States (University of Pittsburgh Medical Center) presented their approaches, which are summarized in Appendix D.

Roles and Responsibilities in an Evolving OTDT Structure

Eight priority areas were identified by the consultation planning committee for the development of recommendations with respect to a coordinated system for OTDT in Canada:

- A. Donation Physician Model – Clinical Service and Professional Qualifications
- B. Education and Training
- C. Performance Management
- D. Remuneration
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- G. Distribution of Physicians and Geographical Considerations
- H. Ethics

The facilitator outlined the meeting process for analyzing and building agreement in five small groups on recommendations related to each of these issues:

1. Read the related system design recommendations and background information.
2. Review the questions designed to address the issue.
3. In small groups, reflect on and discuss each question designed to address the issue, noting areas of agreement and disagreement.
4. Report on small group work in plenary, building agreement among participants on recommendations in response to each question, and noting areas of both agreement and disagreement.

Participant conclusions and discussion highlights are provided below for each issue.

A. Donation Physician Model – Clinical Service and Professional Qualifications

A1. From an overall perspective, which of the systems below do you think would work best within an integrated coordinated OTDT system in Canada?

Most participants selected the UK approach as the system that would work best in Canada. A blend of the Australian and UK systems and of the Spanish and UK systems were also mentioned as possibilities.

Discussion

- The UK model is locally driven and more easily adaptable to models where regional support is important. The relationship between expected donation activity and full time equivalent (FTE) assignment is attractive.
- The integration of the donation physician and the coordinating team (including physicians and nurses, into the hospital) and harmony between intensivists and donation physicians enables opportunities beyond donor care.
- Both the UK and Australian systems parallel Canadian culture and geography. Legal and ethical frameworks in these systems also offer protection and opportunities for accountability, research, and education.
- Various aspects of the Australian and Spanish systems presented also meet goals identified for the Canadian system.

A2. What forms of deceased donation should be provided?

Participants concluded that all forms of deceased donation should be provided while acknowledging regional or physician variation in relation to DCD. Forms of deceased donation include organ donation after NDD (brain death); tissue donation after NDD; tissue donation after cardiac death; organ donation after cardiac death (DCD or non-heart beating donation).

Discussion

- Significant opportunities for tissue donation (particularly in larger centres) in many provinces may be missed in organ donors and this should be rectified as soon as possible.
- There is growing realization that a DCD opportunity for families must exist for those who want it and that systems will need to evolve to respect this, including the option to transfer a potential DCD donor.

A3. What domains of donation care should be administered by the donation physician?

A majority of participants concluded that the domain should encompass the entire hospital (e.g., ICU, ED, special care units with ventilator capacity) and should extend beyond the hospital to include emergency/paramedic medical services, long-term care, etc., particularly for tissue donation.

Discussion:

- There are a lot of opportunities in settings other than the ICU to improve procurement.
- One potential source of tissue donation not previously considered in Canada might be deaths in long-term care facilities where clients (and/or their families) could participate in an education process to increase tissue donation.
- To foster a hospital and health care system culture of donation, all acute care areas, emergency and paramedic/emergency medical services should be included for organ and tissue donation.
- The role of a regional donation physician will depend on the region, but should include all areas of potential for organ and tissue donation.

A4. What aspects of donor care should the donation physician be involved with, e.g., identification referral, consent discussions, death determination, donor management, pre-mortem DCD care, procurement logistics, family follow-up, pre-mortem NDD care?

Although full agreement wasn't reached among or within groups, each of the aspects listed in the question was checked off as appropriate involvement by at least one group. Following are the perspectives provided in response to this question:

- Three of five working groups thought that the donation physician should be involved in donor identification and referral and should support the system in all phases but be limited in terms of direct care, i.e., the donation physician would be responsible for bringing in best practices (education) but not necessarily for actually performing them, e.g., direct care, pre-mortem DCD care and determination of death.
- Three groups saw the donation physician role as minimal or absent in consent discussions, death determination, DCD care and pre-mortem NDD care.
- Two groups thought the donation physician should be involved in all aspects of care at a system level (based on regional and hospital structures) as an organizational leader, educator and resource person for donation.
- One group saw the donation physician as consultant to the ICU depending on how much assistance the ICU attending physician requested. The donation physician would not be involved in determination of death and should maintain a distance from pre-mortem DCD care.

Discussion

- The donation physician should be involved as an active observer for troubleshooting of procurement logistics.
- The optics of maintaining distance from determination of death are important.
- The donation physician shouldn't assume care unless the MRP is comfortable with this. Support or direct bedside care by the donation physician should be there if requested but not mandated.
- While some bedside involvement may be necessary, the donation physician should advise on the process at a system level (by providing consultation services, education, and leadership), and perhaps provide clinical expertise in NDD declaration or donor management based on hospital and regional structure.

- Changing management and culture will be a key part of the donation physician role in supporting increased levels of donation.
- It was suggested that the donation physician handle QA, research duties, and the debriefing of the healthcare team involved with the patient in conjunction with other donation physicians.
- The donation physician could provide donor management after death in consultation or collaboration with the ICU. In some regions it may be appropriate for the donor physician to be directly involved in management depending on the available ICU experience and expertise in that centre.

A5. What is the optimal clinical service model for donation physicians in an integrated/coordinated system, e.g., telephone consultation, on site consultation, assisting in bedside donor care in partnership with the ICU team, assuming responsibility for bedside donor care upon agreement with the ICU team?

A majority of participants concluded that the optimal situation is for the donation physician to assist in bedside donor care in partnership with the ICU team, e.g., as a consultant to the MRP.

- However, it was also recognized that practical logistics such as geography and population density may require other models involving initial telephone consultations that escalate to assistance from the donation physician, e.g., in bedside care.
- It is important to be practical: a telephone consultation may be most efficient but this service requires the involvement of a nurse coordinator at the bedside.
- It is appropriate to assume responsibility for bedside donor care upon agreement with the ICU team if this is requested by the ICU and the donation physician is still in a consultant role, i.e., this would not involve introduction of a new physician.

Discussion

- In the interests of efficiency and consistency, should the donation physician take over responsibility for bedside donor care and NDD?
- Who will pay for the process of donation care in NDD, DCD?
- As the system gets busier with increased donation, the donation physician could act as an additional resource dependent on the wishes of the MRP.

A6. There are 16 pediatric ICUs in Canada. Should there be a distinct and separate donation physician role to provide pediatric donor care to hospitals or should this care be incorporated into the adult donation physician role?

A majority of groups thought there should be a separate donation physician role for pediatrics due to the different issues and ethical challenges involved.

One group said this role should be incorporated into the adult donation physician role and one group did not come to agreement on a response, commenting that depending on case volume, a separate pediatric donation physician may have limited access to the system. In these situations, consultation with the donation physician for adults would be advisable.

Discussion

- The cultures of these two groups are profoundly different. There are differing ethical implications as well.
- An adult donation physician could work in collaboration with a pediatric donation physician to share specialized knowledge in a region.

A7. Should there be a minimum number of years' experience as an attending/consultant physician?

Participants did not reach agreement in their responses to this question. Three groups responded "no", and one "yes", and one did not come to a conclusion. Rationales for these responses were:

- No: A great deal of experience comes from formal as well as on-the-job training. It is important to recognize an individual's skills, leadership, and ability to influence the practice of other ICU physicians. This is not only dependent on seniority and experience.
- Yes: A minimum is required to develop credibility and experience but it should not be number of years needed in terms of length. Personal qualifications should include diplomacy and advocacy (2-4 years experience). Flexibility is also needed for smaller communities with less experienced physicians.
- No agreement: There were divergent views on whether there should be a minimum level of training required for the role.

Discussion

- It is important to include interest and motivation along with minimum training.
- Consider availability to fill the role in various regions as well as opportunities for donation physicians to network with other specialties across the country.

A8. Aside from critical care, which (if any) other medical or surgical specialties should be considered for the donation physician role, e.g., ED anesthesia, trauma, neurosurgery etc.?

A majority of participants concluded that the type of specialty is not the most important determining factor. Instead, individual interest and aptitude, credibility, demonstrated leadership, and an ability to influence the practice of others are paramount.

- The ideal donor physician should have some pre-existing engagement in the donor process.
- One group advocated for a non-exclusionary approach, stating that – depending on the scope – an experienced and credible non-physician could fulfill the role while another advised that intensivists are best suited for the donation physician role, although other specialties should be considered.
- Canadian ED physicians have little to no experience with donation and transplantation. Their maximum engagement should be donor identification and referral.

Discussion

- This role will be more defined by the institution, personalities, and practicalities of those involved.
- A neurosurgery donation physician could be very effective.

A9. Which (if any) specialties should be specifically excluded from the donation physician role?

Participants concluded that medical and surgical transplant physicians should be excluded from the donation physician role along with any other physicians who have real or perceived conflicts of interest.

- One group suggested that both neurosurgeons and transplant surgeons should be excluded, although it was noted that in Quebec they are currently part of the process.
- One group concluded that only critical care physicians are best suited for the donation physician role.

A10. What (if any) formal links to other health care providers do you advise, e.g., palliative care providers, spiritual advisors, social workers, psychologists, bioethicists?

Participants agreed that – depending on the definition of “links” — donation physicians should have formal links with all the aforementioned health care providers.

In addition, links should also be in place with others such as general practitioners, paramedics, the public, the OPO, funeral home directors, coroners/medical examiners, (particularly for legal concerns), donor families, donor recipients, emergency room physicians, nurses (for liaison or as part of the ICU team), key clinical personnel, tissue retrieval personnel, OR staff, respiratory therapists, spiritual advisors, transplantation groups, and other allied health professionals.

- It is essential to have a large number of health care providers involved to support philosophical engagement and the development of a donation culture.

Discussion

- All health care providers who contribute to the role of an effective donation committee should be included.
- It is essential to define the phrase “formal links”. Does this refer to endorsements, active collaboration, bedside care, etc., and who is responsible for making these links? The important issue is to ensure that the individuals consulted are philosophically engaged.

A11. A coordinated OTDT system relies on collective and collaborative efforts. Please describe the role of the attending ICU physician when donation physicians are involved in donor care including how these roles are complementary and/or distinct.

A majority of participants concluded that the donation physician role should be defined in collaboration with the attending physician. Other comments included:

- The ICU physician is the MRP and the donation physician is in a consulting role.

- During the process of care, the roles of the donation physician and MRP should be distinct whenever possible.
- The donation physician role is most relevant in terms of system oversight and in the review of the management of individual patients and should only become 'hands on' once a patient has been declared dead and/or at the request of the ICU team.
- Determination of death (including NDD) should not be handled by the donation physician.

One group concluded that the ICU should manage patients and donor families.

A12. Please describe the donation physician role (point form) with respect to the donation coordinator role including how these roles are complementary and/or distinct.

Participants concluded that the donation physician and donor coordinator roles are distinct, complementary and collaborative.

- The donation physician can support the work of the donor coordinator and vice versa.
- The attending ICU physician is the primary physician (MRP) of the potential donor. A key responsibility of the donation physician is to support the MRP in medical management. It is unclear whether the donation physician should be called for every referral and this will depend on the region/model.
- The donation physician focuses more at a systems level in terms of policies, procedures, and supervision.
- Collegial interpersonal relationships between the donation physician and the coordinator are essential to effective team functioning. The ultimate responsibility for these relationships lies with the donation physician.

One group determined that a distinct responsibility of the donation physician is liaison with the transplant team to address system issues and/or for the management of individual donors.

Another concluded that both the donation physician and the donation coordinator could interact with members of the transplantation team at different levels.

One group advocated for the role of the donation physician as a consultant educator, collaborating with others (e.g., donor coordinators) throughout the system in support of QA, research and engaging non-clinician donation champions such as hospital administrators, and public leaders.

Discussion

- The determination of roles will vary depending on a number of factors related to how the OPOs and hospitals function.
- The 'donation physician' title is inappropriate.
- The donation physician should always be consulted with variable degrees of direct involvement. The donation physician does not have to be at bedside, but the coordinator does.

A13. The governance model for the coordinated-integrated OTDT system is still in development. Depending on location of practice, there are a variety of potential or existing structures within the OTDT system that may include, e.g., donation committees, clinical advisory committees, critical care divisions/departments, OPO's, donation committee at the provincial or national level, national coordinating agency. Given the need to coordinate these relationships, where is the best place to position this role in the proposed structure?

There was general agreement that due to the variation in provincial/territorial health structures and payment systems, approaches would likely vary across the country. They agreed that, depending on the role of the donation physician:

- There is a clear need for the donation physician to interact at a regional/local level with both the hospital (critical care department) and the OPO in some way with respect to coordination and accountability.
- Most participants agreed that payment systems should be at provincial/territorial levels with accountability taking place at regional and hospital levels.
- Most participants were not comfortable with OPOs providing payment to donation physicians
- There should be a role for a national body with respect to standards, monitoring, policy development, education, etc. The provincial/territorial role would be focused on day-to-day operations.

One group commented that, depending on the size of the region, the interface with clinicians at smaller hospital will be important.

Discussion

- The donation physician works for the hospital/health care region and is responsible to the hospital/health care region for practice standards.

B. Education and Training

B1. What should the professional training requirements for future donation physicians be, e.g., advanced professional training in OTD or certification?

Participants agreed to the need for professional training requirements and had several perspectives with respect to how this might be implemented:

- Training should be formalized, inter- and intra-professional, competency-based, asynchronous, and should lead to a certificate, e.g., through the Royal College of Physicians and Surgeons of Canada (Royal College) diploma option for advanced practice competencies.
- There is a need to identify core competencies such as content/knowledge/training in, e.g., brain death declaration, donor care, transplantation/post-transplantation care, how the OTDT system functions, interpersonal skills, clinical skills (best practices), organizational management, end-of-life care, donor management, team development, leadership (role of a champion), ethics.
- Develop training around the four pillars of clinical, education, research, and administration. Keep in mind the need for internal collaboration and alignment with other donation physicians.
- A national level committee could handle oversight and certification standards, with further training/credibility added by local and provincial/territorial jurisdictions. There is a role for the OTDT integrated system in managing the structure.
- This needs to be further explored and developed by experts with a focus on a unique Canadian solution for a credible education and credentialing process.

Discussion

- Certification per se may not be a requirement but adequate completion of a robust program is likely necessary.
- A Canadian university/universities could develop and house programs defined by the role.
- Continuous quality improvement, national uniformity, and a clear skill set are key.
- There is training available internationally to help us launch our national system.
- It is important to include educational requirements and competencies related to tissue in the system design.

B2. Should donation-related education and training of the donation physician be embedded within existing educational structures or be administered by a stand-alone agency (e.g. UK and Spanish Models)?

Participants concluded that both approaches could provide various benefits in the proposed system.

- The challenge is to be accountable but also be embedded in existing structures. Clinical leads need a stand-alone agency, but the role encompasses all areas of medical education.
- If the choice is an existing institution such as the Royal College, the CCCS, or the Canadian Resuscitation Institute (CRI) within the Royal College, benefits could be

accrued by building on existing educational structures. However, new, stand-alone structures are required to provide donation physician-specific training on top of any existing training across medical schools, faculties of medicine, and residency training.

- If the choice is an external agency, a Canadian university could develop a curriculum that addresses key competencies.

Discussion

- On-the-job learning is different than formal education and training.

B3. Should donation-related education and training of other health care providers be embedded within existing educational structures or be administered by a stand-alone agency (e.g. UK and Spanish Models)?

A majority of participants concluded that the education and training of health care providers can be both stand-alone and embedded within existing educational structures, with several provisos:

- Ensure that training is multidisciplinary, inter-professional, team-based, within a collaborative care model, and that it enables physicians and coordinators to be educators themselves in their local environments.
- Develop a national, competency-based curriculum for donor coordinators and hospital-based nurse coordinators that can be delivered at the provincial/territorial level. OPOs should be involved in the development of the program. This would strengthen OPOs in their ability to train staff and deliver training at the local level.
- Build standardized curricula that can be operationally customized to the cultural, geographic and regional needs of provinces/territories.

4. Please advise on the roles of the following (CCCS, Royal College, medical schools, OPOs, national coordinating agency) in the education and training of the donation physician.

Several perspectives were provided in response to this question:

- There is a need for a national coordinating agency of some type to (i) provide oversight, and endorse and support other organizations engaged in the education and training of the donation physician; (ii) set curricula standards, provide a link to research, and give training in coordination with the OPOs.
- One group saw each of the five agencies outlined in the question as having a role in the education and training of the donation physician depending on credibility and relative expertise, e.g., oversight, curriculum development, standards development, on site training, leadership competencies, undergraduate or postgraduate medical curricula, and research.

Discussion

- There were mixed opinions about the potential roles and responsibilities of the Royal College (through CRI) and the CCCS.
- Engage the CCCS in providing advice on leading practice, e.g., in donor management.
- Consult with all the agencies mentioned to determine their interest, motivation and capacity for engagement in this area.
- Consider a national nursing conference on donation.

B5. Please advise on the roles of the following (CCCS, Royal College, medical schools, OPOs, national coordinating agency) in the education and training of other health care providers.

Three groups referred to their responses to questions B3 and B4 with respect to this question.

One group suggested that the CCCS be responsible for critical care medicine trainees; that the Royal College train physicians only; that medical schools focus on medical students; and that Faculties of Nursing, Professional Nursing bodies and the Vice-Presidents of Nursing Education be engaged through nursing coordinators.

Another group suggested that a national coordinating agency should work with an interprofessional team to develop national accreditation standards for education.

Discussion

- There is a need for competency-based adult education that is open to other health professionals.
- The report on this consultation should not reflect physicians telling nurses about their education needs with respect to donation. However, education and multidisciplinary coordination is needed across the healthcare spectrum and this needs to be addressed to support donation education.

B6. What should the role of the donation physician be in the education and training of physician colleagues, physician trainees and other, non-physician, health professionals?

Participants concluded that the donation physician should play a central role at the local and regional level in the education of critical care physicians and other health care providers, in alignment with donor coordinators.

- Inter- and intra-professional and community education should be a basic expectation of the role (e.g., participating in and helping to lead education/mentorship sessions for the local community and hospital staff at all levels.
- Education should be based on adult education principles and should not be prescriptive.
- Community outreach by donation physicians will be key in taking the OTDT conversation beyond the hospital and out into the community so that community experiences and narratives are brought back into the hospital.
- It is essential to protect both resources and time for this aspect of the role.
- Roll out local training based on national training and standards.

Discussion

- A major expectation should be to raise the bar for OTDT in the hospital beyond obtaining Royal College subspecialty certification.
- It is essential to evaluate realistically the scope of the donation physician role to make sure it doesn't evolve into something unmanageable.
- There is a role for transplant surgeons and specialists in advising on and delivering education.
- Encourage collaboration across countries to share leading practices and align national bodies such as CCCS with the CCC trials group and other research initiatives.

Donation Physicians in an OTDT System: Accountability

Three areas constituted the discussion about accountability in the proposed system design: Performance Management, Remuneration, and System Capacity.

C. Performance Management

C1. In what areas [identification, referral, consent, conversion, utilization (organ yield), other] should performance measures be attached to the donation physician role?

Participants concluded that responses to this question depend on how the donation physician role is construed, e.g., as a chief executive officer, employee or team leader.

- One group advised that no individual donation physician or health care professional could be held accountable for all these items: rather, the OTDT team should be accountable.
- Measurements should be standardized but benchmarks must be sensitive to regional and community diversity.
- In the 'other' category participants included:
 - . Donor management and impact on utilization
 - . Education
 - . Family satisfaction
 - . Organ function optimization i.e., medical care of the donor
 - . Oversight on performance metrics and accountability
 - . Relationships, e.g., between the donation physician and intensivist, and other health care professionals, and between the donation physician and families (satisfaction with encounter/interaction)
 - . Staff satisfaction
 - . 360^o evaluation
- The role of the donation physician in relation to performance involves QA, providing and developing leadership, community engagement and education. The donation physician should also be responsible for explaining the importance of these metrics, and addressing issues as they arise to prevent reduced system performance.
- If the donation physician is in a chief executive officer role, then authority, autonomy, and ownership are important, as 'paper' definitions of performance and accountability may be beyond his/her control.
- Performance should be measured relative to the patient population and underlying improvements, not by absolute numbers.

C2. How comfortable are you with performance targets [i.e., no potential donors missed (100% ID and referral), consent rate, number of organ and tissue donors, number of transplantable organ and tissues per donor, other potential targets] attached to the role?

There was a range of perspectives in response to this question.

- Three groups were generally “not comfortable” with having targets attached to the donation physician role for various reasons, e.g., performance and accountability may not be within the role; there may be significant regional differences and unique features of populations; the question does not distinguish between individual and system accountabilities.
- Two groups were “very comfortable” with the target “no potential donors missed (100% ID and referral)”.
- Two groups did not rate these items as they saw their responses as being dependent on the definition of the donation physician role.
- In the “other “category participants included:
 - . Quality of the consent process.
 - . Conversion rates: difficult to apply as external target, but we recognize the importance of targets for external bodies e.g. for funding purposes.
 - . Family satisfaction rates.
 - . Leadership through a 360° feedback process.

Discussion

- There are significant concerns with quantitative targets rather than qualitative components. The quality of the consent process is paramount.
- We were uncomfortable with all of the options and prefer a 360°, qualitative evaluation process.
- Artificial benchmarks are a wasteful exercise. But things should be tracked, and we should track system-based and individual trends. Family satisfaction surveys and other qualitative markers should also be included.

C3. How should donation physicians be accountable in a coordinated system design: quality assurance process as part of the ICU, hospital administration, quality assurance process as part of a donation committee, national coordinating agency?

Participants concluded that donation physicians should be held accountable through all these processes, but ultimately, implementation should depend on system structure. The particular role of the donation physician may vary by region and thus so may the specific deliverables for which they are accountable, e.g., donation programs at regional and national levels.

- In the “other “category participants included:
 - . Education
 - . Research

Discussion

- Donation physicians should be accountable through their "employers" and should be judged on the basis of general performance.
- Although not primarily accountable for the QA process, interactions with hospital administration, and the role of the donation committee, the donation physician should be held generally accountable for these elements.
- QA in the donor process should be an accountability. Evidence of a process and improvement review should be part of the role.
- The donation physician should sit on the hospital medical advisory committee and report to the board in order to support hospital engagement and facilitate links to education and research.
- The National Coordinating Agency should support accountability through an accreditation process.

D. Remuneration

D1. Remuneration for donation physician services should flow directly from which of the following: Government (Provincial Ministries of Health), OPOs, Hospital/Regional Health Authority, Critical Care Department?

A majority of participants saw remuneration flowing from the Ministries of Health or from the highest level possible. There was significant comfort with funds flowing from the Ministries to the hospitals for payment purposes.

One group suggested that the OPO and the hospital could provide a separation between payment and accountability for remuneration purposes. However, others saw this arrangement as a potential conflict of interest and recommended that there be a clear separation of payment and accountability, with the donation physician being responsible to his/her employer. With this in mind, in some situations both OPOs and critical care departments could be in a conflict of interest.

D2. There is a distinction between the system performance measures (e.g., number of donors, transplants etc.) and donation physician performance measures. Should remuneration be provided for performance measures identified in the previous discussion i.e., identification, referral, consent, utilization, and conversion?

Participants unanimously responded “no” to this question, primarily for ethical reasons.

Some groups responded “No, but”:

- It’s reasonable to review and compare traditional statistics.
- There should be some form of annual review process incorporating metrics and standards without salary being tied to performance, which smacks of finder fees and commissions.

Discussion

- Performance-based remuneration may engender real or perceived conflicts of interest and could endanger the structure and integrity of the program.
- Remuneration should allow for protected time to fulfill this role, separate from normal practice.
- While coupling remuneration to some form of performance seems reasonable, defining performance as more organs or tissues is not valid. We want to make sure we don’t create the optics that converting donors results in more income.

D3. Are there any other remuneration deficits that need to be addressed?

Participants offered several additional remuneration deficits:

- Provincial barriers in terms of money allocation.
- Additional funding required to support the role for continuing professional development, research support, QA and improvement, operational office support and information technology.

- Additional support for a call-in stipend, on-call stipend, billing code modifications, allocation of course work (out of pocket expenses) and educational activities in the region or hospital.

Discussion

- It may be easier to remove disincentives rather than to add incentives.
- We agree with hospital funding for the provision of donor care (allocation per potential donor), particularly in settings where an ICU is beyond 100% capacity.

E. System Capacity

Considerable background information, including pre-consultation surveys, provided a backdrop to discussions on system capacity.

Presentation

Dr. Rob Fowler presented the results of The Canadian ICU Capacity Survey Study which provides provincial data on the current situation including the number of hospitals with ventilation capacity (minimum two hours). He used the Severe Acute Respiratory Syndrome (SARS) and H1N1 (influenza) epidemics as examples of what could happen if the proposed system design successfully increases the number of organ and tissue donors. Any surge in demand for ICU capacity would have the potential to overwhelm the system.

