



BMJ Open Protocol for a qualitative pilot study to explore ethical issues and stakeholder trust in the use of normothermic regional perfusion in organ donation in Canada

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ABSTRACT

Introduction The process of controlled organ donation after circulatory determination of death (cDCDD) results in ischaemic injury to organs and leads to poorer outcomes in organ recipients. Although not yet used in Canada, normothermic regional perfusion (NRP) is a perfusion technology used postmortem with cDCDD donors to selectively restore perfusion of oxygenated blood to target organs in situ, reversing ischaemic injury and improving organ viability and post-transplant outcomes. However, NRP poses significant ethical challenges. To preserve trust in deceased donation, these ethical challenges must be addressed to the satisfaction of Canadian stakeholders before NRP's implementation. This study will identify ethical issues pertaining to NRP and explore perspectives of NRP among key stakeholders. By developing an explanatory framework delineating how stakeholder perceptions of NRP's ethical implications impact trust in Canada's donation and transplantation systems, this study will inform the development of responsible policy on NRP's use in Canada.

Methods and analysis This study includes two workstreams. Workstream 1 is a scoping review of medical and bioethical literature to identify ethical issues stemming from NRP. We will apply a common search string across Medline, PubMed (other than Medline) and Embase to identify relevant articles. We will identify grey literature through Google searches, websites of organ donation organisations and consultation with our research network. No date limits will be applied. All peer-reviewed publications, commentaries, editorials or documents that engage with ethical issues in NRP (or conceptual and empirical issues as they relate to these ethical issues) will be included. News articles, conference abstracts and publications not in English will be excluded. Workstream 2 consists of interviews with healthcare providers, institutional stakeholders, organ recipients and deceased donors' family members (n=24–36), as well as focus groups with healthcare providers involved in deceased donation and transplantation (n=20–32). Constructivist grounded theory methodology will guide data collection and analysis in workstream 2.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This pilot study will use a scoping review and qualitative methodology to identify ethical issues stemming from normothermic regional perfusion (NRP) and develop an explanatory model of how stakeholder perceptions of NRP's ethical implications may impact trust in Canada's deceased donation systems.
- ⇒ An interdisciplinary team of donation scientists, clinicians, transplant surgeons, qualitative methodologists, bioethicists and a donor family partner will ensure rigour by assessing data from multiple perspectives.
- ⇒ Three methods of data collection—a literature review, interviews and focus groups—will generate an in-depth understanding of stakeholder perspectives of NRP's ethical implications; findings will inform the development of responsible policy for the implementation of NRP.
- ⇒ Our findings will not make claims to generalisability due to the moderate sample size and the concentration of study participants in Ontario, Canada.
- ⇒ Perspectives on NRP among the lay public are out of scope for this study.

Ethics and dissemination This study was approved by Western University's research ethics committee (Western REM; ID: 120001). All participants will be asked to provide written informed consent to participate. Findings will be shared with Canadian organ donation and transplantation organisations, presented at national conferences and published in medical journals.

INTRODUCTION

Since its implementation in 2006, controlled organ donation after circulatory determination of death (cDCDD) has accounted for the largest quantitative increase in organs available for transplant from any donor category in

Canada.¹ In cDCDD, patients with a poor prognosis who do not meet the criteria for neurological determination of death undergo withdrawal of life-sustaining measures and progress to circulatory arrest.² Following cessation of circulation, physicians observe a 5min ‘no-touch’ period before death determination, after which organ recovery commences.^{2,3}

Unlike in donation after neurological determination of death, cDCDD organs are subject to ischaemic damage due to a variable period of hypoxia and reduced blood pressure following withdrawal of life-sustaining measures.⁴ Ischaemic damage leads to worse outcomes in organ recipients and often renders organs unsuitable for transplantation.⁵

Given the rising proportion of cDCDD donors and the continued shortfall in organs available for transplant in Canada, calls for innovative practices to improve the viability of cDCDD organs are growing.⁶ Practised in some jurisdictions internationally,⁷ normothermic regional perfusion (NRP) is a technology used with cDCDD donors following death determination.⁴ NRP selectively perfuses oxygenated blood to target organs in situ, reversing ischaemic injury sustained during the dying process.⁴ The technique has been shown in case series and observational cohort studies to improve transplant outcomes for recipients of cDCDD donor organs.^{8–10} There is thus growing interest in adopting NRP in Canada, with proposed research to assess its safety, efficacy and feasibility paving the way for implementation.^{6,11}

There are two modalities of NRP.^{4,7,12} Abdominal NRP perfuses organs in the abdomen only, and major vessels are occluded, ligated or transected at the diaphragm. Thoraco-abdominal NRP perfuses organs in the chest and abdomen, and major vessels are occluded, ligated or transected at the neck. In both abdominal and thoraco-abdominal NRP, the rationale for isolating target organs for perfusion is to prevent brain blood flow, which could theoretically lead to brain reanimation.¹²