While the data presented were in a preliminary stage in terms of analysis, it was clear that data quality varied among provinces as did the nature of population groups. A number of interesting geographical variations emerged, potentially as a result of differing regional definitions of critical care units and ICU beds.

Discussion

- Some physicians and nurses value the potential donor and recipient with respect to ICU beds, but there is a relationship between capacity and who gets admitted as well as the ability of transplant programs to function effectively.
- Most of the expansion of donors is in DCD, so most are already located in the ICU. With a massive expansion of donors and a subsequent need to get transplant beds, enhanced donation could overwhelm the ICU, as the recipient beds would already be taken. A donor may need a bed for a few days, but recipients may need a bed for days to weeks.
- In Alberta it is easier to control potential donors because they have to make their way to a central site.
- There are potential problems with the data accuracy:
 - Both central agencies and governments skew data. Is it better for accurate, reliable, and relevant data to be collected by clinical people who own the problem, and then have it analyzed by a trusted expert?
 - The number of hospitals with ICU's per province are often overestimated.
 - How does CIHI define 'special care units' and what is the impact on reporting accuracy?
 - Who is delivering the care (e.g., primary care or critical care physicians) is important. In some provinces there is significant variability in who looks after the ICU beds.
 - In some provinces there was considerable reluctance to provide data.
- Increasing nursing staff and defining the nursing ratio required could profoundly impact the number of beds available.

E1. What innovative approaches can you suggest to improve hospital and ICU access for potential donors in Canada?

Participants made a number of practical suggestions for improvement.

- Make the potential donor a high priority part of the system both inside and outside of the ICU environment. Where access to the ICU is not equal for donors, use the donation physician role and the OPO to support equivalent access for donors.
- Advocate for a national registry and database for ICU beds in order to identify gaps and target jurisdictions for improvement in access to ICU beds.
- Designate specific hospitals as 'no refusal' centres for donation where government resources are activity-based and personnel are guaranteed.
- Take a systems approach by using resources creatively for approaches such as information transfer and telemetry medicine. Find ways to enable technology to help support smaller hospitals.
- Recognize the resources put into donation processes, and have monetary incentives provided to hospitals for donation.
- Discuss the possibilities inherent in advanced care evaluation and transfer if there is the potential for donation.
- Plan for minimal effort on scheduled activities, through a 'scheduled wait list' that can accommodate donors. Commit to honest audits and review the impacts on care.
- Fund only committed hospitals.
- Address back-end challenges such as how to release ICU patients who are ready to leave but have nowhere to go.
- Change the public awareness of death and dying to include accepting the natural end-of-life process.
- Repatriate patients with diagnosis of 'failure to donate or treat'.
- Where access to ICU for donors isn't equal to living patients, make sure that everyone has equal access.
- To expand capacity without stressing existing donor centres, use the donation physician role and OPOs to make donor care available for hospitals that need support for follow through.

Discussion

- Explore the possibility of specific donor/transplant hospitals.
- Funding should follow patients.
- There should be links between neurosurgical decision-makers (regarding patient transfer or triage) and critical care intensivists.
- Individuals and organizations need to be held accountable for performance. The physician specialist needs links to senior leadership for routine on-site discussions around access.
- 'Reserved' beds was often rejected as a concept, although there wasn't agreement.

E2. How might the proposed system accommodate an increase in organ donation and transplant activity?

- More data are required to know where the opportunities and challenges lie, and what we are up against
- Consider setting up networks of hospitals to get patients to centres where they can be accommodated.
- We may need a different and more flexible nursing model (e.g., where there are unstaffed beds), or to look at the Philadelphia model, where recovery is inside the OPO, not the hospital.
- Hospital-level funding incentives will support funding to follow patients.
- Some donors may have prioritization, e.g., through CritiCall (<http://www.criticall.org>) in Ontario.
- Transfer skills, not people – families don't like being moved. Telemedicine is one way to do this, moving nursing staff around is another, but not all provinces/territories have coordinators.
- Step-down beds and more increased long-term care beds can facilitate decompressing ICUs to increase capacity.
- Over the longer term, increasing donation increases recipients, all of whom need beds. This requirement needs to be anticipated to enable downstream transplant capacity in the ICU system.

E3. How could the proposed system accommodate the potential for referrals from non-procurement hospitals (NDD, DCD) for the purposes of organ donation?

- This question should also address the potential for referrals related to tissue donation.
- Don't turn away patients. Give tissue donation the same priority as organ donation.
- Set up mobile donation teams to service a region.
- As mentioned previously, implement 'no refusal' hospitals.
- Organizational readiness and an understanding as to the potential for deceased donation within a jurisdiction and the benefits to donation will need to be widely shared and understood.
- Use telemedicine to manage donors remotely.
- In smaller centres, set up a way to refer calls to a donation physician to evaluate potential.
- Donor referral hospitals don't need to be transplant centres: they need to have an ICU, echocardiography, angiography, bronchoscopy, lab services and a CAT scan.
- We need buy-in at a high level. There is a system-wide conversation that needs to happen at regional and local levels so that there is an honest assessment of organizational capacity for change.

Over-arching Considerations

Two areas were discussed as having over-arching considerations: research and innovation, and distribution of physicians and geographic considerations.

F. Research and Innovation

F1. How could support for research and development be included in the proposed system design?

- Support research and development by:
 - . Building a national consensus on research priorities.
 - . Developing the infrastructure required to support a focused research agenda.
 - . Funding the Canadian Critical Care Trials Group (CCCTG) for feasibility studies.
 - . Funding research fellowships for trainees.
 - . Lobbying CIHR and other national granting agencies for increased profile and funding.
 - . Taking a multi-national, multi-centre approach to clinical research.
 - . Identifying and setting priorities for knowledge translation.
 - . Facilitating networking.
- Create an obligatory data system as soon as possible, i.e., before the formal system is implemented, including:
 - . Collecting and analyzing data/metrics for donor and death data provincially and nationally in an open and accessible system.
 - . Creating a national registry (similar to UNOS) that is linked with provincial registries.
 - . Capacity for data management and analysis on outcomes, QA audit mechanisms and evidence-based care.
 - . A focus on health systems knowledge translation.
- Embed the research function in the donation physician role (education/administration/research/clinical), while keeping cost and access to data in mind.
- Advocate for Canadian Blood Services (in partnership with OPOs and other agencies) to make a commitment to investing in research and innovation in OTDT.

F2. To what extent should research and development be a formalized responsibility within the donation physician role?

A majority of participants concluded that research and development should be a formalized responsibility within the role, either to the greatest extent possible (two groups) or based on the interest and skills of the donation physician (two groups) and recognizing that research may not be part of the donation physician's skill set.

- If research is not considered to be a formal part of the role, the donation physician should still facilitate research activities while not being accountable for the program.

One group did not think the role should include research and development as a formalized responsibility.

Discussion

- Resources are required to ensure local data is robust.
- There is no point in generating interest and developing skills if the infrastructure isn't present to sustain the role.
- Research and development can be a way to attract young ICU physicians to the donation physician role. It can also be a way for critical care physicians to augment their careers.

F3. What should future research priorities be in this domain?

- Creation of a research committee and a data management group similar to the Institute for Clinical Evaluative Sciences (ICES).
- Development of a national research agenda.
- Development of an obligatory national database to support research priorities.

Research Topics:

- Cluster interventions including the donation physician model.
 - Donor management practices.
 - Donor models, e.g., remote management, success with consent, family satisfaction
 - Health policy development.
 - Health systems and services.
 - Inter-professional research.
 - Links between the CCCTG and CCCS.
 - Mining existing data for action on knowledge translation and exchange.
 - Molecular markers.
 - National Database with accepted definitions.
 - NDD.
 - Organ and tissue preservation.
 - Social and cultural health issues.
 - Why families say 'no'.
- Set research priorities and initiate the database set before making any systemic changes.

F4. Which agencies or groups have the potential to be funding partners in donation research?

- Established agencies such as Canadian Blood Services, Canadian Institutes of Health Research (CIHR), Canadian Intensive Care Foundation (CICF).
- International Societies/Groups (for national level partnerships).
- Organ specialty organizations (e.g., heart and stroke, kidney, cystic fibrosis, diabetes).
- Provincial funding organizations (e.g., Fonds de la recherche en santé du Québec (FRSQ), Alberta Innovation).
- Transplant societies.
- World Health Organization.

- Utilize current established 'research' organizations with the capacity to assess research proposals.
- Partnerships should involve more than just funding: they should leverage each other's interests, be mutually supportive and enable both national and international collaborations.
- With larger groups of patients there is the opportunity to partner with other groups to do multi-centre trials.
- Bank on the successful experience and know-how of Canadian Blood Services with respect to a sustainable research and development structure.

G. Distribution of Physicians and Geographical Considerations

G1. How could these geographic challenges be addressed in a coordinated OTDT system?

- Base funding for different systems on an estimate of how many donors may be achievable in a region.
- Develop nurse practitioners on a regional basis as local champions.
- Find new ways to be flexible such as optimizing dedicated Emergency Medical Services (EMS) transport based on population and health services provided in a region.
- Optimize systems that are currently available, e.g., establishing a common 'funnel' for care to align with trauma and cardiac systems.
- Partner with adult educators to develop innovative remote learning strategies for use in donor care and when talking to families about donation and consent.
- Take regional and local approaches to outreach donor teams (either in person or over the phone) with a local role for the physician and a regional role for the team. Advocate for as many teams as possible.
- Use telehealth and telemedicine to enable customization by geographic area.

G2. What would the role of the donation physician be in ensuring opportunity to donate in regions significantly challenged by geographical disparities in donor care or procurement services?

- Facilitate operational challenges creatively, e.g.,
 - . Partnering with regional police services to transport blood and tissue.
 - . Telehealth to help identify and stabilize a donor or to provide 24/7 access to consultation.
 - . Telemedicine continuing medical education programs to support tissue recovery.
 - . Partnering with the ambulance service in the region to ensure the potential donor is a high priority transfer.
 - . Transfer of patients to a donation-capable centre during business hours to optimize the donation process.
 - . Web-based education to enable flexible learning hours and strategies.
- Determine the number of donation physicians required in a region based on OTD activity, the UK approach, and number of ICU beds. There may be a need for two levels: a local hospital physician for in-person consultations and care, and regional stewards to optimize support.
- Facilitate and champion donation by identifying and addressing issues with appropriate levels of government.
- Get Minister of Health approval to make the district activities a reportable item. When the CEO is held accountable, it makes the medical staff pay attention.
- Manage face-to-face meetings with referral hospitals to support a donation culture and facilitate the development of leaders and champions at various sites.
- Contribute to the development of a national system for recognizing and creating pathways to support donation.

- Build collaborative relationships with organizations that partner with local groups.
- Support the development of a data management system that can project estimates and enable responsiveness: death-related data need to inform practice from the ED to the ICU and ultimately be linked with transplant recipient outcomes to inform critical care practice.

H. Ethics

Ethical considerations were an ongoing theme throughout this consultation. The topic was introduced the first morning through a report on the OTDT system Ethics Consultation held in January 2011, and then re-emerged through an international panel focused on related issues, culminating in an opportunity at the end of the consultation for participants to raise any remaining questions or concerns they might have.

There are a number of ethical considerations and recommendations to guide the hospital, the clinicians involved in donation care, and donation physicians in preserving their duty of care, protecting the interests of dying patients, and fulfilling best practices for donation. The potential for real or perceived conflicts of interest associated with the dual role of the donation physician has been recognized as a challenge area. Concerns have been raised that public perception of the dual role may adversely affect the donation experience, creating mistrust, and ultimately reducing donation rates.

OTDT Ethics Consultation

In his opening presentation summarizing the findings of the OTDT System Ethics consultation Dr. Franco Carnevale outlined the proposed system recommendations developed for two issue areas: opportunity to donate, and potential conflicts of interest. These proposed recommendations are provided below, followed by the recommendations made by participants in that consultation in response to specific questions about each of these issue areas.

1. Opportunity to Donate

The proposed system strategy recommends increasing organ and tissue donation by:

- Optimizing and using every possible donation;
- Maximizing identification, referral and consent by ensuring the system offers every opportunity to donate (i.e. NDD, DCD, Living Organ Donation); and
- Building support for and active commitment to donation through public awareness and intent to donate registries.

The system strategy recommends increasing the number of tissue donors to close the most significant tissue supply gaps – corneas, tendons and pediatric heart valves, and an emergency skin supply.

In summary, system recommendations are to increase all forms of donation. To that end, all Canadians should have the opportunity to donate, but some hospitals and health care professionals have declined to provide opportunities for all types of donations because of logistical implications and/or ethical concerns. Ethics consultation participants were asked: How can the system accommodate these conflicting perspectives ethically?

Recommendations Developed at the Ethics Consultation

1. Messaging should be consistent for both organs and tissues at patient, public, and professional interfaces.
2. Although we would want to recognize donor equity so that everyone has fair access to donation, responsible societal management of limited resources may be a determining factor.
3. Hospitals and health care professionals have an obligation to provide an opportunity for all types of donation, e.g. NDD, DCD, living organ donation. The system needs to ensure proximate access consistent with public policy and broader societal values.
4. The system obligation is to inform and disclose appropriate information so that potential donors/surrogates can make an informed decision about donation. It is not mandatory to provide the service in that institution, as long as there is proximate access to that service, and the family is informed of that option.
5. There is an obligation to provide the opportunity to donate to everyone regardless of a previously indicated desire/intention to donate, i.e., the ethical and moral obligation is the same. Registration or advance intent to donate should not influence or enhance the existing obligation to provide the opportunity to donate, though it may influence consent.
6. There should be no specific exclusions to the opportunity to donate for pediatric deceased donations.

2. Potential Conflicts of Interest

The proposed system strategy recommends increasing organ and tissue donation by:

- Specialization of donation care within hospital systems, including the implementation of donation physicians.

Currently, donation care in hospitals remains a professional option rather than a standard part of end-of-life care. In leading countries such as Spain, Italy and Belgium, the presence of dedicated, funded donation physician specialists is a key element in their success. Australia and the UK have recently adopted this proven model of performance enhancements. Establishing donation physicians in major hospitals across Canada (either as a shared or dedicated resource) could increase organ and tissue donation by providing clinical leadership within hospitals, ensuring all potential donors are identified and treated appropriately, and educating other health care professionals on donation.

- Implementation of an optimized funding model to achieve a sustainable system.

Consultations with clinical and administrative leaders have identified barriers or disincentives within current funding models, e.g., lack of adequate funding of hospital costs (staff and space) associated with donation activities, failure of global funding models to reimburse operative services or critical care programs for incremental donation and transplantation activity, lack of incentives to motivate higher performance. It is recommended that an optimized funding model be developed and implemented to ensure a sustainable system that responds to the needs of patients.

- Increased investment for enabling infrastructure and for increased organ donation and transplantation activity.

New activities and increased performance targets will require funding to front line operations. This includes money to OPOs and hospitals to accommodate the increased number of donors and a requirement to fund the new activities including donation physicians.

In summary, health care organizations and professionals must manage the dual obligation of caring for dying patients and their families, while providing donation care to potentially dying patients and their families. What are the ethical considerations and recommendations to guide the hospital and donation physicians in preserving their duty of care, protecting the interests of dying patients, and fulfilling best practices for donation?

Recommendations Developed at the Ethics Consultation

1. The option of participating in organ and tissue donation should be a standard part of end-of-life care for deceased donation. The opportunity to participate is an important dimension of respecting patient values and beliefs.
2. Upholding the patient’s benefit and best interest standard includes the option of organ/tissue donation. Patient benefit is formed by personal preference. Supporting best interest after death applies in this context through the benefit of full sharing of information with the potential donor/surrogate decision-maker and knowledge that the donor's values and beliefs will be followed. Respecting the wishes, values, and beliefs of the patient are in that patient's best interest.
3. There is the potential for OTD to jeopardize the duty of care to the patient and family. Ethics consultation participants commented further:
 - There is a need to address both real and perceived conflicts of interest. Where a physician has a dual role, there has to be a clear disclosure of both roles to family members or surrogate decision-makers.
 - Even with licensing and regulatory frameworks, it is extremely difficult, if not impossible, for individual care providers to manage this conflict (or perception of conflict) by themselves. There should be clear separation of donation, transplantation, and care giving roles.
4. When asked “Does defining the responsibilities and accountabilities attached to the donation physician role have ethical implications beyond current practice where the role is largely unstructured?” participants responded in three ways:
 - Yes: There are ethical implications and they are all positive with significant benefits to the public, both donors and recipients.
 - No: The system should already have responsibilities and accountabilities defined. Formalizing these should make no difference.
 - Yes: If an integrated OTDT system is achieved, defining roles enhances system accountability and benefits patients.
5. While much depends on operational considerations, optimizing funding attached to the donation physician role has ethical implications beyond current practice where the role is largely unfunded.

It is necessary but not sufficient to rely on physician integrity alone and licensing standards, be they from colleges, legal statutes, clinical guidelines, etc. It will be necessary to have structural design considerations and transparent institutional policies to mitigate conflict of interest. Any financial incentives should be consistent with ethical opportunities to donate.

It is not reasonable to ask physicians to do perform additional services without payment.

6. An Ethical Framework including the following could provide initial safeguards to protect the integrity of the donation physician role:
 - Separation of roles.
 - Transparency and disclosure.
 - Funding is required and should be based on providing the ethical opportunity to donate, not on organ yield.
 - It is necessary but not sufficient to rely on physician integrity/licensing standards etc. It is necessary to have structured design considerations and transparent institutional policies to mitigate real and potential conflicts of interest.

International Ethics Panel

Four international speakers contributed their thoughts on ethical challenges related to the role of the donation physician from the perspectives of systems in the United Kingdom, Spain, United States and Australia. Panel members were asked to address two questions:

1. How important are ethical considerations in your system and how do you manage them?
2. How do you address separation of roles between ICU attending physicians and donation physicians?

United Kingdom

Dr. Dale Gardiner commented that legal and ethical best practice guidelines are the basis for ensuring that physicians avoid conflicts of interest in the UK. He provided a practical example to illustrate his point: a physician has four hours weekly of funded time for the donation champion role and must keep two roles separate throughout this work. If the physician makes a withdrawal decision, he/she needs to consult with someone else. In particular, legal and ethical guidelines make a significant difference when doing DCD, which can be very emotional and difficult. In situations like this – where physicians are representing the needs of donor families and the wishes of the donor as well as the expressed direction from government and citizens – legal and ethical practice guidelines are an essential support, e.g., it is illegal and unethical to initiate ventilation in potential donors.

Spain

Dr. Xavier Guasch explained that controlled DCD is not done in Spain, and uncontrolled DCD is not perceived to be an ethical problem. The patient is declared dead (by one team) and the donation team shows up and deals with the cadaver. In situations where a physician is responsible for a patient evolving to brain death, he/she passes this individual on to another colleague to avoid participating in the declaration of brain death.

Pittsburgh

Dr. Raghavan Murugan reported that at the UPMC the focus is on respecting donor wishes and it is assumed that it is unethical not to take organs if the donor wants this to happen. There is a clear separation between caring for the patient and managing the donation process. The DCD policy is explicit and clearly identifies that end-of-life issues precede donation; they never occur at the same time, only in sequence. Dr. Murugan commented that a dilemma occurs with designated donors who have an advanced directive not to have life support. In Pennsylvania, if a family doesn't give consent for donation but the donor has registered their intent, the law allows the OPO to disregard the family and take organs. However, this rarely happens. UPMC has a mandatory ethics consultation for possible DCD: you can always withdraw care – the question is when.

Australia

Dr. Gerry O'Callaghan commented that ethics are central to the donation physician role and that an appropriate ethical framework is essential to having a safe area within which to practice and champion donation. In the Australian context, an ethical framework is indistinguishable from governance, and the two have to work together seamlessly. Prepared documents outlining clinical practice guidelines should be in place to support the donation physician role, along with a mechanism for safe discussion (e.g., national and regional health ethics committees) and a time-sensitive framework to support issues management and resolution during critical decision-making times.

Discussion

- Clear and intentional language is essential. The relationship between patient and physician is based on trust. The obvious approach is to count the numbers of organs transplanted, the consent rate, etc. But we need to stay away from counting organs and stay focused on our trusting relationship with patients, while still being measured and held accountable.
 - How we speak to our colleagues, peers and society is critical. The term “donation physician” sounds like care for donors – champions or stewards might be better terminology.
- Families who donate tend to get more support from the donation team. It is a challenge to provide the same level of support to non-donor families, and they probably need the most support.
- In Spain, roles are clearly separated. While patients do get admitted to the ICU only to become donors (and this practice has been slow to catch on) it is the intensivist, not the donation physician, who talks to the family.
- Overseeing and managing variability in practices will be important at the national level.
- The distinction between donor and patient feels artificial. A patient becoming a donor is an extension of our care and respect for that person – the duty of care doesn't end.
- There should be no distinction between donating organs and donating tissue. Where is the program that ensures that everyone who dies in ICU has the opportunity to donate tissues? We can't have a high performance system without tissue.

- This journey is centered around fundamental emotions and belief systems. If we don't talk openly about these central experiences as donation physicians, we don't establish a platform for honest dialogue.
- We cannot overlook the pre-eminence of the relationship between the attending physician and the patient. In this system, terrible things can happen as a consequence of our decisions – this is a primary responsibility that we face.
- Patients are not donors when they enter the hospital system. When do patients become donors? It is essential to distinguish between when an individual is a patient being cared for and when that person becomes a donor.
- Physicians do not withdraw care – they withdraw non-therapeutic treatments.
- Real and perceived conflicts of interest are to be expected. We need transparent and structurally sound solutions for addressing conflicted situations.
 - The value that we add treating ICU patients cannot be separated from the value of providing donation services. I don't accept the idea of non-therapeutic ventilation.
 - If we design the system to have a detailed focus on examining or second-guessing the professional practices of our peers, we are designing it to fail.
 - There has to be a clear separation of the roles of attending physician and donation physician.
 - We can't have someone whose only role is to procure organs inserting themselves into the circle of care. Only after the patient has been documented as a donor by the attending team (and the attending ICU physician) does it become appropriate for a donation physician to become involved in managing the care of that patient.
 - We can't rely on individual practitioners to extricate themselves from conflicts of interest: we have to build a process for addressing these challenges.
 - Is it more appropriate to celebrate the numbers of donors or the number of opportunities provided for donation?
 - While we have a tremendous sensitivity about conflicts of interest, we mustn't lay our sensitivities at the feet of the public.

The Donation Physician in the OTDT System: Ethical Challenges

Having heard the recommendations from the ethics consultations during the opening morning of the consultation, and after discussing how ethical challenges are addressed internationally, participants were asked:

Are there further ethical considerations that should be addressed in the proposed system design?

Following are their suggestions and questions.

- Address key issues directly such as:
 - . Variability of practice across and within institutions.
 - . Respect for differences in physician comfort with OTD.
 - . Clarification of how to balance the care needs of patients and families with meeting donor, family and system needs.
- Are we creating a discrepancy in care between potential organ donors and non-potential donors?

- Are non-donation potential donor families cared for as well as potential donor families at end-of-life?
- Ask for third party ethical and legal analyses of the donation physician role, e.g., through medical colleges.
- Build in a legal and ethical review of system processes by an external, unbiased and independent agency such as the Royal College.
- Consolidate and integrate the ethics work to date into an accessible and practical framework (e.g., the UK approach) that is diffused throughout the system design at the national level to identify and address:
 - . Cultural and faith-based sensitivities.
 - . Ethical considerations and solutions for persons who are both MRP for a patient and donor physician.
 - . Controversial issues such as DCD, withdrawal of life-sustaining treatment(WLST)
 - . Specific issues such as exceptional release.
- Develop national consensus guidelines in specific areas.
- How will the critical care team be integrated into the system, particularly in terms of mutual respect and recognition?
- Provide access to timely ethics consultation for dealing with hard cases.
- Tissue donation must receive equal priority with organ donation.

Discussion

- Are we creating proper end-of-life care for potential organ donors by segregating care?
- Consider customizing Australia's national document on legal and ethical considerations for Canadian use.
 - A national framework should identify specific issues that need to be addressed and how to address them, e.g., through 'Frequently Asked Questions'.
 - Create a mechanism by which the donation physician and other team members can have access to ethical and legal support in difficult situations.
 - Include opportunities for cultural and faith-based consultation as required.
- Education, either by the donation physician for peers, or for the donation physician as part of the role, will be an important part of addressing any ethical issues that may arise.
- If there is a perception that we are giving priority to donors over other patients, there is a need to consider how we would defend that position relative to law, e.g., by using the Hamilton protocol with H1N1, we could be subject to criminal action.
- There are different levels of commitment to the donation physician role across the country. How can we accommodate these perspectives?
- While it's important to link ethics to specific issues, one of the challenges we face is that each of us thinks about ethics a little differently. All of the questions asked throughout this consultation have ethical components. How can we achieve a rich and shared understanding in our responses to these questions and thus make the problem solving easier? Identifying what is at stake for us will move us toward convergence.

Conclusion

Dr. John Granton, President of the Canadian Critical Care Society (CCCS), thanked Canadian Blood Services staff for all their hard work on the proposed system design and the opportunity for the CCCS to be a partner in improving the Canadian OTDT system through co-hosting the consultation. He commented that while many critical care physicians see donation services as being something that is already a part of their job, having a system in which the role is recognized nationally, clearly defined, and supported with resources, standards and research, provides an opportunity that can't be missed.

Planning Committee Chair Dr. Sam Shemie brought the consultation full circle by referring to the questions and comments participants had raised during their introductions, most of which had been addressed throughout the meeting. He thanked both participants and international and national guest speakers for their hard work and rich input before and during the consultation. In particular, he pointed to the wisdom and preparatory work of planning committee members in contributing to the development of background materials and the overall process.

Dr. Shemie closed the meeting by commenting on next steps: a national ethics framework will be developed based on the considerable input to this area throughout the consultation. A small group of volunteer consultation participants will review a draft consultation report after which it will be finalized and provided to the Canadian Blood Services leadership where the results will be incorporated into recommendations to the Ministers of Health. Throughout the coming months, Canadian Blood Services will be in communication with the CCCS and the larger OTDT community to keep everyone apprised of developments as they occur.

Appendix A: Acronyms

CCCS	Canadian Critical Care Society
CCCTG	Canadian Critical Care Trials Group
CCDT	Canadian Council for Donation and Transplantation
CICF	Canadian Intensive Care Foundation
CIHR	Canadian Institutes of Health Research
DCD	Donation after Cardiac Death
DP	Donation Physician
ED	Emergency Department
EMS	Emergency Medical Services
FRSQ	Fonds de la recherche en santé du Québec
FTE	Full time equivalent
H1N1	Influenza
ICES	Institute for Clinical Evaluative Sciences
ICU	Intensive Care Unit
MRP	Most Responsible Physician
MSN ICU	Medical/Surgical/Neurological Intensive Care Unit
NB	New Brunswick
NDD	Neurological Determination of Death
NS	Nova Scotia
OPO	Organ Procurement Organization
OTDT	Organ and Tissue Donation and Transplantation
QA	Quality Assurance
QEII HSC	Queen Elizabeth II Health Sciences Centre (Halifax, Nova Scotia)
Royal College	Royal College of Physicians and Surgeons of Canada
SARS	Severe Acute Respiratory Syndrome
UK	United Kingdom
UPMC	University of Pittsburgh Medical Centre
WLST	Withdrawal of life-sustaining care

Appendix B: Meeting Terms of Reference

Background

In August 2008, Canadian Blood Services was given a mandate by the Conference of Deputy Ministers of Health to lead the development of a national strategy for organ and tissue donation and transplantation in Canada. As a result, Canadian Blood Services is working in collaboration with the organ and tissue donation and transplantation (OTDT) community to build a national strategy to deliver consistency, improve performance and ensure more Canadians receive the organs and tissues they need.

As a first step in development of the process, a national stakeholder consultation was held in September 2008, to determine how best to establish national, integrated services that will meet the needs of patients and the OTDT community. Building on this, a four-phase process was initiated to develop a national system design for OTDT. Three committees have been struck to advise the process: (i) a Steering Committee to give systems-level guidance on how to integrate organ-and tissue-specific recommendations into the Canadian health system, (ii) a Tissue Expert Committee and (iii) an Organ Expert Committee. All three committees are comprised of experts from across the country.

Since June 2009, the Committees have reviewed the current state of the OTDT system in Canada, drawn from the experiences of other countries, received feedback from experts and members of the public during cross country consultations, and discussed recommendations for a national system design.

This meeting is sponsored by Canadian Blood Services in partnership with the Canadian Critical Care Society.

Purpose and Objectives of the Meeting

The purpose of this initiative is to consult with key stakeholders regarding the proposed OTDT system design recommendation to formalize donation physician roles in health care centres in Canada.

Objectives:

- To provide an overview of work to date on OTDT system design, ethical principles and strategy as a basis for informed discussions by consultation participants.
- To provide a comprehensive overview of current policies and practices with respect to the role of donation physicians in Canada and internationally.
- To review and advise on the preliminary OTDT system design recommendation to formalize the role of donation physicians in clinical service, education, and research and innovation
- To review the implications of ICU bed and physician capacity with respect to the emerging recommendations.
- To provide information on current partners and explore potential partnerships in support of the development of the donation physician role.

- To explore sources of potential real and perceived conflicts of interest in Canada and internationally and advise on mechanisms to explore strategies to mitigate conflicts that may arise.

Assumptions

The following meeting assumptions provide a common starting point for reflection, discussion, and the development of recommendations at the consultation.

- OTDT is a widely accepted and supported medical practice in Canada.
- Improving donation performance and the availability of transplantable tissues and organs is a benefit to Canadians and the Canadian health care system.
- Canada lacks a national and integrated approach to OTDT.

Scope

This 2 day meeting of Canadian critical care and donation experts:

- encompasses deceased donation
- includes organs and tissues
- includes representatives from the ICU physician community, Canadian Critical Care Society, Provincial Organ Procurement Organizations and ethicists who were present at the OTDT Ethics Consultation
- is informed by background reviews and international expert commentary.

Though specialization of donation care extends beyond the role of donation physicians to include nurse-based donor coordinators and other specialist or allied health roles, the scope of this initiative focuses primarily on the donation physician role in the system.

Consultation Process

This consultation is for advisory purposes. A report of the recommendations from this meeting will be developed and confirmed with participants. The report will then be provided to Canadian Blood Services for review and inclusion in the OTDT system strategy and design report. The final OTDT strategy and design documents will be provided to participants and will be publicly available once they have been presented to the Federal/Provincial/Territorial Deputy Ministers of Health, likely in the spring of 2011.

Appendix C: Summary of Provincial Perspectives on Donation Physicians

Pre-Consultation Survey

Dr. Giuseppe Pagliarello presented the results of a pre-consultation survey of participants. The survey yielded information about the current situation in Canada with respect to where donor care is based, who manages that care, what types of organ and tissue donor care are provided, ratings of overall effectiveness and efficiency, how donor care is evaluated, and how educational training is managed.

Ontario

Dr. Pagliarello also described the situation in Ontario with respect to the donation physician role. Trillium Gift of Life, Ontario's Organ Procurement Organization (OPO), uses a 24/7 on-call telephone consultation service to offer advice and suggestions around issues of consent, Neurological Determination of Death (NDD), donor management and DCD. These "Donation Support Physicians" advise the donor coordinator at the bedside as well as the Most Responsible Physician (MRP) when requested. The role is only consultative. Both donation and transplantation expertise are necessary for this to be successful, and thus a separate on-call structure is present for transplantation support. A current goal is to augment existing infrastructure. As the program moves into smaller hospitals there will be a need for more resources to ensure donation programs remain robust.

Manitoba

Dr. Brendan McCarthy reported that Manitoba has recently implemented an organ donation specialist with three prime roles: clinical organ donation service, medical death audit review and accountability and education. Goals of the new system include: increase referral rate from 50% to 90%; establish a DCD program; establish an educational program for the region; and increase the conversion rate to 50%. The program is expected to be cost neutral with two additional donors a year, i.e., a renal transplant is less expensive than long term dialysis. Donation and transplant physicians are to be kept separate in this new program.

After these initial provincial presentations, other delegates described features of their programs in relation to the donation physician role.

Alberta

Dr. Jim Kutsogiannis (Edmonton) explained that northern Alberta uses a regional model in which all head injuries go to one centre, making program oversight easier from a logistical and physician standpoint. Donor management happens regionally as well. Donation support is available on a 24-hour basis for questions and troubleshooting, and there is mandatory calling for everyone who dies in emergency or in an ICU. Current challenges are in public education (e.g., with the family that says 'no' from the start) and this requires promotion and public education with both family physicians and the public.

In the Calgary area Dr. Andreas Kramer explained that donation is managed largely by intensivists, who have increasingly introduced the concept of donation to patients and their families. More formal consent comes from donor coordinators. The departmental website has

links to Canadian Council for Donation and Transplantation (CCDT) documents, and missed donation opportunities are a priority on rounds. Trauma patients are all funneled into one main site. Donation support could be a greater priority in front-line care.

Québec

Dr. Jean- Francois Lizé described Quebec as having a medical director structure, with physicians on call by telephone 24 hours to answer questions and help with managing and diagnosing donors. There are resource nurses in hospitals to support families and the donation team and ease discussions about donation. There has been a donation physician role for ten years in Quebec, and transparency is recognized as being an essential component. A weekly phone conference is held with each case discussed, and a lot of information is centralized. DCD is in the process of being implemented in every hospital. Discussions have begun with the Ministry of Health to better recognize the role of the intensivist, and there is a movement towards a focused procurement centre. Rolling out the donation program to smaller, rural hospitals is a challenge; currently, phone consultation is used to manage cases in these smaller centres.

Nova Scotia and Atlantic Provinces

Dr. Steve Beed outlined the challenges Nova Scotia is facing: there aren't a lot of trained intensivists; there is limited experience with donation outside of Halifax; there is only one cardiac catheterization lab for the province, and there is no protected funding from the province. Successes in Nova Scotia have been in large part because of the work of nurses. Commitment for the intensivist on call for the Medical/Surgical/Neurological Intensive Care Unit (MSNICU) in Halifax, Nova Scotia (NS) to serve as a provincial resource for donation related questions has been in place for 6 years. There are some geographic challenges that need to be addressed as well with respect to rural and remote areas, as the system often doesn't hear about potential donors from intensivists. The Queen Elizabeth II Health Sciences Centre (QEII HSC) in Halifax has a no-refusal policy if contacted regarding a potential donor.

There is one transplant program for the Atlantic provinces (located in Halifax), and this can create problems, as transplanters have to support all four provinces. In addition, the donation programs of Nova Scotia, New Brunswick (NB) and Newfoundland function autonomously. There is no donation program for PEI: potential donors are usually transferred to NB, sometime NS.

Appendix D: Donation Physicians within International OTDT Systems

Dr. Sam Shemie chaired an international panel of four speakers who were asked to provide their perspectives on the donation physician role in their national systems. Following is a brief synopsis of these presentations and examples of key system features that emerged during discussions after the panel. For further details on international systems, see the Literature Review (Appendix E) and the International Survey (Appendix F).

United Kingdom

Dr. Dale Gardiner spoke on defining aspects of the United Kingdom's approach: donation is featured in all end-of-life pathways; it is considered a part of the core business of hospitals; and there is a 'clinical lead' (the title for donation physicians in the United Kingdom (UK)) in every hospital as well as supportive local donation teams. Clinical leads are supported by an independent UK-wide donation ethics committee. The government has published legal guidance for donation and a national DCD consensus statement is in place.

System Features

- While there has been an overall increase in donation in the UK, smaller hospitals without an in-hospital transplant team have been somewhat frustrated and we have tried to guide them towards tissue donation.
- Given the ethnic diversity in the UK, donation teams can interact with local faith leaders and the media to promote local issues – an important strength of the model. Diversity is not without its challenges: one third of the population is on the national donation register, with minorities making up a third of those on the waiting list. We need to make the most of every opportunity in addressing this long-term challenge.
- Donation teams have been in place in the UK since 2009, and we are just starting to hit our stride. We are identifying more donors and changing the culture. The UK model is also very cost effective at the moment.
- Key factors in our strong support for DCD have been the publication of legal guidance from government; the development of a national consensus statement on DCD; and our obligation to approach all people and explore donation with families.
- Having a donation chair as a non-executive member of the hospital board is pivotal to protecting the donation team and its funding.
- The critical care community has gone from support to advocacy, but local and regional doctors aren't there yet.

Spain

Dr. Xavier Guasch discussed the history, system changes, roles and definitions of the Spanish OTDT system. The Spanish model uses Transplant Coordinators (the title for donation physicians in Spain) in every accredited hospital with donor potentiality and has a high level of intensivists involvement in the system. Dr. Guasch also spoke about current issues such as ethical challenges (in particular

around controlled DCD); the rising age of Spanish donors; changing performance metrics; and fair physician compensation.

System Features

- The future for Spain is to have donation move from being a core function of the ICU to being one of the ED. While the logistics of this are difficult, it is how the situation will evolve in the future. In Spain, the emergency department calls the coordinator who is essential to the process. There are also conditional ICU admissions from the ED if families want to donate in severe brain injury cases.
- There has been a dramatic reduction in the incidence of brain death and Spain is accepting more and more older donors, while getting fewer organs per donor than ten years ago.
- The UK has more aggressive ICU withdrawal practices than Spain.
- Spain has a presumed consent law. Doctors and nurses work as a team when interviewing families. We try to explain to the donor family what the deceased wanted, but even with a signed donor card, we don't move forward with donation without family consent, as the media attention could be negative for the donation system.

United States (University of Pittsburgh Medical Centre–UPMC)

Dr. Raghavan Murugan described the UPMC donation program which is unique in that it does not involve a single payer model. At UPMC end-of-life care is independent of organ donation. OPO coordinators are the primary contacts with families: they meet and stay with the family, manage the conversation about donation and consent, and are present during the grieving process. Recently a small group of intensivists have become funded and more engaged in the donation process which has resulted in improved recovery rates. DCD donations include mandatory ethics consultations. The donation physician program in Pittsburgh is unique to UPMC and to their knowledge, does not exist elsewhere in the United States.

System Features

- Donors must be seen by an intensivist within 60 minutes of notification.
- Intensivists are compensated by billing or by nights on call. There is considerable financial pressure: profit and loss determine whether or not physicians keep their jobs: on the academic side, competition for grants determines salary; in the hospital, payment is based on the number of patients seen.
- Payment related to donation processes comes from the OPO and is a flat rate per donor. Payment is not dependent on the number of organs transplanted.
- Mandatory ethics consultations take place prior to all DCD procedures.

Australia

Dr. Gerry O'Callaghan took a high-level process approach when speaking about the Australian experience in designing and implementing a coordinated national system. Development of the Australian system design began with political engagement at the highest level – a factor which provided immediate, comprehensive, and sustained support for building and maintaining the strategy. Australia has paid a lot of attention to building a team-based system based on shared social values and has a strong, practical and accessible national ethical framework that works

well. This framework focuses on things like the pre-eminence of individual autonomy and respect for those who decide not to donate.

A team approach is essential to how the system functions: more attention is paid to improving clinical outcomes than to who does exactly what in the larger donation process.

System Features

- A key priority involves focusing on and supporting donor families, an ongoing challenge. Our surveys indicate that donor families experience high levels of gratitude and satisfaction as surrogate decision-makers and are very grateful for even modest support in relation to donation.
- A designated officer appointed by the hospital may speak with the family, but this person is not involved with patient care.
- Funding to hospitals for medical directors and specialist nurses is activity-based at the point of care in the ED, ICU or Operating Room (OR) for each designated step in the process.
- Public messaging to the clinical community (through branding and consistent themes) is as important as it is for the public.
- Canada and Australia have much in common in their health systems. If the CCCS commits to a guiding set of ethical principles, as was done in Australia, then the next step is to come to agreement at the national level on clearly defined functional priorities for the donation physician.
- A community of practice model supports system implementation and one important component is a national network of hospital staff.

Appendix E: Literature Review, Environmental Scan and Focused International Survey

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Introduction

Internationally, the growing disparity between the number of patients awaiting transplant and the availability of transplantable organs and tissues has been identified as a significant area of concern. Efforts to improve deceased donor donation rates have had variable degrees of success, with Spain widely recognized as a leader in the area. Despite efforts to improve the number of deceased donors in Canada, donation rates across the country have remained relatively stagnant.

One approach which has been employed in many regions is the introduction of a donation specialist program. These programs identify an individual, frequently a critical care physician, who acts as a champion for organ donation at a local level. This person may be involved with various aspects of donation, including the primary process from donor identification through organ and tissue procurement, as well as various administrative and educational activities. By identifying areas of need, the role of the organ donation specialist has been adapted to specifically address specific areas within deceased donation programs. Around the world, there is significant variation in the donation physician programs, including differences in funding, roles and responsibilities.

This document was commissioned by the Planning Committee for the 'Role of the Donation Physician in a Coordinated OTDT System' initiative (Whistler, February 21-22, 2011) sponsored by Canadian Blood Services in partnership with the Canadian Critical Care Society. It is provided as a background document to inform the consultation process with key stakeholders regarding the proposed OTDT system design recommendation to formalize donation physician roles in health care centres in Canada.

The first section of this document provides background information, as well as a review of several key components of donation physician programs, including program structure, roles and responsibilities, performance measures and quality assurance, education and training and funding. The second section provides information on outcomes, successes and lessons learned from existing programs is provided. In the final section, specific challenges to donation physician programs (ICU capacity and conflict of interest and the dual role of the donation physician) are explored.

Methods

A literature review, environmental scan and focused international survey have been used to prepare the document. The literature review provides an overview of the international experience with donation physicians highlighting key aspects of each program, and identifying areas of challenge, including ethical concerns. The existing peer review literature and published experiences in this field is extremely limited. The viewpoints of various critical care societies regarding the role of the critical care physician in deceased donation will be discussed. For the survey, representatives from Australia, Spain, the United Kingdom and the University of Pittsburgh Medical Center were asked to provide information about their programs

Literature Search Strategies

Searches of the bibliographic databases Medline, EMBase & Health star was performed using the OVID search engine. The terms "organ donation program" or "tissue donation program" were used initially. Additional searches were then performed using the terms "donation physician", "physician donation coordinator", "donation coordinator" and "clinical lead", both

alone, and in combination with the above results. The abstracts identified by these searches were reviewed, and those containing information relating to donation physician programs were selected for further review. Only English articles were used.

The bibliographies of the articles selected were reviewed, and used to identify additional articles relevant to the review. In addition, the primary authors of several of the articles were contacted to provide additional information about their work, as well as to provide information about non-English articles that were referenced in their papers.

Additional searches of the previously noted databases were performed using the terms 'organ donation' or 'tissue donation' in combination with 'medical ethics' or 'ethics'.

Finally, a third set of searches was performed using the terms 'organ donation' or 'tissue donation' and 'palliative care'.

Environmental Scan

As part of the environmental scan, a review of critical care and medical society websites in Canada, the US, Europe and Australia was conducted. In addition, donation-related websites in Canada, the US, Europe and Australia were also reviewed. Additional data was collected from documents provided by donation physician programs in Spain, Australia, Pittsburgh and the UK. Finally, data from previous international consultation interviews completed by Canadian blood services was included. This data was used to supplement the formal literature search described above.

Focused International Survey

An informal survey was prepared based on a series of questions generated during planning committee process and from a review of the available literature. The questions were organized into a series of topics, which form a basis for discussions at the upcoming meeting. The survey topics were used to create the headings and subheadings for this document. The survey was administered via email to four donation physician leaders in Spain, the UK, Australia and the US (at the University of Pittsburgh Medical Center). All surveys were completed and returned. Results of the survey were reviewed, clarified and collated. **Unless otherwise indicated, information in this review is from survey data.**

Section I: Background Information and Donation Physician Program Components

THE HISTORY OF DONATION PHYSICIAN PROGRAMS

The donation physician is a relatively new concept, having been introduced within the last five to ten years in most regions. The country of Spain has the longest experience with donation physicians, having had a program since 1989³.

In general, donation physician programs have been introduced in parallel with other initiatives aiming to improve the deceased organ and tissue donation process and performance. An

³ Matesanz, R., & Dominguez-Gil, B. (2007). Strategies to optimize deceased organ donation. *Transplantation Reviews*, 21, 177-188.

important exception to this is the University of Pittsburgh Medical Centre, where a donation physician program providing 24/7 coverage has been in place since 2008. No other interventions were made when the program was introduced, creating an ideal setting for analyzing the specific effects of this program. Examples of initiatives which have accompanied the introduction of donation physicians include developing national organ and tissue donation systems, expansion of donation coordinator (non-physician) programs and increased training of individuals involved with various aspects of the donation process.

Universally, a shortage of organs and tissues for donation has been the driving force behind these initiatives. Specific reasons for introducing the physician donation specialist role cited in our survey include missed opportunities for donation after cardiac death, missed opportunities for donation due to non-optimal donor management, missed opportunities for donation after neurologic determination of death and high rates of failure to consent to donation.

Overall, it was felt that having a physician uniquely involved in the donation process was the best way to address these specific issues, which may have been sub optimally addressed by other interventions.

The donation physician is frequently a local figurehead, offering unique expertise to a hospital or region. In regions where many changes were initiated together, a key role of the donation physician specialist was to translate the recommendations from national guidelines on donation to a local level (Clinical Taskforce on Organ and Tissue Donation, 2008).^{4,5} In this way, the donation physician is reported to be essential in the translation of other donation-related initiatives to the local level.

DONATION PHYSICIAN PROGRAM STRUCTURE

Hiring & Reporting

As with most other clinical medical specialties, the donation physicians reports to senior managers or leaders within the hospital – typically the hospital medical director, and in some cases the head of the critical care unit. In the setting of national donation programs (e.g. Spain, Australia), the donation physician also reports to administration at the regional level. In the UK, the lack of a formal supervisor of donation physicians has led to additional discussion about how best to supervise the role. In a positive sense, the relative independence from a national donation agency might encourage the physician to develop innovative local programs, and may reduce concerns about conflict of interest. However, in a negative sense, it may be difficult to identify underperformance of the donation specialist without the involvement of an external supervisor.

⁴ Clinical Taskforce on Organ and Tissue Donation. (2008). *National Clinical Taskforce on Organ and Tissue Donation - Final Report*. Commonwealth of Australia.

⁵ Organ Donation Task Force. (2008). Job Description: Clinical Champion for Organ Donation. United Kingdom: National Health Service Blood and Transplant.

In the programs surveyed, hiring is carried out by some combination of regional bodies, hospital medical directors and critical care unit directors.

Distribution of Donation Physicians

Various methods have been used to distribute donation physician throughout hospital systems. Both donor volume and geography are used to optimize distribution.

Spain

In Spain, there is a donation physician positioned in any public hospital capable of managing a donor.⁴ Private hospitals do not typically manage donors, but may be affiliated with a public hospital that has a donation physician, as well as the capability to take over care should a potential donor be identified. The arrangement in Spain has likely been facilitated by the relatively high number of physicians in Spain, and may also be affected by the relatively low physician wage (which would be expected to reduce the cost of the donation physician program).⁶ In countries where this is not the case, other methods have been used to determine the distribution of physician donation specialists.

UK

In the UK, a potential donor audit has been ongoing since 2003. This audit provides data on the donation potential within a region, and has been used to determine the amount of funded donation specialist time, as well as the number of funded nurse donation coordinators, for each geographical area. Allocation is as indicated in table 1.

Table 1 Allocation of UK Donation Physicians and Nurse Donation Coordinators

Regional (Trust) Ranking	Donation Potential	Donation physician Funded Time (per week)	Funded Nurse Donation Coordinators
Level 1	> 10	4 – 8 hours	2
Level 2	5 – 10	4 hours	1
Level 3	< 5	4 hours	0.5 - 1

This method attempts to ensure that each geographical area has both physician and nurse representation, theoretically providing an appropriate level of support for all regions.

Australia

The distribution of donation physicians in Australia matches its population distribution. In larger centres, individual hospitals have their own donation physicians. In less populous regions, a local clinical champion (hospital-based nurse donation coordinator) is supported by a donation physician who works with several hospitals within the region.

⁶ Matesanz R. Factors influencing the adaptation of the Spanish model of organ donation. *Transpl Int* (2003):16:736-741.

University of Pittsburgh Medical Centre

This program provides coverage for the hospitals which are part of the University of Pittsburgh Medical Centre program. Consultation may be provided to other centres, but no formal arrangements are present.

Base Medical Specialty

In all programs reviewed in the international survey, the vast majority of donation physicians are critical care physicians. This represents a significant change from the past, where the majority of physicians involved with donation were nephrologists associated with renal transplant programs. Other areas of specialization include pulmonary medicine, nephrology, palliative care, emergency medicine and anaesthesiology. It is thought that critical care physicians are particularly well suited to the role of donation physician, as they work in an area that cares for potential donors, are trained in the use of life support and have ties throughout the hospital as part of their consultant practice.

Paediatric Donation Physician Programs

The literature search did not reveal any specific information relating to paediatric donation physicians. Many programs do include paediatric donors, but unique features of the paediatric donation physician are not described.

Our survey found that in Spain, donation physicians, and the donation team, may become involved with potential donors in the paediatric intensive care unit.

A similar arrangement occurs in the UK, where donation physicians are involved with paediatric and adult donation. In hospitals with larger paediatric intensive care units, a paediatric intensivist may be part of the donation committee. There are a few donation physicians with base practices in paediatric intensive care who play a significant role in the development of national recommendations for paediatric donation in the UK.

In Australia, larger children's hospitals have paediatric donation physicians. Within the national donation program, a special interest working group led by paediatric critical care physician who is a donation physician has been created.

The University of Pittsburgh Medical Center program is not involved with paediatric donors.

ROLES AND RESPONSIBILITIES OF THE DONATION PHYSICIAN

The donation physician role varies significantly from program to program. In some cases, the specialist plays a front line role in the donation process, while in others, the role is more consultant-based, and to some extent administrative. In all cases, the role is strongly integrated with other aspects of the donation program, particularly with nurse donation coordinators.

Primary Roles and Interaction with Nurse Donation Coordinators

The donation physician works closely with (nurse) donation coordinators in all settings described. Their specific roles vary, but both are seen to be essential to providing comprehensive full time coverage for the donation process. For this reason, the two roles, and their relationship will be discussed together in this section

Spain

The Spanish model uses the donation physician on the front line of donor management. Spain is unique as, prior the introduction of their program, physicians (typically nephrologists) held this role, alongside their traditional clinical roles. In other locations, this role has usually been held by non-physician donation coordinators. Currently, the donation physician is responsible for donor detection, evaluation, family interviewing and consent, retrieval logistics and communication with the national allocating office. In addition, the donation physician supervises donor management and brain death diagnosis, as well as providing training for critical care staff, and other hospital personnel.⁷

In Spain, nurse donation coordinators are part of the donation team, under the direction of the donation physician. They rotate call with the physician, providing 24-7 coverage for donation, and can carry out the many of the same primary roles as the donation physician.

United Kingdom

The UK used a slightly different approach in developing their donation physician program. In their design, the donation physician is tasked with promoting donation within the hospital through provision of knowledge, leadership, education and administrative guidance. They do not attend to every donor. The original description of the donation physician role did not involve any clinical care, but as some local programs have matured, clinical care has occasionally become part of the donation physician's role. The donation physician works closely with nurse donation coordinators, providing guidance and support for the donation coordinators frontline management. He is also a member of the regional donation committee, whose functions include promoting the national recommendations for donation.⁸ The donation physician also works with organ and tissue retrieval teams to optimize the donation process. Clinical oversight of performance reports and audits are provided by the physician donation specialist. Finally, they are involved with local education and training for all staff likely to be involved with donor care.^{9,10}

In the UK, the nurse donation coordinator is directly involved with all donors and their families. They take on the visible role relating to donation in the hospital, with an active presence in

⁷ Matesanz R, Dominguez-Gil B. Strategies to optimize deceased organ donation. *Trans Rev.* 21 (2007). 177-188.

⁸ National Health Service Blood and Transplant. Donation Committee – Information for Donation Committee Chairs.

⁹ Murphy PG and Logan L. Clinical leads for organ donation: making it happen in hospitals. *JICS* (2009):10(30); 175-178

¹⁰ Organ Donation Task Force. (2008). Job Description: Clinical Champion for Organ Donation. United Kingdom: National Health Service Blood and Transplant.

critical units and emergency rooms. They also provide on call coverage. In addition to their clinical role, they are involved with education and system audits.^{11,12}

University of Pittsburgh Medical Centre

In the UPMC program, there are seven donation physicians who rotate coverage for approximately 170 intensive care beds. In this program, the donation physician also plays a front line role. He or she directs donor management, carries out donor assessments (i.e. bronchoscopy) and communicates their assessment with transplant surgeons. Donation coordinators are also involved with every donor. They carry out interactions with the family, including interviewing, obtaining consent and providing family support. The donation coordinator is also responsible for retrieval logistics.

Australia

In Australia, the individual donation process frequently does not involve physicians or nurses that are part of the national donation program. Instead, this role is carried out by coordinators from the organ procurement organization. The donation physicians and associated hospital-based nurses are instead involved with promoting donation in the hospital, educating hospital staff, data collection and reporting and development of the donation system. As the donation physician program has become more established, there has been an increase in the clinical role the donation physician, particularly in the setting of donation after cardiac death.

Consent Discussions

In the UK, the Assessment of Collaborative Requesting (ACRE) study assessed the impact of a collaborative approach (donation coordinator, along with the treating team) versus a traditional approach (families are approached by the treating team only) on consent to donate rates in the UK. This trial included 201 families. It did not show a significant difference in consent rates between the groups. Reported consent rates were consistent with previously reported rates.¹³ In contrast, data from the US¹⁴ as well as Ontario¹⁵, suggest that family approach by the donation coordinator improves consent rates as compared to the traditional approach. Refusal rates have decreased in Spain following the introduction of the Spanish model.¹⁶

There is no national data available on donation consent rates in Canada.

¹¹ Organ Donation Task Force. (2008). Person Specification: Specialist Nurse - Organ Donation. United Kingdom: National Health Service Blood and Transplant.

¹² Organ Donation Task Force. (2008). Job Description: Specialist Nurse - Organ Donation. United Kingdom: National Health Service Blood and Transplant.

¹³ The ACRE Trial Collaborators. (2009). Effect of "collaborative requesting" on consent rate for organ donation: randomised controlled trial (ACRE trial). *British Medical Journal*, b3911.

¹⁴ Williams, M., Lipsett, P., Rushton, C., Grochowski, E., Berkowitz, I., Mann, S., et al. (2003). The physician's role in discussing organ donation with families. *Critical Care Medicine*, 31 (5), 1568-1573.

¹⁵ Trillium Gift of Life Network. (2008). *The Use of Quality Improvement Methods to Incorporate Organ Donation as Part of Routine End-of-Life Care and Increase Organ Donation Rates in Ontario*. Centre for Healthcare Quality Improvement.

¹⁶ Matesanz, R., & Dominguez-Gil, B. (2007). Strategies to optimize deceased organ donation. *Transplantation Reviews*, 21, 177-188.

Role in Tissue Donation

There is considerable variability in the level of involvement with tissue donation between the different programs. In the UK and Pittsburgh, tissue donation is not listed as part of the donation physician's role. Instead, the nurse donation coordinator takes the lead in tissue donation. Spain differs in that the specialist is involved equally with both tissue and organ donation. In Australia, tissue donation is also part of the donation physician's role, although a formal audit process for this aspect of the donation program has not yet been established.

Involvement in Donation-Based Research

The majority of donation physician programs are involved in research, although this is not a primary mandate for any of them. Spain has been particularly active, and has published a significant amount on the subject. The Australian donation program has provided funding to the Clinical Trials Group of the Australian and New Zealand Intensive Care Society for donation related research, making use of this group's existing structure for academic research.

Links with Palliative Care and Bereavement

Palliative care teams could potentially be involved with controlled donation after cardiac death donors. The palliative care team can provide guidance during withdrawal of life sustaining therapy, and can also take over care if the patient survives for more than 90 minutes after withdrawal of life sustaining therapy. At this time, there are no descriptions of formal relationships between donation physician programs and palliative care programs in the literature, although the potential for such a relationship has been described.¹⁷

Bereavement support is provided through a number of means. In general, family support is initially provided by members of the donation team – either the donation coordinator or the donation physician – during the family interview. Families are then linked to external bereavement resources.

CRITICAL CARE SOCIETY PERSPECTIVES & THE DONATION PHYSICIAN ROLE

Many critical care societies have developed position statements or policies related to donation in the critical care unit. As most donation physicians are critical care physicians, the views of these societies on donation physicians can provide helpful insights into the donation physician's role within the critical care culture.

Spain

The Sociedad Española de Medicina Intensiva, Crítica y Unidades Coronarias (Spanish Society of Intensive Care Medicine, Critical and Coronary Units; SEMICYUC) supports organ and tissue donation in its code of ethics, specifically describing donor detection, assessment for brain death, obtaining consent for donation, family support, donor maintenance in addition to caring for pre- and post-operative transplant patients as part of the critical physicians duties. Finally,

¹⁷ Kelson et al. Palliative care consultation in the process of organ donation after cardiac death. *J Pall Med* (2007);10(1): 2007; 118-126.

the SEMICYUC code of ethics pledges ongoing support to the organ and tissue donation program in Spain. Thus the society supports the role of the donation physician in the critical care unit.¹⁸

United Kingdom

In the United Kingdom, the Intensive Care Society has endorsed a consensus document with recommendations on controlled donation after cardiac death. These recommendations outline the role of the intensivist in the management of potential DCD donors. There are no recommendations on the role of the intensivist as a donation physician. While support for the donation process is present in the society, recommendations around the donation physician program in the UK are still under development.

United States

The Society of Critical Care Medicine (SCCM), through its consultative body, the American College of Critical Care Medicine, includes deceased donation in its consensus statement for end-of-life care in the intensive care unit. Organ and tissue donation is described as an integral part of end-of-life decisions and bereavement practices, and the practice of routinely requesting donation is advised. The statement also recognizes that “critical care professionals are responsible for the integrity of the organ donation process in collaboration with the organ procurement organization.” Specific training for individuals involved in the process is recommended. The role of the donation physician is not specifically addressed by the SCCM.¹⁹

Australia

The Australian and New Zealand Intensive Care Society (ANZICS) published the most recent edition of their statement on death and organ donation in 2010. This document addresses the responsibilities of the critical care physician throughout the donation process. While the donation physician is not explicitly identified in the document, ANZICS recommends that “Intensivists must accept responsibility for leadership in organ and tissue donation because they, with other members of the intensive care team, care for dying patients and their families in the ICU, and donation occurs in this end-of-life context. Leadership and support for donation may also extend outside of the ICU.”²⁰

Canada

In 2001, members of the Canadian Critical Care Society produced the CCCS Position Paper on Organ and Tissue Donation.²¹ The paper recognized that management of the potential donor is the responsibility of the critical care specialist in Canada. In addition, it recognized that Canadian critical care specialists play an important role in the development, implementation and evaluation of processes aiming to increase donation rates. Further, the society recommended

¹⁸ Sociedad Española de Medicina Intensiva, Crítica y Unidades Coronarias. Código Ético. 2005.

¹⁹ Truog RD et al. Recommendations for end-of-life care in the intensive care unit: A consensus statement by the American College of Critical Care Medicine. *Crit Care Med* (2008);36(3):953-963.

²⁰ Australian and New Zealand Intensive Care Society. (2010). *The ANZICS Statement on Death and Organ Donation (Edition 3.1)*. Melbourne: ANZICS.

²¹ Canadian Critical Care Society. (2001). CCCS Position Paper on Organ and Tissue Donation. *Organ and Tissue Donation Workshop*, (pp. 1-13). Lake Louise.

that members of the society participate in and/or lead local, provincial and national initiatives to increase organ and tissue donation rates in Canada.

PERFORMANCE MEASURES, TARGETS AND QUALITY ASSURANCE

In the programs surveyed, in-house evaluation (typically in the form of audits that monitor variable such as the number of potential brain dead donors, the number of consented donors and the conversion rate for consented donors), is performed by the regional donation team, including the donation physician. In Spain, the UK and Australia, collecting and analyzing this data is part of the role of the donation physician.

External audits, usually performed by regional donation agencies, provide external validation of internal assessments. In addition, historical audits are used to monitor donation trends from year to year. The UK, Australia and Spain all have national registry programs which collect the data required to perform an external audit. At this time, only Spain regularly performs these external audits for the purpose of quality assurance.

None of the programs surveyed reported incremental funding attached to performance targets.

EDUCATION AND TRAINING

Donation Physician Training

United Kingdom

In the UK, training for donation physicians, as well as non-clinical leads (non-physicians who work with donation physicians and nurse donation coordinators as part of the regional donation committee), is provided through a professional development program created by an external management organization (Deloitte) hired the National Health Service Blood and Transplant. This professional development program was first delivered in 2010, with sessions held from January through November.²² The components of this program are listed in Appendix 2.

This program was attended by 96% of donation physicians in UK hospitals. It was well received, and has received recognition by several agencies for its innovative educational approach. Survey feedback indicated that working with an external agency to develop the program was more successful, and cost effective, than originally anticipated. Plans are underway to create continuing medical education programs, as well as to continue to provide this training program to newly appointed donation physicians.

Several modifications were made to the program throughout its inaugural run. The regional peer consulting group session was abandoned, as it was felt this duplicated the role of the hospital donation committee. Instead, regional collaboration (between different programs) is being developed, and a regional clinical lead position is being introduced.

²² Deloitte. (2009). NHS Blood & Transplant: Professional Development Programme for Organ Donation. National Health Service.

Spain

Training for donation physicians in Spain has been developed by a group called Transplant Procurement Management, with the support of the Institute for Life Long Learning at the University of Barcelona and the European Training Program on Organ Donation.²³ This group offers an International Masters in Organs, Tissues and Cells Donation and Transplantation, with certification through the University of Barcelona. The educational objectives are to provide health care professionals with the tools and resources to support their work in donation, and to facilitate the translation of knowledge into practice. This is achieved through the year-long curriculum that is described in Appendix 2.

Representatives from various countries have participated in this training and education program since its inception in 1991.²⁴

Continuing medical education is also provided to Spanish donation physicians. This focuses on family interviews, media relations and program administration and management.

University of Pittsburgh Medical Center

Donation physicians at the University of Pittsburgh medical centre do not receive any formal training, beyond their medical specialty training. The physicians involved with this program had pre-existing experience with aspects of donor care such as assessing for brain death and donor management. As these specialists do not play a large role in family interviews, consent, etc., training in these areas may be less applicable.

Australia

Donation physicians participate in a local orientation program which covers legal and operational processes, an introduction to tissue typing, a discussion of transplantation outcomes and medical suitability and a review of the local referral process. Team building activities and an introduction to the Donatelifelife network are also part of this program. In addition, there is a one day program which introduces the donation physician to the National System, including national policy, funding and reporting arrangements. Recent scientific advances in donation, as well as updates on donation data, are also discussed during this program

Trainee Education

Donation related education in the programs surveyed is limited. Spanish critical care trainees participate in a three day training course on donation sponsored by the Spanish Intensive Care Society and the national transplantation agency. Australian trainees participate in the Australasian Donor Awareness Program (ADAPT)²⁵, a medical module which includes training on determination of brain death, donor management and the process of donation, including DCD.

²³ Paredes, D., Valero, R., Navarro, A., Miranda, B., Viedma, M., Cabrer, C., et al. (1999). Transplant procurement management: A training tool to increase donation. *Transplantation Proceedings*, 31, 2610-2611.

²⁴ Transplant Procurement Management. (n.d.). *Transplant Procurement Management*. Retrieved November 2009, from <http://www.tpm.org>

²⁵ Australian Government Organ and Tissue Authority. (n.d.). *The Australian Donor Awareness Program (ADAPT)*. Retrieved November 2010, from Donatelifelife: <http://www.donatelifelife.gov.au/The-Authority/Education/ADAPT.html>

Other medical staff, including nurses and other allied health professionals are also eligible to participate in the ADAPT course.

Trainees in the UK and the US do not typically receive additional training beyond exposure during on-service rotations.

FUNDING

Source of Funds

Among countries with donation physician programs, most are funded by national government, usually indirectly through ministry of health or equivalent agencies. Funds are designated for donation activities, and then allocated to the donation physician program using various approaches as discussed below. The University of Pittsburgh Medical centre is funded through an alternative method - from the organ procurement organization, as well as the hospital.

Duration of Funding

According to survey data, the Spanish program has indefinite funding, based on historical success. The Australian and UK programs have upcoming reviews, but based on survey responses both are likely to receive ongoing and potentially increased funding based on their positive results.

Allocation of Funds

The allocation of funds to the donation physician program may be tied to program performance. In Pittsburg, donation physicians are paid a fixed amount for each donor that they manage. Similarly, in Spain, program funding is based on potential and actual donors, tissues donated and organs donated. These programs differ from the British and Australian programs, which provide funding that is guaranteed independent of performance. In Spain, unlike the UK and Australia, funding allocation to donation physicians varies from region to region, and is determined by the individual regional health authority.

In the UK and Australia, donation physicians receive a portion of full time physician wages, determined by the number of hours of service that they provide. As previously outlined, donation physicians in Spain and Pittsburg receive funding based on their consented donor rates, rather than as a portion of full time wages.

Performance based funding, while providing an incentive for maintaining a successful program, and providing graded reimbursement for workload, may have limitations. Firstly, the use of incentives in organ and tissue donation is often discouraged, due to concerns about real or perceived conflict of interest by those involved with the process. Secondly, in smaller centres, this type of funding may reduce financial support, potentially to levels too low to maintain a donation physician program.²⁶ This consequence is likely to be more important in regions with

²⁶ Matesanz R. Factors influencing the adaptation of the Spanish model of organ donation. *Transpl Int* (2003):16:736-741.

hospital that see only a small number of potential donors each year, as would be expected in some parts of Canada.

Incremental Funding

None of the programs surveyed reported funding that was dependant on meeting performance targets. There are also no descriptions of this type of funding in the literature.

Section II: Outcomes, Successes and Lessons Learned

OUTCOMES AND SUCCESSES

Uniformly, based on survey responses and the existing literature (discussed below), programs that have implemented a donation physician program have reported an improvement in deceased organ and tissue donation rates. While not always directly attributable to the introduction of the program in isolation, the consistent results suggest that the intervention has been effective. Interestingly, the area of improvement varies from program to program, likely reflecting differences in the donation physician's role, along with other changes in the program.

Spain

In Spain, the donation physician program, along with the other changes introduced as part of the Spanish Model, has been associated with an improvement in donation rates to levels consistently above 32 donors per million people (pmp).²⁷ This increase is primarily due to an increase in donation after neurological death. This increase has been maintained despite a slight decrease in the overall number of patients who meet the criteria for neurological death.²⁸ The remainder of the increase is due to an increase in uncontrolled donation after cardiac death. Controlled donation after cardiac death is not performed in Spain.

The marked improvement in the Spanish donation rate following NDD is likely partially due to improved identification of potential NDD donors, and partially due to increased consent rates. Indeed, the family consent rate for potential donors in Spain rose to 84% in 2009.

Tissue donation rates have also increased in Spain since the introduction of the Spanish Model.²⁹

Italy

The Tuscany region of Italy has applied the Spanish model, including a donation physician program, to its deceased donation program. Prior to applying the model, the region identified

²⁷ Organizacion Nacional de Trasplantes. (2010). Annual Report. Retrieved January 15, 2011, from Organizacion Nacional de Trasplantes: <http://www.ont.es>

²⁸ Rodriguez-Arias, D., Wright, L., & Paredes, D. (2010). Success factors and ethical challenges of the Spanish Model of organ donation. *Lancet*, 376, 1109-1112.

²⁹ Navarro, A., Cabrer, C., De Cabo, F., Paredes, D., Valero, R., & Manyalich, M. (1999). Importance of the transplant coordinator in tissue donor detection. *Transplantation Proceedings*, 31, 2606.

significant variation in the rate of identification of potential NDD donors. Using this as a key role for their donation physicians, the region has seen a significant increase in donation rates.³⁰

Greece & Turkey

The Spanish model for donation physician has also been introduced in Greece³¹ and Turkey³². Both have reported an improvement in donation rates following the introduction of their donation physician programs.

United Kingdom

Since beginning to implement the changes recommended by the 2008 taskforce report, the UK has had a 28% increase in the rate of deceased donation, from 12.9 pmp in 2007 to 16.4 pmp in 2010. The most significant increase in deceased donors has been in the DCD group (a 17% increase from 2009 to 2010). The number of NDD donors increased by 2%. This mimics the pattern from 2007 to 2008, and from 2008 to 2009, in which an increase in DCD has been responsible for the majority of the overall increase in deceased donor rates. Possible explanations for the lack of increase in the rate of NDD donors include a reduction in the potential donor pool, due to improved prevention and management of neurological catastrophies, optimal donor participation prior to implementation of changes or ongoing ineffective interventions.³³

In an effort to identify problems in the NDD donation process, the UK carried out a potential donor audit (PDA) from April 2007 through March 2009. This showed a conversion rate of 51% (from potential NDD donors to actual donors). From this analysis, consent emerged as the most significant barrier to donation, with overall consent rates of 63%. This analysis was made during the period of implementation of the task force recommendations, but there were not significant differences in consent rates between the first and second years.³⁴

Other successes reported by the UK include the development of a donation tool for the Map of Medicine, an online tool for health professionals and the public. This tool outlines the process used for NDD donation and controlled DCD.

University of Pittsburgh Medical Center

A before and after observational study was performed comparing organ yield (utilization) from consecutive donors (both DCD and NDD donors). The organ yield from NDD donors increased significantly (OR 1.4, $p = 0.0082$) when the program switched from intensivist led donation to

³⁰ Bozzi, G., Matesanz, R., Saviozzi, A., & Rossi Ferrini, P. (2004). Summary: The quality improvement program in organ donation of the Tuscany Region. *Transplantation Proceedings*, 36, 424-425.

³¹ Karatzas, T., Menoudakou, G., Chatzixiros, E., Kyrkou, B., Maleskou, S., & Kostakis, A. (2007). Improving the organ transplantation program in Greece: Institution of local transplant coordinators' network. *Transplant Proceedings*, 39, 793-796.

³² Yucetin, L., Kececioglu, N., Akaydin, M., & Ersoy, F. (2004). The solution to organ shortage in Turkey: Trained transplant coordinators. *Transplantation Proceedings*, 36, 24-25.

³³ National Health Service Blood and Transplant. (2010). *Transplant Activity in the UK. Activity Report 2009/10*. National Health Service.

³⁴ National Health Service Blood and Transplant. (2009). *Potential Donor Audit*. National Health Service.

the donation physician program.³⁵ The program’s survey response described an increase in both DCD as well as NDD donation, although NDD remains the primary type of donation.

Australia

In 2010, there were 309 deceased donations in Australia, a 25.1% increase over 2009, a 51% increase over a historical baseline (using the previous nine years). This works out to a donation rate of 13.8 pmp, increased from a previous high of 12.1 pmp in 2008. While the majority of deceased donors are NDD donors, there has been a steady increase in the number of DCD donors in Australia since 2005.³⁶

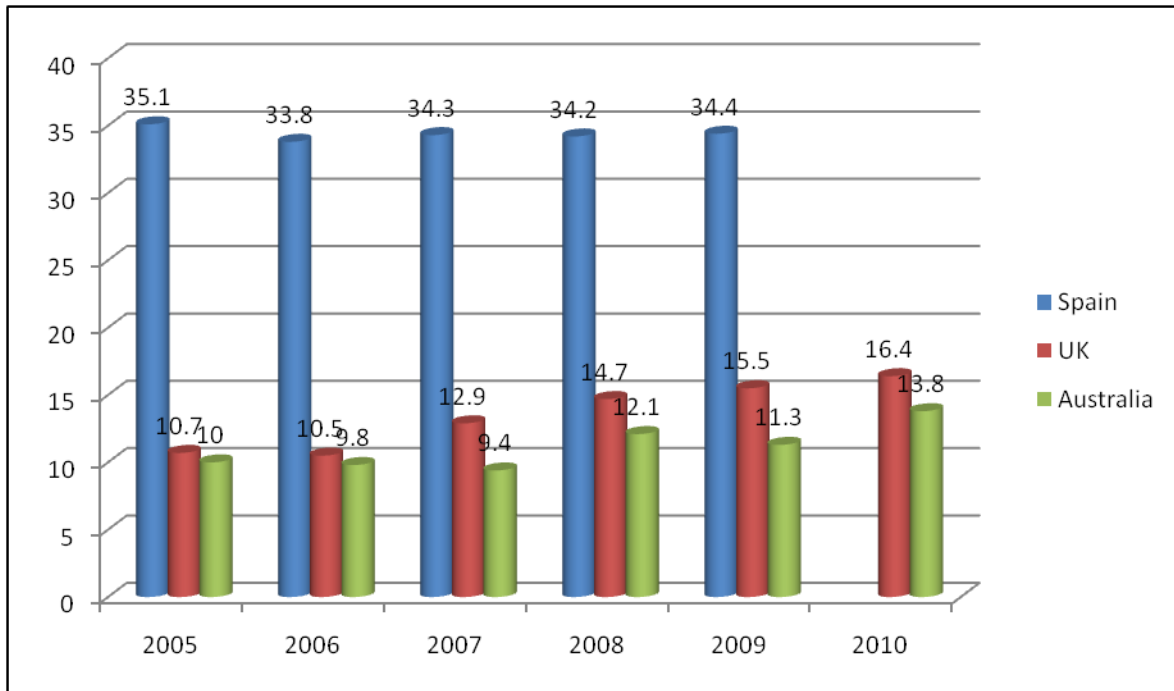


Figure 1 Annual Deceased Donor Rate (pmp)³⁷

LESSONS LEARNED

The international survey asked respondents to provide information about anything that they would do differently if they were starting their program over, as well as to describe any

³⁵ Singbartl, K., Crippen, D., Kaynar, A., Murugan, R., Tisherman, S., Shutterly, K., et al. (2010). Intensivist-led donor management increases organ yield from brain-dead donors. Pittsburgh, Pennsylvania, United States of America.

³⁶ Excell, L., Hee, K., & Russ, G. (2010). *ANZOD Registry Report 2010*. Adelaide: Australia and New Zealand Organ Donation Registry. The data reported here have been supplied by the Australia and New Zealand Organ Donation Registry. The interpretation and reporting of these data are the responsibility of the Authors and in no way should be seen as an official policy or interpretation of the Australia and New Zealand Organ Donation Registry.

³⁷ Data from ANZOD registry reports (2005 – 2010), IRODat registry reports (2005 – 2009) and international survey.

challenges that they faced during the establishment of their program. The following summarizes their responses.

Things to Do Differently

- Ensure that greater resources and adequate numbers of individuals are available to lead the training program for donation physicians and oversee the recruitment and development of donation physicians as well other members of the donation team
- Keep established nurse donation coordinators informed as to their roles in the new program.
- Consider creating regional donation physicians, who can provide support for local donation specialists
- Ensure that a performance framework for donation is in place in order to hold donation physicians (and their teams) accountable for their activities
- Identify future educational needs and goal for donation physicians and other members of the donation team earlier in the process
- Increase the emphasis on tissue donation throughout the process
- Ensure professional bodies are kept up to date and involved with the program activities

Challenges

- Working with donation physicians across regions with different laws and administrations
- Working with donation physicians from a large geographical area, creating challenges with communication
- Lack of an electronic forum for communication with donation physicians, as well as providing them with a location for idea sharing and collaboration
- Higher than predicted turnover at a central government level, affecting the capacity and continuity of particular projects
- Addressing competency challenges faced by donation physicians

Section III: Ethical Challenges & Relationship with Medical Ethics

ICU CAPACITY

In Canada, critical care services are considered a limited resource. It is widely recognized that there is a limited capacity to support additional patients in our current system.³⁸ An recent Ontario study reported 8.7 mechanically ventilated beds and 14.9 critical care beds per 100 000 people, and suggested that even with an 80% predicted capacity, the province will need an additional 810 ventilated beds by 2016.³⁹

Organ donors require special care, the type of care which is generally only offered in the critical care environment. Thus ICU capacity must be considered when expansion of the donation program is being sought.

³⁸ Adhikari, N., Fowler, R., Bhagwanjee, S., & Rubenfeld, G. (2010). Critical care and the global burden of critical illness in adults. *Lancet*, 376 (9749), 1339-1346.

³⁹ Hill, A., Fan, E., Stewart, T., Sibbald, W., Nauenberg, E., Lawless, B., et al. (2009). Critical care services in Ontario: a survey-based assessment of current and future resource needs. *Canadian Journal of Anaesthesia*, 56 (4), 291-297.

In Spain, where the number of ICU beds per population has historically been significantly higher than in most European countries, ICU capacity was not a concern in the development of the Spanish Model. Authors analyzing the Spanish Model have suggested that the availability of ICU beds may be a key factor in the model's success.⁴⁰ In Adhikari's (2010) review, Spain is described as having fewer ICU beds per population than Canada, however our survey documents a higher ICU capacity in Spain (8.2/100 000).

Both the UK and Australia have lower numbers of ICU beds per 100 000 people (3.5 beds in the UK; 7.6 beds in Australia) and fewer physicians per 100 000 people than Spain. Their ICU occupancy approaches 80 - 90%. The UK taskforce recognized that caring for potential and actual donors might represent a financial disincentive for the hospital, and recommended set funding for consented donors. Further to this, hospitals in the UK now receive £2055 for each consented donor that they care for.⁴¹ A similar type of funding is provided for potential donors in Australia. In both cases, these funds are used at the discretion of the hospital to cover the costs associated with caring for potential donors, as well to develop donation related activities in the hospital.

Besides funding, physical space and staffing also contribute to limited ICU capacity. Designated staff, who have training in donor management, are currently used in many centers in an attempt to reduce general critical care staffing demands. Since many of these individuals are primarily employed in the ICU, it is difficult to identify if they truly alleviate staffing concerns, and no objective data is available.

Overall existing programs seem to have absorbed increased donor numbers without major modifications to their ICU capacity. Indeed, one survey response indicated "we always seem to find room", and no program describes a formal mechanism to permit accommodation of donors in the at-capacity ICU. It is also unclear if donors who are admitted from outside the ICU for management (e.g. from the emergency room) are considered separately from donors who are identified in the ICU, and receive their management in the same location. It is possible that externally identified donors would be a more significant concern with respect to capacity, although both would affect overall ICU admission numbers.

It is unclear whether, or to what extent, hospital reimbursement for donor care, as in the Australian and UK models, contributes to creating a sustainable program or addresses ICU and OR capacity limitations. In Canada, some provinces have hospital reimbursement programs for donor care. It is unclear if these programs have an impact on ICU or capacity for donor care.

POTENTIAL CONFLICTS OF INTEREST AND DUAL ROLES

The potential for real or perceived conflicts of interest associated with the dual role of the donation physician has been recognized as an area of challenge for the role. Concerns have

⁴⁰ Matesanz R. Factors influencing the adaptation of the Spanish model of organ donation. *Transpl Int* (2003);16:736-741.

⁴¹ National Health Service Blood and Transplant. (2008, August 14). Appendix 1 - Additional Information. *Letter to Trust/NHS Board Chief Executives*. Watford, Hertfordshire.

been raised that public perception of the dual role may adversely affect the donation experience, creating mistrust, and ultimately reduce donation rates.

A review of the Spanish model recognized that with the current arrangement, such a conflict is unavoidable, and recommends disclosure to prevent these conflicts from causing harm.⁴² In practice, Spanish donation physicians do not participate in declaration of death (neurologic determination of death) if they are the patient's attending physician. They can, however, participate in the rest of the donation process. The results of our survey indicated that the dual role is not a significant area of concern in the Spanish Program.

In contrast, the issue conflict of interest related to the dual role of donation physician has created significant controversy in the UK. Members of the Intensive Care Society, which represents intensive care professionals in the UK, have expressed concern about perceived conflict of interest for those working both as a critical care consultant, and as donation physicians.⁴³ The society has not yet published a formal recommendation on this issue.

The UK Donation Ethics Committee, which is part of the Academy of Medical Royal Colleges, has published a consultation document on donation after cardiac death which addresses the issue of the dual role of a physician during DCD. Specifically, their recommendations are:

1. Two doctors, one of whom should be a consultant, should independently verify that further active treatment is no longer in the patient's best interests...
2. If organ donation has been identified as part of the end of life care pathway for a patient, then caring for that patient during the dying process in such a way as to maintain the organs in the best possible condition for donation does not represent a conflict of interest on the part of the treating clinician. Because it is considered to be in the patient's best interests to become a donor, interventions to facilitate this are likely to reflect those interests unless they may cause harm or distress or risk causing harm or distress.
3. The Specialist Nurse for Organ Donation [nurse donation coordinator] should not care for the potential donor whilst they are still alive
4. Members of the retrieval team and the recipient's clinical team should not be involved in the care of the potential donor. There should, however, be effective liaison and communication between the retrieval team and those caring for the potential donor in order to ensure that the interests of the patient as a potential donor are maintained at all times.
5. After death, the potential conflict of interest between saving the life of the patient and respecting their interest to be an organ donor disappears. Once the decision to accept the organs has been taken, it is in the best interests of the deceased patient for procedures such a re-intubation ... to be carried out by a suitably trained individual. Thus, although this professional may have been a member of the donor's clinical team prior to death, this no longer represents a conflict of interest.
6. Some actions carried out after death to facilitate donation ... carry a theoretical risk of re-starting the heart. An appropriately trained member of the staff, not part of the

⁴² Rodriguez-Arias, D., Wright, L., Paredes, D. (2010): Success factors and ethical challenges of the Spanish Model of organ donation. *Lancet*, 376, 1109-1112.

⁴³ Wright, J., Ridley, S., & Morgan, G. (2010). Letters to the Editor. *Journal of the Intensive Care Society*, 11 (3), 206.

retrieval team, should re-confirm cardiac standstill if necessary before the retrieval operation commences.⁴⁴

As previously described, donation physicians in the UK do not directly care for donors, and as such, individual donations can proceed without the involvement of the donation physician. If a potential donor is present when the specialist is functioning as critical care consultant, the physician continues to function in their role as a critical care consultant, and donation can proceed without their direct involvement in the process. This prevents the physician from holding a dual role for the individual patient.

An additional challenge inherent to the UK program is that the donation physician is recognized as a donation expert, regardless of his/her current role (e.g. attending intensivist). This may generate perceptions of conflict from staff and public who feel that the physician cannot separate the two roles. In these situations, it has been recommended that disclosure and open discussion of the conflict is the best way to prevent harm.⁴⁵

In Australia, critical care physicians have historically cared for their patients who become donors throughout the donation process, alongside representatives from organ procurement organizations. Thus the dual role has been the normal situation. Physicians may function both as critical care attendings and donation physicians at the same time.

The reforms to Australia's donation system have introduced a separation between the roles of end-of-life care by the intensivist, and donor management by members of the donation team. Some physicians did not feel that this separation was necessary, while others supported the initiative, identifying its potential as an additional resource in terms of capacity and expertise. Since the programs introduction, it has been noted that the separation of roles has been particularly helpful in the DCD process, as it is often more time intensive than the process of NDD donation.

The survey response from Pittsburgh did not report any issues relating to conflict of interest and the dual role. Donation physicians may function as both the donation physician and the intensivist at the same time, as long as they are not covering the intensive care unit which cares for peri-operative transplant patients.

RELATIONSHIP WITH MEDICAL ETHICS PROGRAMS

In Pittsburgh, there is a mandatory ethics consultation for all potential controlled DCD donors, creating a strong link to the local medical ethics program. The UK typically includes a medical ethics representative on their regional donation committees, and involves a medical ethics representative in individual cases as required. Spain also involves medical ethics representatives on an as needed basis.

⁴⁴ UK Donation Ethics Committee. (2011, January). *An ethical framework for controlled donation after circulatory death*. Retrieved January 2011, from UK Donation Ethics Committee - Academy of Medical Royal Colleges: <http://www.aomrc.org.uk/donations-ethics-committee.html>

⁴⁵ Rodriguez-Arias, D., Wright, L., & Paredes, D. (2010). Success factors and ethical challenges of the Spanish Model of organ donation. *Lancet*, 376, 1109-1112.

Summary & Conclusions

Experiences with physician donation programs as described in this review have been universally positive. Each of the surveyed programs, as well as those identified in the literature, have reported an increase in their deceased donation rate following the introduction of their donation physician program. The available data supports the hypothesis that the involvement of a local physician dedicated to the donation process leads to improvement in the deceased donation system.

Several key points are identified from the available data:

Donation Physician Program Structure

- Donation physicians are a key part of the local donation structure within a larger national framework designed to improve deceased donation rates.
- All programs have a physician assigned to all hospitals in their system. Physicians may be responsible for more than one hospital, particularly in less populous areas.
- Most donation physicians are critical care physicians.
- Paediatric donation physician programs are still under development, but are an important part of donation programs at paediatric hospitals

Roles and Responsibilities of the Donation Physician

- Depending on the program, the primary role of the donation physician is either to provide primary care for donors, or to act as an advisor and advocate for deceased donation.
- The interaction between donation physicians and nurse donation coordinators is an important part of successful programs.
- Overall, the role of the donation physician in tissue donation has been under-represented in the development of donation physician programs.
- Research is part of most programs, often in association with pre-existing critical care research networks.

Performance Measures, Targets and Quality Assurance

- Ongoing hospital audits are used to monitor the effectiveness of donation physician programs. These audits are carried out both internally, by members of the local donation physician program and externally by regional and national donation agencies.

Education and Training

- Most programs have a training program for new donation physicians. Those that do not rely on either prior experience, or send new donation physicians to participate in an existing training program at another site.
- Continuing education for donation specialist is under development in most programs.

Funding

- National government provides funding for donation physician specialist programs in most cases.
- Funding allocation for donation physicians may be based on performance (Pittsburgh, Spain) or independent of performance (UK, Australia). When funding is independent of performance, it is based on estimated number of donors and expected hours of work of the donation physician.
- No programs use funding that is dependent on meeting performance targets.

Ethical Challenges

Ethical challenges, particularly relating the dual role of the donation physician, have been encountered by existing programs. Policies and recommendations of national critical care societies, as well as other national policies supporting the role of the donation physician, have been a helpful approach to managing perceived conflict due to the dual role. Despite this, the dual role remains an ongoing area of challenge to the donation physician role.

In the programs surveyed, ensuring adequate critical care capacity has not been specifically addressed by the donation physician programs. Some programs provide hospital funding for each potential deceased donor, but this is to offset the cost of donor management, rather than address capacity related issues. The potential impact of additional deceased donors on Canadian critical care capacity is difficult to assess.

In summary, there is considerable variability in features and approaches between donation physician programs. In selecting features best suited for a Canadian program, various characteristics such as geography, population distribution and local donation culture must be considered.

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Appendix 1 – Description of Training Programs

UK PROFESSIONAL DEVELOPMENT PROGRAM FOR DONATION PHYSICIANS AND NON-CLINICAL LEADS: ORIGINAL PROGRAM COMPONENTS

National Launch Event

Non-heart beating donation
Law
Fundamentals of leading change

Master Class 1

Diagnosis of death
Regional peer consulting group launch

Master Class 2

Donor management and physiology
Emergency Medicine
Making change happen

Master Class 3

Consent/Authorization
Donor simulation & Pediatrics
Regional peer consulting groups
National Review Event

SPANISH INTERNATIONAL MASTERS IN ORGANS, TISSUES AND CELLS DONATION AND TRANSPLANTATION PROGRAM COMPONENTS

Online Modules

- Donor detection systems
- Brain death diagnosis
- Training for trainers
- Donor management and organ viability
- Family approach for organ donation
- Organ retrieval organization, preservation and allocation criteria

In-Person Sessions

- Professional training on organ donation (2 days)
- Managers training on organ donation (2 days)
- Training for trainers (2 days)

Internship

4 weeks spent with a tutor in a hospital centre in Italy, Spain or the US

Appendix F: International Survey Responses

A focused international survey was developed and administered by Dr. Shavaun Macdonald and the Planning Committee to support development of background documentation for the Donation Physician consultation. The survey was conducted December 2010 to February 2011. We are grateful to the international experts and respondents, representing their jurisdictions: Dr. Gerry O’Callaghan (Australia), Dr. Dale Gardiner (United Kingdom), Dr. Raghaven Murugan (University of Pittsburgh Medical Center), Dr. Xavier Guasch (Spain). The following are verbatim responses to the questions.

HISTORY	
When was the donation physician role implemented in your country?	
Australia	Employment of donation specialist nurses and physicians commenced mid 2009 and was completed early 2010 nationally. We have approx. 160 staff in 74 hospitals with FTE allocated as determined by local health authority and largely related to hospital size.
United Kingdom	In 2008, following the publication of the Government sponsored Organ Donor Taskforce Report http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_082120.pdf
US (Univ. of Pittsburgh Medical Center)	The U.S. does not have a donation physician at every hospital. However, we have a dedicated group of 7 Intensivists at the University of Pittsburgh Medical Center who are on call 24/7 for organ donation, servicing approximately 170 adult ICU beds in several hospitals. This system has been in place since 2008.
Spain	In 1989
Were other changes to the deceased donation system introduced during the same period (e.g. change in consent regime, public awareness, consent registries etc)? If so, please briefly describe these changes.	
Australia	During this time we have had a major public awareness campaign starting in May 2010, “DonateLife. Discuss it today, OK?” with TV, radio and print coverage. We also developed a brand and website during the period from July and Oct 2009 and have continued to increase the information available to the public (www.donatelife.gov.au). Our donation register, the Australian Organ Donor Register was consolidated as a consent register from 2005 and provides regular demographic data to the Organ and Tissue Authority. A National Protocol for Donation after Cardiac Death was developed during this period and published in July 2010.
United	All 14 recommendations by the Organ Donor Taskforce (ODTF) were accepted by

Kingdom	<p>all four health administrations in the UK.</p> <ol style="list-style-type: none"> 1. A UK-wide Organ Donation Organisation should be established. 2. The establishment of the Organ Donation Organisation should be the responsibility of NHSBT [National Health Service Blood and Transplant]. 3. Urgent attention is required to resolve outstanding legal, ethical and professional issues in order to ensure that all clinicians are supported and are able to work within a clear and unambiguous framework of good practice. Additionally, an independent UK-wide Donation Ethics Group should be established. 4. All parts of the NHS must embrace organ donation as a usual, not an unusual event. Local policies, constructed around national guidelines, should be put in place. Discussions about donation should be part of all end-of-life care when appropriate. Each Trust [large hospital or group of geographically linked 2-3 hospitals] should have an identified clinical donation champion [now called Clinical Lead for Organ Donation or CLOD] and a Trust donation committee to help achieve this. 5. Minimum notification criteria for potential organ donors should be introduced on a UK-wide basis. These criteria should be reviewed after 12 months in the light of evidence of their effect, and the comparative impact of more detailed criteria should also be assessed. 6. Donation activity in all Trusts should be monitored. Rates of potential donor identification, referral, approach to the family and consent to donation should be reported. The Trust donation committee should report to the Trust Board through the clinical governance process and the medical director, and the reports should be part of the assessment of Trusts through the relevant healthcare regulator. Benchmark data from other Trusts should be made available for comparison. 7. Brain stem death testing (BSD) should be carried out in all patients where BSD is a likely diagnosis, even if organ donation is an unlikely outcome. 8. Financial disincentives to Trusts facilitating donation should be removed through the development and introduction of appropriate reimbursement. 9. The current network of DTCs [Donation Transplant Coordinators, now called Specialist Nurses for Organ Donation or SN-OD; equivalent to US nurse organ procurement officers] should be expanded and strengthened through central employment by a UK-wide Organ Donation Organisation. Additional coordinators, embedded within critical care areas, should be employed to ensure a comprehensive, highly skilled, specialised and robust service. There should be a close and defined collaboration between DTCs, clinical staff and Trust donation champions. Electronic on-line donor registration and organ offering systems should be developed. 10. A UK-wide network of dedicated organ retrieval teams should be established to ensure timely, high-quality organ removal from all heartbeating and non-heart beating donors. The Organ Donation Organisation should be responsible for commissioning the retrieval teams and for audit and performance management. 11. All clinical staff likely to be involved in the treatment of potential organ donors should receive mandatory training in the principles of donation. There should
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	<p>also be regular update training.</p> <p>12.Appropriate ways should be identified of personally and publicly recognising individual organ donors, where desired. These approaches may include national memorials, local initiatives and personal follow-up to donor families.</p> <p>13.There is an urgent requirement to identify and implement the most effective methods through which organ donation and the ‘gift of life’ can be promoted to the general public, and specifically to the BME [Black and Minority Ethnic] population. Research should be commissioned through Department of Health research and development funding.</p> <p>14.The Department of Health and the Ministry of Justice should develop formal guidelines for coroners concerning organ donation.</p>
US (UPMC)	No.
Spain	Both the Spanish national agency responsible for Donation and Transplantation (Organizacion Nacional de Trasplantes) and the Coordinators network started in 1989
<p>Prior to implementation of the donation physician program, who was typically responsible for the primary donation process (i.e. identification, assessment, family discussion, overseeing donor management, etc)?</p>	
Australia	Donor identification, management and the family consent conversation were the sole responsibility of the intensive care physician. Once in principle consent had been obtained from family members, referral to the Donation agency was initiated and Donor Coordinators attended the hospital and formally complete Donation Consent and Confidential Donor Data paperwork and then manage the donation, offer and provide family support.
United Kingdom	<p>The vast majority of donation was from intensive care.</p> <p>Identification: Intensive Care Consultant and Intensive Care Bedside Nurse</p> <p>Assessment: Specialist Nurse for Organ Donation would assess both over the phone and in person the potential for donation. It was often the case that the Specialist Nurse for Organ Donation was not called until after the family discussion and agreement for donation had been given by the family. Only then would full patient assessment proceed.</p> <p>Family Discussion: Intensive Care Consultant [It was routine to contact the Specialist Nurse for Organ Donation only if the family agreed for donation. Occasionally the Specialist Nurse for Organ Donation was contacted prior to family approach if the Intensive Care Consultant wished to access the National Organ Donor Register but this was entirely at the discretion of the Intensive Care Consultant].</p> <p>Overseeing donor management: The Specialist Nurse for Organ Donation would lead in donor management in collaboration with the Intensive Care Consultant</p>
US (UPMC)	Organ procurement organization’s coordinator.
Spain	Mainly nephrologists in transplant centers


Prior to implementation of your donation physician program, what was the most recent annual deceased donation rate (donor per million people) in your country?	
Australia	The current program began in 2009. In 2010, the Australian population had 13.8 donors per million people. This exceeds the 2008 (12.2 dpmp), 2009 (11.3 dpmp) and the 9 year baseline average (10.2 dpmp).
United Kingdom	12.9 pmp in April 2006 – April 2007 13.4 pmp in April 2007 – April 2008 (the ODTF report was launched in January 2008 and it quoted the 2006-2007 rate, as it was on the back of this rate the Taskforce was commissioned by the government to investigate ways to improve donation) I would use the figure 12.9 pmp for the purposes of this survey.
US (UPMC)	Not sure.
Spain	In 1989, 14.3 donors pmp (there is no reliable information from previous years)
What is your current annual deceased donation rate?	
Australia	13.8 dpm, increased from the 9 year baseline average (10.2 dpmp).
United Kingdom	15.5 pmp in April 2009 – April 2010 16.4 pmp in calendar year 2010 (resulting in a landmark 1014 deceased donations, a 28% increase in deceased donation since the beginning of calendar year 2008) http://www.organdonation.nhs.uk/ukt/newsroom/news_releases/article.jsp?releaseId=260 I would use 16.4pmp for the purposes of this survey.
US (UPMC)	3 organs per donor.
Spain	In 2009, 34.5 donors pmp
Why was a donation physician program implemented? (For example, what problem were you trying to fix?)	
Australia	Low donation rate
United Kingdom	The UK had one of the lowest organ donation rates in Europe and compared to the USA. It was in recognition of this that the Organ Donation Taskforce was established, at the request of the UK Government. The Organ Donor Taskforce felt that International experience – particularly of the Spanish model – demonstrated the value of the formal appointment of clinical ‘champions’ – typically consultant-level clinicians responsible for ensuring that all opportunities for donation are realized. It was recommended that champions were appointed in every acute Trust that treats potential donors. Clinical champions should be employed for 4–12 hours per week, depending on the size and donor potential of the Trust, and be responsible for developing and

	implementing local policies to maximize donation, ensuring that all appropriate staff receive necessary training, and reporting donation activity to the Trust donation committee (see below). This model called for every champion to be partnered to a specialist nurse for organ donation embedded into their local intensive care unit and also partnered to a non-clinical donation champion, perhaps a patient or well-known local figure, chairing a donation committee accountable to the Trust Board. The Trust's chief executive and medical director should be responsible for the Trust's donation performance. (page 37 of the ODTF report and elsewhere)
US (UPMC)	We had issues with loss of donors due to cardiac arrest, non-procurement of organs due to poor physiology and organ loss.
Spain	To increase cadaveric donation and to expand the availability of organs other than kidney

FUNDING

Who provides funding for your donation physician program (e.g. government, transplant agency, organ procurement agency, hospital, critical care department)?

Australia	<p>Funding for the current program is predominantly from our federal or commonwealth government which pays the salaries of almost all of the organ donor coordinators, nurses and physicians who have responsibility for the clinical service at a hospital or agency level.</p> <p>Funding for eye and tissue or the transplantation programs is provided by state governments who fund the public hospital system.</p>
United Kingdom	<p>Direct funding Clinical leads for organ donation (Donation physicians) are appointed by each individual Trust. A Trust is an acute hospital or group of 2-3 acute hospitals. The Trust is reimbursed 4-12 hours / week at the consultant's usual salary by NHSBT (National Health Service Blood and Transplant) for the clinical lead's activity. NHSBT is a Specialist Health Authority. Their funding is from the government but they are an 'Arms Length Body' also known as a quango, which means the government does not directly interfere with their internal management. Specialist Nurses for Organ Donation (SN-ODs, US equivalent nurse organ procurement officer) are employed and funded directly by NHSBT but are based (embedded) into each Trust.</p> <p>Indirect funding Each Trust is reimbursed £2055 for every consented donor. That is once consent is taken from the family, by the specialist nurse for organ donation, the Trust receives this money whether or not donation proceeds. This is particularly important in Donation after Circulatory Death, where conversion is not a high percentage of consents, yet the Trust has mobilised substantial resources of staff and facilities to attempt the donation. This is considered reimbursement and funding for the purposes of reimbursing clinical costs and the intention is that the donation monies are used to support future donation activity. It is not regarded as payment to the hospital for donation.</p>

US (UPMC)	Organ procurement organization provides a fee to the physician as well as the department for managing each individual donor.																																
Spain	The regional governments (Spain is divided in 17 autonomous regions)																																
Is this funding guaranteed indefinitely, or has it been provided for a fixed period of time?																																	
Australia	Funding is provided over a 4 year period until mid 2012																																
United Kingdom	<p>The Organ Donor Taskforce (ODTF) outlined a plan to have a 50% increase donation by 2013. A substantial increase in funding (Grant in Aid by the National Specialist Commissioning Advisory Group – the NSCG oversees the national commissioning of highly specialized services) was made available to implement the ODTF recommendations.</p> <p>This funding and the future national strategic direction will be fully reviewed in 2013.</p> <p>Organ Donation was given a £41.0m investment over the 2008/11 period attributable to phased revenue expenditure to commence the programme of work to deliver those recommendations of the ODTF.</p> <p>In more detail see below; taken from: http://www.nhsbt.nhs.uk/about/strategy/nhsbt_strategic_plan_2008_11.pdf</p> <div style="text-align: right;">  </div> <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th>Organ Donation Planned Initiatives</th> <th>2008/09</th> <th>2009/10</th> <th>2010/11</th> </tr> </thead> <tbody> <tr> <td>• OD1: Implement clinical "Donor Champions", Organ Donation Committees and effective performance management (ODTF 4&6)</td> <td>£0.6m</td> <td>£3.2m</td> <td>£4.0m</td> </tr> <tr> <td>• OD1: Implement financial reimbursement to all hospitals for the additional costs incurred when facilitating a potential or actual donor (ODTF 8)</td> <td>£2.4m</td> <td>£2.6m</td> <td>£3.0m</td> </tr> <tr> <td>• OD2: Implementation of a centrally employed Donor Transplant Co-ordinator network (ODTF 9)</td> <td>£1.9m</td> <td>£8.9m</td> <td>£12.8m</td> </tr> <tr> <td>• OD3: Implement nationally commissioned Organ Retrieval Teams (ODTF 10)</td> <td>£0.3m</td> <td>£9.7m</td> <td>£19.4m</td> </tr> <tr> <td>• OD5: Promote organ donation and identify appropriate methods of public recognition (ODTF 12&13)</td> <td>£1.0m</td> <td>£4.1m</td> <td>£0.4m</td> </tr> <tr> <td>• EA1: Establish a UK wide Organ Donor Organisation (ODTF 1&2)</td> <td>£1.5m</td> <td>£0.6m</td> <td>£0.7m</td> </tr> <tr> <td>TOTAL INVESTMENT</td> <td>£7.7m</td> <td>£29.1m</td> <td>£40.3m</td> </tr> </tbody> </table>	Organ Donation Planned Initiatives	2008/09	2009/10	2010/11	• OD1: Implement clinical "Donor Champions", Organ Donation Committees and effective performance management (ODTF 4&6)	£0.6m	£3.2m	£4.0m	• OD1: Implement financial reimbursement to all hospitals for the additional costs incurred when facilitating a potential or actual donor (ODTF 8)	£2.4m	£2.6m	£3.0m	• OD2: Implementation of a centrally employed Donor Transplant Co-ordinator network (ODTF 9)	£1.9m	£8.9m	£12.8m	• OD3: Implement nationally commissioned Organ Retrieval Teams (ODTF 10)	£0.3m	£9.7m	£19.4m	• OD5: Promote organ donation and identify appropriate methods of public recognition (ODTF 12&13)	£1.0m	£4.1m	£0.4m	• EA1: Establish a UK wide Organ Donor Organisation (ODTF 1&2)	£1.5m	£0.6m	£0.7m	TOTAL INVESTMENT	£7.7m	£29.1m	£40.3m
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US (UPMC)	As of now it is indefinite.																																
Spain	Indefinitely																																

Is funding linked to, or predicated on, performance? If yes, how is this done?	
Australia	No
United Kingdom	<p>Indirect Funding as given above.</p> <p>There is no direct funding per donor to the donation physician and as yet no direct governance structure to scrutinize each hospitals donation activity. The clinical lead for organ donation is responsible to the medical director at his/her hospital.</p> <p>Each donation committee reviews their local donation activity and the committee is accountable to the Trust Board through the usual governance procedures. The Trust's chief executive and medical director should be responsible for the Trust's donation performance but as yet there is no direct governance structure in place to ensure this.</p>
US (UPMC)	No. The funding is solely for the physician to see, evaluate, and provide critical care management of the organ donor.
Spain	The funding system is different in each region, but in general the payment is by donation activity (per donor or per organ and per piece of tissue).
What proportion of a full time salary does the donation specialist receive?	
Australia	The model varies in different states, there are some full time donation specialists but generally intensive care specialists split the salary between 1 to 3 individuals depending on the allocated FTE which is based on hospital size and is usually not less than 0.5 (approx 0.5 per 500 hospital beds. Smaller hospitals often have nurses with support from an adjacent physician.
United Kingdom	10%. A UK consultant's full time salary is usually 10 PAs (programmed activities) per week. One PA (4 hours / week) is the typical time funded for clinical lead activity.
US (UPMC)	We get a fixed amount of \$1000 per donor managed.
Spain	It would depend on the donation activity (organs and tissues) and the donation potentiality of the hospital. As an example in my region (Valencia), in a medium size hospital (around 500 beds, 25 ICU beds, Neurosurgery dept.) the donation physician receives a fixed amount representing 10% of a full time salary, but, the variable amount (linked to donation activity) could represent up to 50% the full time salary.
How much funded time is allocated to the donation physician position?	
Australia	Approx 0.5 FTE per 500 hospital beds
United Kingdom	As above, 90% of clinical leads are funded for 4 hours / week.
US (UPMC)	None.
Spain	Only in big transplant centers the donation specialist is full-time dedicated to donation. In all other cases is part-time but there is not an established time.
How were the number of specialists and amount of time dedicated to donation	

services determined?																	
Australia	On advice from state health departments based on analysis of hospital case mix and population distribution.																
United Kingdom	<p>The UK potential donor audit has been running since 2003. Using the potential donor audit every acute trust was ranked according to their donation potential. Roughly, since there are many exceptions based on local circumstances and geography, this forms the pattern of clinical leads for organ donation and the embedded specialist nurses for organ donation.</p> <table border="1"> <thead> <tr> <th>Trust Ranking A Trust is a large hospital or group of geographically linked 2-3 hospitals</th> <th>Donation Potential</th> <th>Clinical Lead Funded time</th> <th>Number of Specialist Nurses for Organ Donation embedded into the intensive care/s of each Trust</th> </tr> </thead> <tbody> <tr> <td>Level 1</td> <td>>10</td> <td>4-8 hours</td> <td>2</td> </tr> <tr> <td>Level 2</td> <td>5-10</td> <td>4 hours</td> <td>1</td> </tr> <tr> <td>Level 3</td> <td><5</td> <td>4 hours</td> <td>1 or shared with another small Level 3 hospital</td> </tr> </tbody> </table> <p>Typically this looks like:</p> <ul style="list-style-type: none"> • 90% clinical leads are on 4 hours per week • 10% clinical leads have 8 hours due to a national role e.g. - sit on Donation Advisory Group or have some specific project or geographical area to cover etc. All those on 8hrs are in larger Trusts based on more than 1 site with a neurological ICU. • 1-2 individuals on 12 hours / week 	Trust Ranking A Trust is a large hospital or group of geographically linked 2-3 hospitals	Donation Potential	Clinical Lead Funded time	Number of Specialist Nurses for Organ Donation embedded into the intensive care/s of each Trust	Level 1	>10	4-8 hours	2	Level 2	5-10	4 hours	1	Level 3	<5	4 hours	1 or shared with another small Level 3 hospital
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US (UPMC)	Our organ donor intensivist group consists of 7 intensivists who are interested in caring for the donors in our department. We don't have a specialized protected time for managing donors. We try to do it as a part of clinical service.																
Spain	There is a specialist in each hospital with donation potentiality. The official name is "Transplant Coordinator". In most cases a team will be created under the direction of this person, involving mainly nurses but also other doctors, on the basis on the activity. Those other people only get paid for the donation activity. Only in large transplant centers will be full-time dedicated nurses (as a rule, a nurse by each active transplant program). Some of the tasks associated with transplantation are also undertaken by this team.																
ICU CAPACITY																	
Please provide the following information (based on national or regional statistics) a. ICU beds / population b. ICU nurses / population c. Physicians / population d. ICU physicians / population e. Typical ICU occupancy rate																	
Australia	<p>The following data is from 2008, at which time the population of Australia was 21.4 million</p> <ol style="list-style-type: none"> 1,622 ICU beds funded and available i.e. 7.6 beds/100,000 pop. 8,975 nurses working in permanent/rostered positions within ICUs in Aus. based on actual hours worked equaling 6,967 full time equivalent nursing positions. 																

	<p>c. [no response]</p> <p>d. ICU physicians / population: 527.4 FTE of ICU consultant positions with 82% filled by qualified intensivists</p> <p>e. Median Occupancy (no. of bed days/available beds/365) was 72% (IQR 58%-84%, min 13%, max 116%) Predicted risk of death of ICU patients was 14% by APACHE III and 22% by APACHE II. Hospital mortality of ICU patients was 11.1%- 2.8% of patients were admitted to ICU with a treatment limitation order.</p>
United Kingdom	<p>a. If ICU is defined as staffed ventilator beds there are approximately 2200 in the United Kingdom giving 3.5 per 100,000 population, one of the lowest rates in the Western World. UK Population 62 million. Wales (population 3.0 million), Scotland (population 5.2 million) and Northern Ireland (1.8 million) and England (51.5 million).</p> <p>b. It takes approximately 7 nurses to staff one ICU bed for ventilation capacity. Therefore 25 per / 100,000 population as an approximation [for ventilator beds], as the exact number is unknown.</p> <p>c. 1 doctor for every 416- 440 population. http://www.bmj.com/content/336/7640/353.2.extract http://strangemaps.files.wordpress.com/2007/10/276540-poster594x420mm_eng.jpg</p> <p>d. Approximately 2000 consultants in the UK (the majority are anaesthetists who do not work exclusively in intensive care) 3.2 ICU physicians per 100,000 population. http://www.ficm.ac.uk/assets/pdf/the_cct/2011%20cct%20in%20icm%20part%20i%20-%20handbook%20(cd).pdf (page I-8)</p> <p>e. >87% if high dependency beds are taken into account. [personal communication President Intensive Care Society]. Most intensive care units in the UK have a mixture of intensive care and high dependency funded beds. An ICU occupancy rate of >85% would seem appropriate. My own intensive care is 100%. Figures greater than 100% are possible if more than one patient occupies a bed within the same 24 hour period.</p>
US (UPMC)	<p>a. We have approximately 170 ICU beds in our hospital system.</p> <p>b. Not sure.</p> <p>c. approximately 5000 in the UPMC health system</p> <p>d. approximately 60 intensivists in our hospital</p> <p>e. Virtually 100%.</p>
Spain	<p>a. Adult ICU beds (OECD 2005), National= 8.2 /100,000</p> <p>b. Adult & Pediatrics (Neonatal excluded) Province of Castellon (data 2010) = 9.1/100,000</p> <p>c. No National data</p> <p>d. Province of Castellon (data 2010): Nurses 19.5/100,000; Assistant Nurses 13.7/100,000</p> <p>e. National 3.65/1000 (OECD 2007)</p> <p>f. Province of Castellon (data 2010): 6.9 / 100,000</p> <p>g. 85%</p>

Does your program also include specific funding and support for capacity issues related to an increased number of donors? If so, what types of support were provided (physical bed space, nurse funding, etc).	
Australia	Yes ,we have a funding mechanism which allocates aliquots of funding up to a fixed ceiling per potential donor (whether or not donation proceeds) based on additional support provided in ED, ICU or OR to explore the possibility of donation, seek family consent, provide physiological support and progression to procurement surgery.
United Kingdom	No
US (UPMC)	No. We somehow always manage to have beds.
Spain	Most of the funding is based on activity. This facilitates to pay for extra personnel participating in the donation process.
Is there a specific mechanism or funding in place to permit you to accommodate donors in your ICU? (Examples: incremental funding, specifically funded donor bed, specific donor referral hospital, etc.)	
Australia	This funding is reconciled against hospital based audit mechanisms and applications for funding authorized by State Medical Directors for each region. The funds are provided to the cost centres within hospitals where the activity occurred and may be used for the purposes outlined above.
United Kingdom	No – nothing directly. From question 7: Each Trust is reimbursed £2055 for every consented donor. That is once consent is taken, from the family by the specialist nurse for organ donation, the Trust receives this money whether or not donation proceeds. This is particularly important in Donation after Circulatory Death, where conversion is not a high percentage of consents, yet the Trust has mobilised substantial resources of staff and facilities to attempt the donation. This is considered reimbursement and funding for the purposes of reimbursing clinical costs and the intention is that the donation monies are used to support future donation activity. It is not regarded as payment to the hospital for donation.
US (UPMC)	No.
Spain	No
DONATION PHYSICIAN SPECIALIST PROGRAM STRUCTURE	
Who is responsible for recruiting and hiring donation physicians?	
Australia	State Medical Directors and Health Departments in partnership with hospitals or regional structures. The National Organ and Tissue Donation and Transplantation Authority is responsible to Government for the discharge of public expenditure and so that the posts are occupied and the policy agenda implemented. Currently there are 160 hospital based staff in 76 hospitals occupying 94 FTE with an occupancy percentage of 96%. We also fund 86 Organ and Tissue Donation

	Agency Staff (mainly nurses with a small fraction of admin staff) occupying 58 FTE with an occupancy of 92%.			
United Kingdom	Each hospital Trust [large hospital or group of geographically linked 2-3 hospitals] using a generic job description. This is a local appointment and NHSBT (the organ donation organization in the UK), usually has no say in the appointment. In larger Trusts and where the clinical lead for organ donation is likely to receive more than 4 hours of funded time for their duties, a representative from NHSBT may have been at the interview.			
US (UPMC)	We have a team leader who is one of our intensivists who manages the program.			
Spain	The Regional government in agreement with Hospital and ICU directors			
<p>How are donation physicians distributed throughout your hospital system? Do all hospitals have a specialist, or do some specialists cover multiple hospitals? If the latter, how were hospitals identified to require donation physicians?</p>				
Australia	All donation specialists have senior nurse colleagues in organ and tissue donation in the same hospitals. Many physicians have responsibility for multiple hospitals as part of regional health care delivery structures			
United Kingdom	<p>From question 12 (repeated but developed further): The UK potential donor audit has been running since 2003 and every acute trust was ranked according to their donation potential. Roughly, since there are many exceptions based on local circumstances and geography, this forms the pattern of clinical leads for organ donation and the embedded specialist nurses for organ donation.</p>			
	Trust Ranking A Trust is a large hospital or group of geographically linked 2-3 hospitals	Donation Potential	Clinical Lead Funded time	Number of Specialist Nurses for Organ Donation embedded onto the intensive care/s of each Trust
	Level 1	>10	4-8 hours	2
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	<p>Another way of looking at this, which again is rough because there are many exceptions, is:</p> <p>4 hours / week Standard payment for all Trust Clinical Leads Additional Criteria for 8 hours / week Trust Clinical Lead for level 1 hospital (as defined above)with neurological specialty</p> <p>OR</p> <p>Trust Clinical Lead for an area where brainstem death donation potential is more than 20 per annum and NHB programme established.</p> <p>OR</p>			

	<p>Trust Clinical Lead for greater than 4 ICUs in one Trust As well as one of the following Chair/ Member of a National Donation Ethics Committee Chair/Member of NHSBT Donation Advisory Group Chair/Member of Scottish Transplant Group Chair/Member of Welsh Assembly Implementation Group Chair/Member of Irish Assembly Implementation Group Act as lead Donation Champion for a network of donation champions Taking on additional work for reasons such as a specific project agreed at time of interview.</p> <p>Additional Criteria for 12 hours / week</p> <p>Member of NHSBT Workstream 3</p> <p>OR</p> <p>Meets criteria for 8 hours / week As well as one of the following Chair/Member of more than 2 regional or national groups that relate to donation Trust Clinical Lead for an area where HB donation potential is more than 30 per annum and NHB programme established.</p> <p>Nationally this looks like:90% clinical leads are on 4 hours per week</p> <p>10% clinical leads have 8 hours due to a national role e.g. - sit on Donation Advisory Group or have some specific project or geographical area to cover etc. All those on 8hrs are in larger Trusts based on more than 1 site with a neurological ICU. 1-2 individuals on 12 hours / week</p> <p>The model is designed to have a clinical lead for organ donation in EVERY acute Trust in the UK. To date:</p> <ul style="list-style-type: none"> • 189 out of 191 (99%) Clinical Leads appointed • 156 out of 177 (89%) Donation Committee Chairs appointed • 166 out of 177 (94%) Donation Committees established <p>There is a higher number of clinical leads vs donation committees. In some Trusts, for local or geographical reasons, 2 clinical leads have been appointed (e.g. in one Trust an intensive care consultant and an orthopaedic consultant who leads on tissue donation have both been appointed as clinical leads each on 4 hours per week of funded time).</p> <p>Additionally a full-time Specialist-Nurse for Organ Donation (SN-OD) is embedded or in-house, in every Trust and covering that Trust’s intensive care units. In the smallest of Trusts, with the least donation potential, the SN-OD may be responsible for more than one Trust but usually no more than two.</p>
US (UPMC)	We only cover our hospital system. Other neighboring hospitals are planning to come up with similar programs.

Spain	All public funded hospitals with an ICU have a donation specialist. Very few private hospitals have a “true ICU” and donation potentiality. The most important ones have agreements with local public hospitals and in case they detect a potential donor, the donation team of the public hospital will be activated and assumes the donor. In most cases the donor is then transferred to the public hospital.
Are there geographical challenges for your program? If so, how are hospitals grouped within a region, and how are they serviced by the donation physician program?	
Australia	Australia like Canada is a vast country with uneven population distribution and great difficulty recruiting and retaining medical staff in regional centres. As a consequence it has very well developed mechanisms of patient referral for advice (such as telemedicine) and evacuation to large metropolitan centres. Some physicians and nurses in these large centres also support regional or remote hospitals with which their employing organization has a historical referral pathway related to tertiary services such as trauma, neuro or cardiothoracic surgery and paediatrics.
United Kingdom	Geographical challenges do exist particularly in the East of England, the south-west of England and in Scotland. The adopted model of appointing a clinical lead for organ donation in every acute Trust, even if that Trust has low donation potential, offsets some of these geographical challenges. More challenging is ensuring that specialist nurses for organ donation can satisfy the demands of being embedded on multiple and geographical dispersed intensive care units. Regional surgical retrieval teams have been established to overcome geographical barriers to retrieval but these are still substantial, especially in Northern Ireland.
US (UPMC)	We only cover our hospital.
Spain	The National Health Service is divided in 17 regions and each one autonomous. Donation and Transplantation, as part of the NHS depending on the region. The National organ sharing office policies seeks that the donor organ are transplanted in the same region, unless a patient needs the organ in urgency in other region. There are no major differences in donation rate between different regions.
How do you service referral or peripheral hospitals that are not university affiliated urban centers?	
Australia	The physician and senior nurses form the larger centres (often in coordination with an Organ Donor Coordinator from the State Agency), visit and provide education to staff at regional centres. They help these regional hospitals to develop policies and protocols to clearly identify a referral pathway for potential organ and tissue donors as well as identifying clinical champions who can help problem solve at a local level. These clinical champions are then included in state and national educational programs.
United Kingdom	As above

US (UPMC)	We consult over the telephone for nearby hospitals in our health system.
Spain	All public funded hospitals with an ICU have a donation specialist. In some regions a new figure, the Area Coordinator, which is a senior coordinator of a University Hospital, sets up a network with the coordinators of the peripheral hospitals of the area, mainly to guarantee logistical support for donor evaluation or for brain-death diagnosis.
Which base medical specialties are represented by your donation physicians? (Are they all intensive care physicians, or are other specialties also involved?)	
Australia	Over 90% of our physician group is intensive care specialists. The next largest group is ED physicians which we have selectively targeted in several of our very large tertiary referral centre with busy trauma programs. We have one or two anaesthetists, palliative care physicians and 1 nephrologist who no longer practices in a transplant program.
United Kingdom	90% Intensive Care/anaesthetics (including paediatric intensivists in appropriate hospitals) 10% Other: Emergency Medicine Consultants/Renal Physicians/Specialist Bereavement Nurses/orthopaedic surgeon/ ophthalmologist/respiratory physician
US (UPMC)	All intensive care physicians.
Spain	In 2008 80% were intensive care physicians, and the % is rising quickly.
ROLES & RESPONSIBILITIES	
Please provide a description of the donation physician role, if available.	
Australia	Please see Appendix A
United Kingdom	<p>The original title of clinical champion, probably best describes the role of the UK clinical lead for organ donation (donation physician). The role is to overcome local barriers to donation by promoting, leading, educating and providing expert knowledge and strategic guidance within the hospital, not to attend every donor or to provide clinical care to a donor. More officially the role is outlined below:</p> <p>JOB SUMMARY</p> <p>To provide clinical leadership within the Trust/hospital to raise the profile of organ donation; to maximise the local organ retrieval rates and to ensure the Trust implements the recommendations of the Organ Donation Task Force (ODTF) across the whole Trust, focusing particularly on critical care and emergency medicine.</p> <p>To champion the value of organ donation and to establish effective working relationships with key stakeholders throughout the Trust/hospital to promote organ donation.</p> <p>RESPONSIBILITIES</p> <ol style="list-style-type: none"> 1. To provide clinical leadership within the Trust/hospital on organ donation and to champion improvements in the way in which potential organ donors

	<p>are identified and organs are donated. In particular to focus on implementing the recommendations of the Organ Donation Taskforce Report including the performance of diagnosis of death by neurological criteria in all appropriate patients, the identification and referral of potential donors to the donor transplant network, and the consent process for organ donation.</p> <ol style="list-style-type: none"> 2. To identify and contribute to resolving local barriers to these actions. 3. To develop a close working relationship with the specialist nurse for organ donation, embedded into that hospital, and clearly define and articulate roles and responsibilities so that all relevant hospital staff are aware of the Taskforce recommendations and their implementation. 4. To be a source of knowledge regarding the ethical and legal aspects of organ donation and provide advice as required. 5. To ensure that all areas of the Trust/hospital where potential organ donors are treated have appropriate policies in place, developed in line with national policy and guidelines. 6. To contribute towards the establishment of a Trust Donation Committee and ensure that it functions effectively. 7. To provide clinical oversight of performance reports including suitable metrics to facilitate the monitoring of donor identification, referral and management. 8. To work with the regional organ retrieval teams to ensure optimal donor management. 9. To ensure the development of local educational and training opportunities for all staff likely to be involved with the care of a potential organ donor.
US (UPMC)	Brain death evaluation, manage hemodynamics, fluid resuscitation, bronchoscopy, discuss physiology with transplant surgeons etc.
Spain	Their main tasks are: donor detection, donor evaluation, family interview, communications with the national allocating office, Logistics of the retrieval and relation with the Judge / Coroner (in case of violent death). Also supervises donor management and brain-death diagnosis. The training of ICU staff (doctors and nurses) and other hospital personnel (i.e. Emergency, Neurology) are also under his responsibility.
Who do donation physicians report to? e.g. OPO?, hospital structure?, organ donation committee?	
Australia	The State Medical Director and the Divisional Head within their Hospital.
United Kingdom	Currently the clinical lead for organ donation is a Trust (hospital) appointment, since the clinical lead is not paid by the organ procurement organisation (NHSBT) but has their time reimbursed to the Trust. The clinical lead therefore reports locally to the Medical Director and the Trust Donation Committee. Governance would be provided by the Medical Director.
US (UPMC)	OPO
Spain	To the Hospital director and to the Regional transplant coordinator. There is an Organ & Tissue donation committee in the hospital where all the actors involved

	in the donation process are represented. The chairman of this committee is the donation physician.
What is their role regarding tissue donation, both within the ICU and outside the ICU?	
Australia	Tissue donation is certainly considered part of their remit and they are expected to report on the actual numbers of tissue donations in tissue-only donors and multiorgan donors in their hospitals. However an audit mechanism for the assessment of the potential for tissue donation in each hospital has not yet been developed and this process is at an early stage of development.
United Kingdom	This is an area of growing focus despite the donation physician having the title of clinical lead for ORGAN donation. Where there is a local corneal retrieval service, such nurses/practitioners often sit on the Donation Committee. The specialist nurses for organ donation are increasingly encouraged to take a greater role in tissue donation.
US (UPMC)	We do not deal much with tissue donation.
Spain	In theory the same as for organs, but for years tissue donation has been a secondary activity. In most hospitals it has been restricted mainly to brain-death organ donors or to living donors (umbilical cord blood, femoral heads). Now this is changing rapidly and DCD tissue donation is becoming the main daily activity in terms of numbers. This is causing an increase in the size of the donation teams (mainly nurses).
Are donor coordinators (non-physicians) part of your program? If yes, what are their respective roles in comparison with the donation physicians? Please provide a description of their role if possible.	
Australia	Please see Appendix A. Donation physicians and hospital based nurses may not always be involved in each donation episode depending on when it occurs so the primary responsibility for coordinating donation rests with the agency and the ODC's. The hospital based staff focus on preparing the hospital culture and education staff to support donation with education, data reporting and system development. Increasingly as the system is maturing, the hospital staff provide more clinical support to their colleagues - this is particularly the case in DCD.
United Kingdom	The specialist nurse for organ donation (non-physician donor coordinator) is the main face of organ donation in the hospital, particularly in intensive care and the emergency department. It is she (the vast majority are women), in collaboration with the duty intensive care consultant, who takes consent from the family, offers the organs to retrieval services and prepares the hospital for the arrival of the surgical retrieval teams. When not on-call and covering hospitals throughout the region, the specialist nurse for organ donation is, since 2008, embedded in one Trust (1-2 hospitals) intensive care units, such that she aims to become part of the intensive care team. When not directly dealing with a donor, she is involved in donor family follow-up, education and the Potential Donor Audit, which since 2003 has sought to evaluate all deaths on UK intensive care units (now expanded into emergency departments) to assess donation potential. In more detail the role is outlined below:

JOB SUMMARY

1. Responsible for promoting and facilitating the entire donation process by working in close conjunction with all staff in critical care areas to support and maximise organ/tissue donation.
2. Responsible for system building and working closely with identified individuals (particularly the clinical lead) in order to maintain a robust infrastructure to support and maximise donation. This includes analysis, planning, design, implementation, evaluation and continuance of educational and quality assurance programmes with all stakeholders within agreed and defined clinical area.
3. To provide support and appropriate information to families of those that are critically ill and the acutely bereaved, relating to end of life choices, specifically to include organ and tissue donation.
4. To ensure that donation proceeds in line with appropriate legislation and national policies and procedures.
5. Participate in the training and development of donation services team members
6. To obtain all relevant information enabling transplant centres and tissue establishments to assess the suitability of potential donors. This may include the requirement to negotiate further tests and investigations.
7. To maximise the placement of organs for transplant following the national offering sequence. This process will include assessment of the patient's clinical condition, implementation of donor management protocols, review of medical records and obtaining a history from the patient's General Practitioner.
8. Advise and support the clinical staff in the optimisation of organs for transplant through appropriate donor management.
9. Communicate with tissue establishments and refer tissue for retrieval in accordance with consent/authorisation obtained.
10. Collect and collate data for the Potential Donor Audit and any other audits within defined area of responsibility in a timely manner.
11. Facilitate and support education of health care professionals and the general public, in line with agreed service strategy.

PRINCIPAL RESPONSIBILITIES

1. Work in conjunction with the designated hospital clinical lead and others on the donation committee to ensure that trust/division donation activity is maximized in line with agreed key performance indicators.
2. Work in conjunction with the designated hospital clinical lead and others on the donation committee to ensure that robust and timely data is available to all relevant parties involved in monitoring donation performance against mutually agreed goals
3. Develop and maintain influential relationships with consultant anaesthetists, intensivists, nursing staff, retrieval teams and laboratory and mortuary staff at participating hospitals and with HM Coroner/Procurator Fiscal in the advancement of the organ/tissue donation process.

	<ol style="list-style-type: none"> 4. Establish and maintain effective lines of communication with transplant surgeons, recipient transplant coordinators, and other relevant staff in Transplant Units 5. Work in conjunction with clinical staff to develop and implement local policies (constructed around national policy) to maximise donation. 6. Provide expert on site advice to hospital and staff during donor cases. 7. Act as the designated expert within the hospital in relation to organ and tissue donation. 8. Maintain high visibility by conducting structured programme of hospital development. 9. Develop, provide and evaluate in-house training and in-service educational programmes on all aspects of donation for hospital staff. 10. Develop and deliver comprehensive evidence based hospital strategies to promote organ/tissue donation and evaluate effectiveness of strategies working closely with the team manager and regional managers. 11. Motivate senior clinicians through negotiation and influencing skills to maximize organ donation within the designated clinical area. 12. Provide education to healthcare professionals where required about the benefits of organ/tissue donation and transplantation. 13. Participate in on call rota to ensure that potential donor referrals are facilitated 24 hours a day, 365 days per year to ensure maximum quality and quantity of organs/tissues for the benefit of transplant recipients. 14. Receive all donor referrals within the donation area when on call; facilitate the organ/tissue donation process. 15. Ensure the safe transfer of the patient to theatre. 16. Maintain a presence in theatre to ensure continued coordination of the donation process. 17. Support the local staff and aid communication between local staff and visiting teams. 18. Undertake perfusion of the abdominal organs in line with responsibilities set out in the 'Role of the Coordinator in Abdominal Perfusion' protocol, as required. 19. Respond promptly and take any necessary action to emerging clinical information throughout the theatre donation process. 20. Dependent upon local services provided and in line with local business plan objectives, facilitate the referral of tissue from tissue only donors to tissue establishments. 21. Ensure every potential organ donation is attended in a timely manner following a referral 22. Provide clear and accurate information about the patient's prognosis and where appropriate diagnosis of death, consistent with that provided by the clinical staff responsible for the patient. 23. Ascertain the families understanding of the patient's prognosis and determine the most appropriate time to discuss the opportunity for donation with the family. Help the family to accept the prognosis and diagnosis of death as described by the patient's physician. 24. Communicate highly sensitive and complex information to bereaved families
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	<p>where there are barriers to understanding and acceptance, using a high level of communication skills due to the emotive atmosphere.</p> <p>25. Where there is self consent /authorisation work closely with the family to assist their understanding of this and to obtain any additional consent/authorisation required.</p> <p>26. Obtain consent / authorisation in line with legislation and all other relevant policies, ensuring that appropriate documentation is complete.</p> <p>27. Perform an on-site physical assessment of the donor, examine documentary evidence, and liaise with the Consultant medical staff and the General Practitioner, to ascertain suitability for organ/tissue donation.</p> <p>28. Work closely with the medical and nursing team(s) to initiate appropriate care, interventions and provide advice on the clinical management of the donor in accordance with local/national guidance, to optimize organ donation.</p> <p>29. Discuss with the family their wishes regarding seeing their relative after the donation operation and arrange to accompany the family or identify another appropriate individual to undertake this depending upon timings and workload.</p> <p>30. Establish and maintain cooperative relationships with all other members of the donating hospital and donation services team to ensure when clinical events occur, they run smoothly and allow for the best support for donor families.</p> <p>31. Ensure that the donor family, and the critical care staff are treated with respect and given information appropriate to their needs, in line with national standards 32 Act as advocate for the potential donor and donor family.</p> <p>32. Offer ongoing emotional support to all donor families during and after the process of donation.</p> <p>33. Inform by letter relevant donor hospital staff about the outcome of the donation process in line with national policy.</p> <p>34. Offer face-to-face feedback meetings to relevant hospital staff following the donation process. Identify and advise donor hospitals and donor families of bereavement services available locally and nationally.</p>
US (UPMC)	Yes. The Organ procurement coordinators make sure that the orders are implemented in a timely manner. They get consent, support the family, arrange OR timing and coordinate with surgeons and place organs.
Spain	Yes, nurses. They have the same tasks as the physician. They are part of a team, under the direction of the physician. There is a team member on call 24h a day. It could be either the physician or any of the nurses.
Are there formal links with bereavement / end of life / palliative care – if yes, please describe.	
Australia	No. Currently we have a Donor Family Support Program with an employed individual in each Agency to coordinate family support in each jurisdiction.
United Kingdom	There are no formal links but the majority of donation committees have representation from bereavement / end of life / palliative care. Additionally the clinical lead and specialist nurse aim to ensure donation is considered in any new

	guidelines developed locally touching on these areas.
US (UPMC)	Yes. For DCDs there is a mandatory ethics consult.
Spain	For DBD donors, during the family interview support is offered to the family (psychological, religious, administrative) About DCD, controlled DCD donation (Maastrich III type) has not take place in Spain, so no relation with palliative care. We only have uncontrolled DCD (Maastrich types I & II)
Has there been focus on donation-based research in your donation physician program? If yes, please describe. If no, why not?	
Australia	The National Program has identified academic seeding and support for donation based research as critical to supporting the implementation of the National Reform Agenda, to this end we have contributed funding to several projects concerned with the identification of barriers to donation in ED, the expertise of ICU physicians in predicting the time period after withdrawal of cardiorespiratory support and cessation of circulation to improve advice to families and colleagues when considering DCD and finally reasons for family refusal in Australia. These projects are being undertaken and supervised in different operational structures for DonateLife. Currently we are not sufficiently well established to provide a governance and quality control process for research and there are very well established pathways for this activity in Australian ICUs with a Clinical Trials Group with the Australian and New Zealand Intensive Care Society.
United Kingdom	No, not in any organized way. The priority since 2008 has been in embedding the specialist nurses for organ donation into intensive care units, appointing clinical leads for organ donation and establishing donation committees with appointed chairs. Any research is locally driven e.g. Nottingham is in the process of carrying out a Cochrane review into CT angiography for diagnosing brain death. Whilst not research, the Potential Donor Audit is a powerful tool to investigate donation activity locally, regionally and nationally and all hospitals take part in this. The data is collected and collated by the embedded local specialist nurse for organ donation.
US (UPMC)	Yes. we have several ongoing projects.
Spain	Donor management in DCD uncontrolled donors (ECMO) Public opinion and donation Impact of Training on donation
PERFORMANCE MEASURES, TARGETS & QUALITY ASSURANCE	
Is there a quality assurance process attached to the position? If yes, please describe. If no, why was this omitted?	
Australia	Although there are KPI's attached to each position description within the network and we report on activity and output we have yet to develop an analytical system and reporting process and recognize this as a priority for this year.

United Kingdom	<p>Not directly. Quality assurance for an individual organ donation is provided by the specialist nurse for organ donation, who falls under the governance structure of NHSBT and has an honorary contract with the hospital she is embedded in.</p> <p>The clinical lead for organ donation (donation physician) is a hospital appointment and not directly under NHSBT governance. Donation activity for that hospital and its comparison to the Potential Donor Audit and other hospitals, is provided by NHSBT regularly to the clinical lead for organ donation, the chair of the donation committee and the chief executive of that hospital.</p>
US (UPMC)	<p>We have a very informal way of monitoring any issues related to organ donation, DCDs etc and addressing issues as soon as they occur.</p>
Spain	<p>Yes, the Spanish Quality Assurance Program on Organ Donation. It's a registry of brain-deaths and causes of not becoming donors. Is managed by the donation physician and reported to the National Agency (ONT).</p>
<p>How do you measure the success of your donation physician program overall?</p> <p><i>a. Are there performance measures attached to the donation physician role? If yes, what are they?</i></p> <p><i>b. Who is responsible for performance assessment?</i></p> <p><i>c. Is there incremental funding attached to performance targets? If yes, please describe.</i></p>	
Australia	<p>The main current measures of success are the donation rates, consent and conversion rates and the percentage of DCD and referrals from new areas within hospital systems. This data is gathered from the Hospital Audit Process.</p> <p><i>a. Please see Appendix A.</i></p> <p><i>b. State Medical Directors</i></p> <p><i>c. No</i></p>
United Kingdom	<p>The creation of the clinical lead for organ donation (donation physician) was only one aspect of one Recommendation of the Organ Donor Taskforces 14 recommendations. The aim was to see a 50% increase in organ donation in five years. There has been a 28% increase in 3 years.</p> <p><i>a. No, not directly. The clinical lead is responsible to the medical director but only indirectly to the donation committee of their hospital and NHSBT. No clinical lead for organ donation has been removed, as of yet, for poor performance.</i></p> <p><i>b. The medical director of that hospital. NHSBT, through their governance of the specialist nurse for organ donation have a robust performance assessment, but have no direct influence over the hospital, the clinical lead or the donation committee and it's chair.</i></p> <p><i>c. No, as stated above there is Indirect funding only.</i></p> <p>Each Trust is reimbursed £2055 for every consented donor. That is once consent is taken, from the family by the specialist nurse for organ donation, the Trust receives this money whether or not donation proceeds. This is particularly important in Donation after Circulatory Death, where conversion is not a high percentage of consents, yet the Trust has mobilised substantial resources of staff and facilities to attempt the donation. This is considered</p>

	<p>reimbursement and funding for the purposes of reimbursing clinical costs and the intention is that the donation monies are used to support future donation activity. It is not regarded as payment to the hospital for donation.</p> <p>The lack of ‘control’ NHSBT has over clinical leads for organ donation (donation physician) is an area of concern within NHSBT for some and also within some donation committees where the clinical lead is felt to be less effective than they might be. This is an area in need of development. Perhaps the newly proposed role of regional clinical lead might address some of these issues.</p> <p>Alternately, a more direct governance by NHSBT of clinical leads might make them less effective in delivering cultural change to other clinicians and increase accusations of conflict of interest.</p> <p>Recommendation 6 of the Organ Donor Taskforce called for, “The Trust donation committee should report to the Trust Board through the clinical governance process and the medical director, and the reports should be part of the assessment of Trusts through the relevant healthcare regulator.” This assessment structure for a hospitals donation activity has yet to be put in place, but if it were so, this would naturally impact on the performance management of the clinical lead for organ donation in that hospital.</p>
US (UPMC)	<p>By no. organ yield, family and OPO satisfaction.</p> <ol style="list-style-type: none"> a. None b. We have a team leader. c. No.
Spain	<ol style="list-style-type: none"> a. The yearly donation activity (in comparison with historical series, population covered) as well as the results of the Quality Assurance Program (in terms of donor’s losses) b. The Regional coordinator. He can order external evaluations (Audits) to selected hospitals of the region to verify the internal evaluation results of the Quality Assurance Program done by the hospital coordinator. About 10 hospitals pass the external audit each year (from around 175 Spanish donor hospitals). c. No
<p>What changes (if any) have you seen as a result of your donation physician program?</p>	
Australia	<p>We have seen a 25% increase over last year in donor numbers and an increase of 50% when compared to long term donation rates.</p>
United Kingdom	<p>The Organ Donor Taskforce made 14 recommendations in 2008, of which the creation of clinical leads for organ donation, donation committees and their chairs, and the expansion of the number of specialist nurses for organ donation and embedding these nurses into intensive care units, was only one of the recommendations.</p> <p>Since 2008 the UK has seen a 28 percent increase in donation, some of which must be attributable to the creation of this new infrastructure for donation.</p>

	This new infrastructure has made donation a local concern for every hospital and brought donation into the core business of every intensive care unit.
US (UPMC)	Increase in organ recovery (organ utilization).
Spain	Maintaining a high brain-death donation rate (over 32 pmp) since 1999 despite a steady decline in the incidence of brain-death.
<p>If you have seen an increase in deceased donation, what type of donation has caused this increase and to what extent? (DCD, brain death/NDD, tissue donation, organ utilization)?</p>	
Australia	Significant increase in both DCD and brain dead donors.
United Kingdom	<p>Since 2008 there has been a 28 percent increase in deceased donation in the UK. There were more deceased donors in the UK in 2010 than ever before.</p> <p>Unfortunately there has been minimal increase in the number of donation after brain death donors, though it is believed the new initiatives have halted the preceding decline in DBD numbers and there was a slight increase on 2008 and 2009 number in 2010.</p> <p>Donation after cardiac death has seen a tenfold increase over the past 10 years and in 2010 accounted for 35% of all deceased solid organ donation.</p> <p>More specifically to illustrate this point in more detail, there was a 7% increase in the number of deceased organ donors in 2009-2010 compared to the previous year. This was a result of 2% more donors after brain death (DBD) and 17% more donors after cardiac death (DCD).</p> <p>The 959 deceased solid organ donors gave 3,361 solid organs in the UK compared with 899 donors and 3,218 organs in 2008-2009. This represents a 4% increase in organs donated.</p> <p>DCD has increased by 68% since 2007/2008 to 2009/10, compared to a 2.2% rise in DBD over the same period.</p> <p>Interestingly, and concerning, the consent for organ donation remains essentially unchanged at around 60% despite the changes to infrastructure and the embedding of specialist nurses into intensive care units.</p> <p>Therefore it can be concluded, that the 28% increase in UK deceased solid organ donation seen since 2008, is because of increased donation after cardiac death, as a result of increased identification and referral of these cases. Wide regional variation gives hope that the numbers for both DBD and DCD donation can be increased even further.</p> <p>The number of corneas donated in 2009-2010 was 21% increased on the previous year but it is believed this had more to do with the expansion of eye retrieval services than directly linked to the Organ Donor Taskforce Recommendations and the creation of clinical leads for organ donation.</p>

US (UPMC)	Mostly brain death as well as successful DCDs.
Spain	Uncontrolled DCD is compensating the light decrease in brain-death donation
EDUCATION AND TRAINING	
Do donation physicians receive special training for their positions? If yes, please provide details about the type of training.	
Australia	<p>Currently training consists of a local orientation program of 2-3 days. Smaller states have been included with their adjacent larger states where the transplant programs are based.</p> <p>These programs cover legal and operational processes, introduction to tissue typing, transplantation outcomes and medical suitability, local referral processes as well as team building and establishing an affiliation with the Donatelife network and mission. Subsequent to that there is a one day induction program to the National System covering the national policy framework, funding and reporting arrangements, recent advances in donation data and science etc. We are currently developing a family consent discussion training module for Donatelife staff.</p>
United Kingdom	<p>Throughout 2010, NHSBT ran a professional development programme for the clinical leads for organ donation (and the chairs of donation committee (non-clinical champions). These masterclass sessions consisted of clinical sessions led by clinical experts in their field, change and management theory and media training; as well the sessions sought to build the infrastructure for Regional Peer Consulting Groups, to support clinical leads and donation committee chairs once the professional development programme ended.</p> <p>Its success:</p> <ul style="list-style-type: none"> It reached donation leads in 96% of all UK acute hospitals Attended by 350 clinical leads and committee chairs Consistently well evaluated It led to clinical pathways published onto the Map of Medicine http://www.mapofmedicine.com/ Runner-up for The Guardian Public Services Awards 2010 Skills Development http://www.guardian.co.uk/publicservicesawards/winners-2010 Health Service Journal Awards 2010 Finalist http://www.hsj.co.uk/Journals/2/Files/2010/11/29/HSJawardsBestPracticeReport.pdf <p>Programme outline is below</p>

	<p style="text-align: center;">The progression of your PDP journey</p> <p style="text-align: center;">Professional Development Programme for Organ Donation</p>
US (UPMC)	There is no special training. Most of them are intensivists who manage surgical/trauma ICUs and very familiar with brain death evaluation etc.
Spain	<p>Since 1991 all donation physicians have to attend a specific course. It's a five days training on theoretical contents (Donor detection, Donor evaluation, Brain-death, Donor management, Family, Organ allocation, Law) as well as practical simulations.</p> <p>This training has been the basis of TPM courses, which are now implemented regularly also in France, Italy and Portugal.</p>
Is there a continuing medical education program for your donation physicians?	
Australia	Each of the 8 agencies under the leadership of the State Medical Directors and supported by a funded education officer in each jurisdiction have an annual program based on bi-monthly face to face meetings and teleconferences. I will provide an exemplar program.
United Kingdom	After the completion of the 2010 professional development programme, new work is being carried out to make use of the education materials created for the programme to provide refresher opportunities as well as for the education of newly appointed clinical leads for organ donation and chairs of donation committees. This is a piece of ongoing work that will hopefully be in place by mid 2011.
US (UPMC)	No.
Spain	Yes. It includes courses on Family interview, Relations with Media, Management

Is training available for other medical or allied staff involved in your deceased donor program? If yes, please describe.	
Australia	We make available a basic introduction one day course (ADAPT) to interested hospital staff, there are nursing and medical modules. Participants are identified by hospital Donation physicians and expenditure authorized by SMD's. Variations are acquitted by the National Authority from annually agreed activity targets for each state and increased activity supported.
United Kingdom	<p>All the specialist nurses for organ donation, embedded into intensive care units are employed and trained by NHSBT.</p> <p>The roles and responsibilities of both the clinical lead for organ donation and the specialist nurse for organ donation includes a strong component of local education for other clinical staff, particularly in critical care and the emergency department.</p> <p>Recommendation 11 of the Organ Donor Taskforce Report (2008) called for, "All clinical staff likely to be involved in the treatment of potential organ donors should receive mandatory training in the principles of donation. There should also be regular update training."</p> <p>As yet this recommendation has not been realised.</p>
US (UPMC)	No.
Spain	All members of the donation team participate in TPM courses, and continuing medical education programs courses.
Do physician trainees in relevant areas (e.g. critical care) receive training on deceased donation? If so, under what structure (e.g. Royal College training, critical care curricula etc)?	
Australia	ICU trainees must complete a 1 day workshop (ADAPT) before becoming eligible for fellowship of the College of Intensive Care Medicine. This course is funded by AOTA and we are responsible for the delivery and quality of the course for which we have developed a MOU and review process with ANZICS and CICM. Trainees of other colleges i.e. Emergency, Internal Medicine, Neurosurgery and Anaesthesia have no formal training processes. We are currently discussing with these groups how we might provide tailored education to both fellows and trainees of these programs/colleges.
United Kingdom	There is no formal programme for the mandatory training of junior doctors but organ donation features in the exam and competency syllabus for specialisation in emergency medicine, anaesthesia and critical care. It is hoped that through local and regional initiatives more can be done.
US (UPMC)	No. Not that much. The CCM fellows learn a little when they round in the Neuro ICU. Not sure about the nurses.
Spain	All intensive care residents pass a three days training course organized by the Spanish society of intensive care (SEMICYUC) and the National transplantation agency (ONT)

DUAL COMMITMENT AND POTENTIAL CONFLICT OF INTEREST

What is the perspective of your professional society (local ICU group, intensive care society, other national group) on the role of the donation physician?

Australia	<p>Name of group: ANZICS Perspective: Supportive The ANZICS statement of Death and Organ Donation 3rd Edition clearly identifies donation as a core expertise of intensive care physicians and raising the possibility of donation and seeking family consent as the responsibility of treating intensive care physicians. The integration of the Donation physician role within this culture of ownership of a clinical issue has been challenging but I believe the role has the support of the majority of our physicians provided the implementation is well handled and the quality of the educational and data analysis process is consistent with other similar professional developments within our community.</p>
United Kingdom	<p>The UK Intensive Care Society is in support of the role of clinical leads for organ donation (donation physical specialists). Under the direction of the Department of Health, and working with the British Transplantation Society and NHS Blood and Transplant, the Intensive Care Society supported the one-day consensus meeting on Donation After Circulatory Death. The consensus document was published with the endorsement of the intensive care society. http://www.ics.ac.uk/intensive_care_professional/standards_and_guidelines/dcd A new Intensive Care Society clinical guidance on diagnosing death and organ donation is in draft form and awaiting publication. It would be reasonable to say however, that not all members of the Intensive Care Society Council are in full support.</p>
US (UPMC)	SCCM, AOPD.
Spain	<p>Name of group: The Spanish society of intensive care (SEMICYUC) Perspective: SEMICYUC strongly supports the role of intensivists as the key professionals of cadaveric donation. There is a special workgroup of the Society dedicated to Donation</p>
<p>How do you address the potential for conflict between donor optimization and end-of-life care?</p>	
Australia	<p>It has been the practice in Australian ICU's for many years for ICU physicians to care for donors and their families having established strong supportive relationships with patients and families as the treating physicians. The process has a Designated Officer appointed by the hospital to maintain probity and provide governance oversight and these 2 roles are mutually exclusive. Interestingly DCD is changing this practice with its greater need for more time, family discussion and planning resulting in Donation physicians increasingly providing the physician role in the process caring for both donor families and supervising the process of withdrawal of cardiorespiratory support and transfer to the operating room in collaboration with Organ Donor Coordinators. The</p>

	<p>responsibility for the declaration of death and coronial reporting remains with the treating intensive care team.</p>
<p>United Kingdom</p>	<p>This is a real concern for intensive care physicians who are also clinical leads for organ donation (donation physicians). In July 2010 a letter to the editor by three intensive care consultants (two of whom were past presidents of the Intensive Care Society) was published in the UK Journal of the Intensive Care Society. They suggested, "A problem arises when Clinical Leads for Organ Donation are consultants working in critical care and so look after potential donors. Such consultants could be perceived as having a conflict of interest. Clinical leads are offered funding for a minimum of one programmed activity per week to allow this role to be incorporated into an individual's job plan." http://journal.ics.ac.uk/journal_article_detail.html?edition=10 Heavy debate followed in the next issue of the Journal of the Intensive Care Society. http://journal.ics.ac.uk/journal_article_detail.html</p> <p>The UK Donation Ethics Committee (DEC), which is an independent committee under the auspices of the Academy of Medical Royal Colleges, has published a consultation document, "AN ETHICAL FRAMEWORK FOR CONTROLLED DONATION AFTER CIRCULATORY DEATH." http://www.aomrc.org.uk/donations-ethics-committee.html</p> <p>In this consultation document the DEC has made the following recommendations to minimize perceived or real conflicts of interests for clinical leads for organ donation and specialist nurses for organ donation. Sir Peter Simpson, chair of the DEC, in a statement he made in January at the closing national Professional Development Programme event for Clinical Leads and Donation Committee Chairs said that he did not see that a conflict of interest exists provided usual best practice was adhered to. The draft recommendations of the DEC to prevent / reduce perceived conflict of interest are:</p> <p>Recommendation 1: Two doctors, one of whom should be a consultant, should independently verify that further active treatment is no longer in the patient's best interests. It would be preferable for this to be the case for all patients, not only those where organ donation is a possibility (although the UKDEC remit extends only to organ donation). This matches the process adopted for diagnosis and confirmation of brain stem death.</p> <p>Recommendation 2: If organ donation has been identified as part of the end of life care pathway for a patient, then caring for that patient during the dying process in such a way as to maintain the organs in the best possible condition for donation does not represent a conflict of interest on the part of the treating clinician. Because it is considered to be in the patient's best interests to become a donor, interventions to facilitate this are likely to reflect those interests unless they may cause harm or distress or risk causing harm or distress.</p> <p>Recommendation 3: The Specialist Nurse for Organ Donation should not care for the potential donor whilst they are still alive.</p>

	<p>Recommendation 4: Members of the retrieval team and the recipient’s clinical team should not be involved in the care of the potential donor. There should, however, be effective liaison and communication between the retrieval team and those caring for the potential donor in order to ensure that the interests of the patient as a potential donor are maintained at all times.</p> <p>Recommendation 5: After death, the potential conflict of interest between saving the life of the patient and respecting their interest to be an organ donor disappears. Once the decision to accept the organs has been taken, it is in the best interests of the deceased patient for procedures such as re-intubation to facilitate lung retrieval, to be carried out by suitably trained individual. Thus, although this professional may have been a member of the donor’s clinical team prior to death, this no longer represents a conflict of interest.</p> <p>Recommendation 6: Some actions carried out after death to facilitate donation (such as moving the deceased patient to theatre) carry a theoretical risk of re-starting the heart. An appropriately trained member of staff, not part of the retrieval team, should re-confirm cardiac standstill if necessary before the retrieval operation commences.</p> <p>Legal Guidance from the Departments of Health in England, Wales and Scotland has likewise been extremely helpful in giving clear guidance to what is acceptable in DCD. http://www.ics.ac.uk/intensive_care_professional/legal_issues http://www.sehd.scot.nhs.uk/cmo/CMO(2010)11.pdf</p> <p>The latest UK General Medical Council guidance on end of life care (2010) supports organ donation:</p> <p>Organ donation</p> <p>81 If a patient is close to death and their views cannot be determined, you should be prepared to explore with those close to them whether they had expressed any views about organ or tissue donation, if donation is likely to be a possibility.</p> <p>82 You should follow any national procedures for identifying potential organ donors and, in appropriate cases, for notifying the local transplant coordinator. You must take account of the requirements in relevant legislation and in any supporting codes of practice, in any discussions that you have with the patient or those close to them. You should make clear that any decision about whether the patient would be a suitable candidate for donation would be made by the transplant coordinator or team, and not by you and the team providing treatment. http://www.gmc-uk.org/static/documents/content/End_of_life.pdf</p>
US (UPMC)	That’s a difficult issue. It is a balance involving, family, primary service and OPO.
Spain	There is no conflict at present. There could be in the near future if controlled DCD donation starts. A debate is promoted among intensivists in order to start in next future.

Do you have provisions to separate duties of ICU attending (consultant) intensivists from those of the donation physician?	
Australia	No
United Kingdom	<p>No. The role of the clinical lead for organ donation is predominantly to overcome local barriers to donation by promoting, leading, educating and providing expert knowledge and strategic guidance within the hospital, not to attend every donor or to provide clinical care to a donor. If the clinical lead for organ donation is also an intensive care consultant who happens to be on duty for their intensive care when a potential donor is present, then their primary focus is on their intensive care role.</p> <p>Naturally separation of these dual-roles is not easy in practice, or always desired, for a key responsibility of a clinical lead for organ donation is to demonstrate best practice and lead by example. It is this dual-role, which may open the clinical lead to accusations of conflict of interest.</p>
US (UPMC)	No.
Spain	No
How do your donation physicians manage their dual roles as ICU attending (consultant) intensivists versus donation physician?	
a. Can your donation physician function as a donation physician and the attending (consultant) intensivist at the same time?	
Australia	<p>Generally most donation physicians fulfill both roles although not at the same time. Most of our medical staff are part time Donation physicians who also practice as intensive care physicians in the same hospitals. This allows for the Donation physician role to develop as an additional resource to support other hospital staff and provide the specific additional support necessary for that organization, that donation opportunity and group of clinicians. We are yet to collect information concerning the diversity and variability of this process nationally.</p> <p>Yes</p>
United Kingdom	As above in question 37.
US (UPMC)	Yes. Mostly this is the case in our hospital during the daytime. The only exception is when the intensivist is rounding in an organ transplant ICU.
Spain	They cannot participate (by Law) in the declaration of death of the potential donor. But for the rest of the donation process there is no problem
Have you had significant divergent views within your ICU community, hospital community or the general public with respect to the donation physician role? If so, how did you address these?	
Australia	Yes, many older intensivists did not see the need for change and were very influential in affecting the prevailing views of the profession while younger busy practicing physicians were supportive of the additional resource both in terms of

	increased capacity and expertise that would be provided to families, units and colleagues. As the National Medical Director I spent considerable time engaging opinion leaders and using their knowledge, experience and influence to integrate this program within Intensive Care Medicine with the explicit support of leaders in Transplantation, Anaesthesia and Emergency Medicine. The National Clinical Taskforce report development process provided us with a strong platform to achieve this and we started this process in 2006.
United Kingdom	As above, this remains a highly contentious issue within the intensive care community. As yet, there has been no expressed public concern. It is hoped that the conclusions of the independent Donation Ethics Committee will allay the fear of many.
US (UPMC)	No
Spain	No
PEDIATRICS	
Do you have separate provisions for pediatrics? If yes, how do you manage this? If no, why not?	
Australia	We have not really addressed this area yet other than forming a special interest working group lead by one of the SMD's who is a paediatric intensivist and this group has meet twice.
United Kingdom	In all the large stand alone paediatric hospitals in the UK there is a clinical lead for organ donation e.g., Alderhay, Birmingham, Manchester, Great Ormond Street. In other acute hospitals, which have paediatric intensive care units, the clinical lead and the specialist nurse for organ donation is responsible for both adult and children in that hospital. These are often large hospitals and would ideally have two specialist nurses to support donation. It would be routine for a paediatric intensive care consultant to sit on that hospitals donation committee were they not to also the clinical lead for organ donation. In smaller hospitals, without paediatric intensive care units and therefore where paediatric donation potential is small, the clinical lead and specialist nurse are responsible for both adult and paediatric donation.
US (UPMC)	No. There are no interested intensivists in our hospital to do pediatric donors.
Spain	No. Cadaveric donors younger than 15 represent 3% of cadaveric donors.
Is the donation physician involved with your pediatric donation program? If yes, please describe this role.	
Australia	There are paediatric donation physicians in the large paediatric hospitals.
United Kingdom	Directly - As above. In most mixed paediatric and adult hospitals, the clinical lead is responsible for both paediatric and adult donation. For larger hospitals that have a paediatric intensive care it is routine to have a paediatric intensive care consultant representative on the donation committee and therefore in a position to guide and modify guidelines to be paediatric appropriate. Indirectly - The few paediatric clinical leads for organ donation, from the large

	stand-alone paediatric hospitals in the UK, are all involved nationally in drawing up guidelines and supporting paediatric donation.
US (UPMC)	No
Spain	Yes. The donation team monitors the evolution of Pediatrics ICU patients with severe neurological damage. Some nurses/doctors from Pediatric ICU may be part of the donation team.

HINDSIGHT AND LESSONS LEARNED

Have there been any unanticipated problems or successes of your program?

Australia	Most challenges and problems have been entirely predictable. Staff turnover at a central government level has been higher than anticipated and this has affected capacity and continuity of particular projects.
United Kingdom	<p>CHALLENGES</p> <ol style="list-style-type: none"> 1. Working with clinical leads for organ donation and donation committee chairs across four health administrations (England, Scotland, Wales and Northern Ireland) and particularly where the laws, in that administration, are slightly different. 2. Working with geographically isolated individuals as well as those in large urban centres made communications difficult. 3. The launch of an electronic forum for communication to clinical leads and to provide an accessible location for them to collaborate and share ideas, has not been successful. More work is required. 4. The recruitment of clinical leads, the establishment of donation committees and their chairs and the education of these individuals through the Professional Development Programme in 2010, was driven by a team of only three. They are exhausted. 5. Changing the perspective of NHSBT (the national organ procurement organisation) from an historical inward facing, to an outward facing organisation and finding the infrastructure from within NHSBT to support this change. 6. A performance framework for donation, led by the Department of Health in each health administration was planned but with a change in national government has not been enacted. The governance structures are therefore not in place to hold clinical leads and their hospitals accountable for their donation activity. 7. Not all clinical leads for organ donation have been successful in their role. 8. Ensuring that the professional bodies were kept up to date, involved and knew exactly what we were doing. <p>SUCSESSES</p> <ol style="list-style-type: none"> 1. To have seen within three years, the publication of legal guidance on DCD, an endorsed consensus document on DCD and donation from the emergency department, and the consultation document on DCD by the independent Donation Ethics Committee. 2. The addition of donation into the Map of Medicine (a national online tool for

	<p>health professionals and the public), which outlines patient flow pathways for DBD and DCD, linked into end of life care.</p> <ol style="list-style-type: none"> 3. The use of the Transformation Map to give clear achievable goals to the strategic vision. 4. To have completed, through 2010, a comprehensive Professional Development Program for the clinical leads and the donation committee chairs. The clinical masterclasses proved very successful. 5. Working with an external professional management organisation (Deloitte) for the Professional Development Program was more successful, cost effective and helpful than first envisaged. 6. To have the Professional Development Program nominated for two national awards. 7. To have provided media training for clinical leads. 8. To have established over 180 beacons of light championing donation across the United Kingdom in the form of clinical leads each linked to a donation committee and donation committee chair. 9. This new infrastructure has made donation a local concern for every hospital and brought donation into the core business of every intensive care unit. 10. To have achieved a 28 percent increase in donors over three years!
US (UPMC)	The program has been very successful. The OPO is happy since the number of organs recovered per donor has increased. The CCM department as well as the physicians are happy because of reimbursement for donor management.
Spain	An unanticipated success: the low opposition rate (16% in 2009) once the population is familiar with donation and transplantation.
<p>Describe any significant modifications you have made to the donation physician role since implementation of your program. Are you considering modifying your program in the future and if yes, in what way?</p>	
Australia	<p>Currently the major issue in terms of the donation physician role is whether a full time focus on this clinical activity is more effective than a shared role model. Perhaps a mixture of the two models provides greater flexibility which may result in different models for different kinds of hospitals related to their size, location and case mix.</p> <p>A secondary issue is how to match combined medical and nursing FTE against activity, defined as the potential for deceased donation (organ and tissue) and the organizational readiness/capacity to achieve this potential. The effort and skills necessary to establish hospital systems and integrate the mission of organ and tissue donation into the culture of an organization are necessarily different from the ongoing maintenance of an established national program. The way in which physician and nursing roles are complimentary and synergistic and the time over which the allocated FTE should be funded differently are important planning considerations from a workforce recruitment and retention as well as from an educational perspective.</p> <p>We are only beginning to come to terms with these complexities and have not yet analysed our national experience in a qualitative or quantitative way.</p>

United Kingdom	<p>One of the strengths of our programme is the determination for continuous modification and a desire to review clinical lead and donation chair feedback to get it right.</p> <p>All professional development masterclasses were piloted, which led to changes, as well there were changes as the programme was delivered though 2010:</p> <ol style="list-style-type: none"> 1. We did away with the Regional Peer Consulting Group idea for clinical leads and chairs. Feedback suggested such conversations were likely to occur in hospital departments and so there would be repetition. A move was made toward developing a vision around Regional Collaboratives as there was a gap there and it was felt that such a structure might be more long lasting than the main professional development programme. Linked into this vision is the new decision to create regional clinical leads to support the Regional Collaboratives. 2. It was initially felt that brain stem death testing and donor optimization simulation could fit into the programme but it was concluded that this aspect was best targeted toward pre-consultant trainees and this is being explored as part of wider ICU training. 3. The launch of the UK Donation Ethics Committee and the National Institute for Health and Clinical Excellence decision to review consent for organ donation, led to a review of the timings in the latter stages of programme. 4. Ongoing work is being carried out to see how the education materials, created for the professional development programme, can best be delivered in the years to come, when the potential size of the audience (new clinical leads and donation committee chairs, who were not present during the first programme) and the financial resources will be more constrained.
US (UPMC)	There are constant refinement to how we provide care, in terms of evaluation of donor, supervision of DCD's etc.
Spain	<p>There have been two main aspects not planned at the beginning and that have had a very positive impact on the program: the high involvement the intensivists and the quality assurance program.</p> <p>Future plans include to start DCD uncontrolled programs in more cities (at present only Madrid and Barcelona) and starting DCD controlled donation in all the country.</p>
What would you do differently if starting the program again?	
Australia	<p>In no particular order</p> <ol style="list-style-type: none"> A. Have an operational role for a medical director of clinical programs at a national level. B. Only employ at a leadership level, including clinical roles, individuals who have been recruited to these "new" roles by the executive group of the new model/organization. This does not preclude established individuals from applying and participating in the new model but benchmarks expectations and establishes relationships. C. Do the hard yards of work flow and work processing analysis prior to initiating change in order to demonstrate in an objective manner the benefits (safety

	<p>and quality, financial etc.) of a new model.</p> <p>D. Prepare the educational tools with which to change culture in the hospital system at the earliest opportunity.</p> <p>E. Spend the time and effort in the early stages to create an executive team to manage and drive change. Make sure you all have a shared vision and direction and understand what each member needs to contribute in a visible/tangible way in order to successfully implant the program and meet the expectations of colleagues/coworkers. Policy is not a plan and a plan is not a strategy etc.</p> <p>F. Educate clinical staff with executive roles on matters of public service governance, structure etc and likewise prepare a clinical introduction program for non clinical executive staff.</p> <p>G. Have a well organized communication strategy to deal with bad news, good news, excessive political interest or expectation.</p>
United Kingdom	<ol style="list-style-type: none"> 1. Ensure greater resources and individuals of quality and commitment were available to lead the professional development programme and oversee the creation of clinical leads, donation committees and their chairs. 2. Keep the established specialist nurses for organ donation better informed as to the vision of senior NHSBT and Department of Health for embedded specialist nurses on intensive cares, and their envisaged relationship with clinical leads, donation committees and donation committee chairs. There has been a touch of resentment from specialist nurses for organ donation in some areas about the clinical lead role. 3. Consider creating the position of regional clinical lead for organ donation, to support and oversee other clinical leads, from the very beginning. Identifying appropriate individuals at such an early stage, when immense restructuring of specialist nurses for organ donation was occurring simultaneously, would not have been easy. 4. Identify the future education needs and goals for clinical leads and donation committee chairs earlier. Again, since much was new and not attempted before in the UK, this is no easy ambition.
US (UPMC)	Probably none.
Spain	More emphasis on tissues from the beginning

Appendix A: Australia

HOSPITAL-BASED MEDICAL DIRECTORS OF ORGAN AND TISSUE DONATION ROLE AND RESPONSIBILITIES

Overarching principles

The Hospital-based Medical Directors' role and responsibilities reflect the overarching principles of the national reform package:

- A new, nationally consistent and coordinated approach and system for organ and tissue donation to boost the number of transplants for Australians;
- Increased, dedicated capacity within the health system to focus on organ and tissue donation; and
- The implementation in the Australian context of proven international and national best practice taking into account individual State and Territory legislative, structural and operational requirements to maximise success.

Summary of role

The Hospital-based Medical Directors' primary focus is to lead and drive at the local level the national effort to increase organ and tissue donation across Australia. The Hospital-based Medical Directors will be responsible and accountable for the process to optimise organ and tissue donation for transplantation, including the education of hospital staff and obtaining consent.

Specifically the positions will be responsible for systems that will ensure:

- that all potential cadaveric donors are properly recognised and evaluated, and the opportunity for donation is available; and
- integrated management of the donation process to assure quality and national consistency of all procedures from donor identification to donor family follow up and aftercare.

The positions will be full time for at least the first six months to enable the incumbents to commence the implementation of nationally consistent systems, programs and processes within the hospital and to establish key networking channels. After this initial period the positions may have up to 0.5 FTE time spent in clinical practice, research or academic work to attract quality candidates to the roles and to ensure clinical skills are maintained.

Responsibilities

The Hospital-based Medical Directors will ensure that local hospital practice and systems are in line with nationally consistent policy and processes set by the Australian Organ and Tissue Donation and Transplantation Authority, which will be established on 1 January 2009. In essence they are the local champion and driver of all aspects of the process and must be seen as part of the hospital team. They will have professional working relationships with relevant hospital departments. Specifically, Hospital-based Medical Directors will be responsible for:

- educating medical, nursing and allied health staff in intensive care units (ICU), emergency departments (ED) and the health institution as a whole in accordance with programs set by the Authority;
- implementing, monitoring and evaluation of national protocols and practices in their hospital;
- facilitating organ and tissue donation by working with hospital teams to identify potential donors and optimise actual donations;
- being the primary point of contact for the donor family and responsible for the consenting process with family members;
- championing the use of nationally consistent clinical triggers to improve the identification of potential organ and tissue donors;
- liaison between ICU, ED, Organ and Tissue Donation Agency staff, eye and tissue banks, transplant and retrieval teams, private hospitals, to manage barriers to organ and tissue donation;
- reporting against the performance targets and goals set by the Authority; and
- liaison with the jurisdictional Organ and Tissue Donation Agency for donor family support and follow up services such as bereavement counselling.

Skills, experience and personal attributes

- Enthusiasm for organ and tissue donation
- Commitment to champion, educate and lead others to improve organ and tissue donation rates and outcomes;
- The leadership ability and values needed to inspire and drive significant change;
- Team spirit, leadership and peer esteem;
- Personal resilience and strength to overcome adversities and find solutions to complex problems;
- Ability to communicate with influence including active listening and ability to easily build rapport; and
- Advanced clinical skills (in intensive care, emergency medicine or another specialty connected with the donation process) with a strong interest / working knowledge of organ and tissue donation.

Summary

Funding: Commonwealth

Employer: Hospital or health service as applicable

Report to:

- a senior administrator (e.g. hospital CEO) on a daily operational basis;

- to the State/Territory Medical Director in an organ and tissue donation program capacity, including performance and compliance with the national framework; and
- the National Authority's National Medical Director in a professional/craft capacity.

Role:

- responsible and accountable for the process to optimise organ and tissue donation for transplantation; - from driving the education of hospital staff to obtaining consent;
- working with hospital staff to:
 - identify potential donors; and
 - ensure local hospital practice and systems are in line with nationally consistent policy and process; and
- local champion and driver of all aspects of the process.

Appendix G: Consultation Participants

International Experts

Dr. Dale Gardiner; Clinical Lead, Organ Donation, Nottingham University Hospitals, Nottingham, United Kingdom

Dr. Xavier Guasch; Intensive Care Consultant, Hospital de La Plana, Villa-Real, Spain

Dr. Raghaven Murugan; Assistant Professor, Department of Critical Care Medicine, Clinical and Translational Science Institute, CRISMA Centre, University of Pittsburgh, Pittsburgh, Pennsylvania, United States of America

Dr. Gerry O’Callaghan; National Medical Director, Australian Organ and Tissue Authority, Adelaide, Australia

Canadian Critical Care Society

Dr. Chip Doig; Director, Department of Community Health Services, Foothills Medical Centre, Calgary, Alberta

Dr. John Drover; Chair and Program Medical Director, Critical Care Program, Kingston General Hospital, Kingston, Ontario

Dr. Robert Fowler; Associate Professor, University of Toronto, Departments of Medicine and Critical Care Medicine, Sunnybrook Hospital, Toronto, Ontario

Dr. Alison Fox-Robichaud; Associate Professor, Division of Critical Care, McMaster University, Hamilton, Ontario

Dr. John Granton; President, Canadian Critical Care Society , Head, Division of Respiriology, University Health Network, Mount Sinai Hospital and Women’s College Hospital, Toronto, Ontario

Dr. Brendan McCarthy; Transplant Manitoba - Gift of Life, Winnipeg Manitoba

Dr. Giuseppe Pagliarello; Surgeon, The Ottawa Hospital, Assistant Professor, University of Ottawa, Ottawa, Ontario

Ethicists

Dr. Franco Carnevale; Associate Professor, School of Nursing, Affiliate Member, Biomedical Ethics Committee, McGill University, Montreal, Quebec

Dr. Bashir Jiwani; Ethicist & Director, Fraser Health Ethics, Fraser Health Authority, Surrey, British Columbia

ICU Based OPO Medical Directors

Dr. Steve Beed; Medical Director, Legacy of Life, Capital District Health Authority, Halifax, Nova Scotia

Dr. Sonny Dhanani; Chief Medical Officer (Donation), Trillium Gift of Life Network, Ottawa, Ontario

Dr. Greg Grant; Provincial Executive Director, BC Transplant, Vancouver, British Columbia

Dr. Jim Kutsogiannis; Medical Director, Northern Alberta HOPE Program, Edmonton, Alberta

Dr. Andreas Kramer; Intensivist, Clinical Assistant Professor of Medicine, Southern Alberta Organ and Tissue Donation Program, Calgary, Alberta

Dr. Jean-François Lize; Medical Director Assistant, Québec -Transplant, Montréal, Québec

Intensivists

Dr. Ian Ball; Medical Chair, Organ Transplant Committee, Kingston General Hospital, Kingston, Ontario

Dr. Tony Best; Queen Elizabeth II Hospital, Grande Prairie, Alberta

Dr. Mark James; Anesthesia and Critical Care, Saskatoon Health Region

Dr. Brian Kavanagh; Chair, Department of Anesthesia, University of Toronto, Departments of Critical Care Medicine and Anesthesia, Hospital for Sick Children, Toronto, Ontario

Dr. Stephan Langevin; Hôpital de l'Enfant-Jésus, Québec City, Québec

Dr. Shavaun MacDonald; Emergency & Critical Care Physician, St. Paul's Hospital, Saskatoon, Saskatchewan

Dr. Sharon Peters; Vice-Dean, Faculty of Medicine, Memorial University, St. John's, Newfoundland

Dr. Jag Rao; Surgeon & Critical Care Medicine, Regina General Hospital, Regina-Qu'Appelle Health Authority, Regina, Saskatchewan

Dr. Mike Sharpe; Professor, Department Anesthesia Perioperative Medicine and Medicine Program in Critical Care, London Health Sciences Centre-University Campus, London, Ontario

Canadian Neurosurgical Society

Dr. Brian Toyota; Chair, Brain Cancer Surgical Tumour Group, British Columbia Cancer Agency, Vancouver, British Columbia

Canadian Association Emergency Physicians

Dr. John Tallon; Medical Director, Nova Scotia Trauma Program and Queen Elizabeth II Health Sciences Centre Trauma Program; President, Canadian Association of Emergency Physicians, Halifax, Nova Scotia

Organ Procurement Organizations

Mr. Louis Beaulieu; Chief Executive Officer, Quebec Transplant, Montreal, Quebec

Mr. Laszlo Kalmar; Organ Donation Specialist, BC Transplant, Vancouver, British Columbia

Ms. Janet MacLean; Vice President, Clinical Affairs, Trillium Gift of Life Network, Toronto, Ontario

Dr. Frank Markel; President and CEO, Trillium Gift of Life Network, Toronto, Ontario

Canadian Blood Services

Mr. Mathias Haun; Director Strategic Planning (Tissues), Canadian Blood Services, Ottawa, Ontario

Ms. Sherri Kashuba; Director Organs and Tissues, Canadian Blood Services, Edmonton, Alberta

Dr. Sam D. Shemie; Division of Critical Care, Montreal Children's Hospital, McGill University Health Centre, Medical Director, Extracorporeal Life Support Program, Professor of Pediatrics, McGill University Montreal, QC; Executive Medical Director (Donation) Canadian Blood Services

Ms. Kimberly Young; Executive Director Organs and Tissues, Canadian Blood Services, Edmonton, Alberta