NRP raises ethical questions which provoke concern among some stakeholders, with three areas of concern dominating discussion.^{13–16} First, postmortem resumption of in situ circulation in NRP contradicts the traditional standard for death determination in cDCDD (ie, permanent cessation of circulation),¹⁷ a standard endorsed in Canada’s 2006 cDCDD guidelines.² This may entail subsequent violations of the dead donor rule,¹⁸ the injunction that organ recovery cannot cause death.¹⁹ Restoration of spontaneous cardiac function in thoraco-abdominal NRP exacerbates this concern—a spontaneously beating heart may be perceived as unacceptable by some.²⁰ Second, there is empirical uncertainty over the efficacy of the surgical techniques to prevent brain reperfusion^{11,12,17}; reanimation of the donor’s brain may result in harm to the donor should they regain sentience. The latter concern is more pronounced in thoraco-abdominal NRP, where the interruption of brain arterial supply at the supra-aortic vessels does not preclude collateral arterial supply.²¹ Finally, some argue that the act of deliberately preventing

brain blood flow is a violation of the dead donor rule: by actively preventing brain reperfusion, the intent to maintain brain death is perceived as an intent to ‘induce’ brain death.²²

Stakeholder trust is the cornerstone of Canada’s deceased donation systems. Any practice perceived as unethical could undermine this trust. Because of the importance of stakeholder trust, the promise of NRP cannot be realised until ethical issues have been addressed to the satisfaction of stakeholders. Foundational work on the ethics of NRP is a critical step on the path to its implementation. Knowing how stakeholder perspectives on NRP’s ethical implications impact trust in donation and transplantation will allow for the development of policy that responds to these perspectives. If it is known what drives trust, and how NRP may impact it, policymakers will be in a better position to preserve and promote trust in the context of NRP’s implementation.

As recently as 2019, a scoping review identified no qualitative studies exploring stakeholder views on NRP.²³ While recent surveys explored public and healthcare provider perspectives of thoraco-abdominal NRP in the context of cardiac donation in cDCDD,^{24,25} these important studies did not specifically target donor families, organ recipients or institutional stakeholders, nor did they seek to systematically assess NRP’s potential impact on trust in donation and transplantation. Moreover, the focus on only one NRP modality (ie, thoraco-abdominal NRP) leaves gaps in our understanding of the implications of NRP for stakeholder trust. The relationship between stakeholder perspectives of NRP and trust in donation and transplantation is currently unknown. While essential research into NRP’s perceived acceptability among the public and healthcare providers is ongoing,¹³ calls for further investigation into other key stakeholders’ perspectives on NRP are growing louder.²¹

Objectives

This pilot study seeks to inform the development of responsible policy regarding NRP. Specifically, the study’s objectives are:

1. To identify ethical issues raised by NRP.
2. To develop a preliminary explanatory model of how stakeholder perceptions of NRP’s ethical implications may impact trust in Canada’s donation and transplantation systems. An explanatory model is a framework for understanding the connections between conceptual categories and issues which emerge from inductive analysis of data.²⁶ Our model will describe those factors which may influence the social construction of trust in donation and transplantation should NRP be implemented in Canada, and account for the relationships among these factors.
3. To inform policymakers and medical professionals designing policy governing the use of NRP in Canada.
4. To provide pilot data to inform future, national-level research into stakeholder perspectives on NRP.

METHODS AND ANALYSIS

Study design

This pilot study consists of two workstreams. In workstream 1, we will conduct a literature review of ethical issues in NRP using a methodology proposed by Levac *et al.*²⁷ In workstream 2, we will conduct semi-structured individual interviews and focus groups with stakeholders; data collection and analysis will be guided by Constructivist Grounded Theory (CGT) methodology.²⁶

Patient and public involvement

A donor family partner (LB) has been a member of the study team since its inception. LB participated in defining study objectives, study design and the development of educational materials for participants. LB will contribute to data collection, analysis and knowledge translation activities. LB's contributions will help to ensure that the study remains responsive to the perspectives of patients, donors and families.

Workstream 1: scoping review

As an emerging technology, NRP's ethical implications have yet to be comprehensively explored. Scoping reviews are used to map a heterogeneous body of literature concerning a phenomenon of interest.^{28 29} In the context of normative literature, scoping reviews are useful for identifying and describing the breadth of perspectives on a given topic. Moreover, scoping reviews invite analytical re-interpretation of data and are hence increasingly used in bioethics.³⁰

Employing a methodology appropriate for reviews of mixed normative and medical literature,²⁷ we will conduct a scoping review of the literature on NRP. The aims of the scoping review are to identify ethical issues in NRP, inform the development of workstream 2's interview and focus group guides and serve as a resource for policy-makers considering NRP's implementation.

Review questions

What are the real or perceived ethical issues in the use of normothermic regional perfusion?

1. What normative arguments support these ethical concerns?
2. What conceptual issues/uncertainties underlie these ethical concerns?
3. What empirical issues/uncertainties underlie these ethical concerns?
4. How are ethical concerns addressed/resolved in the literature through normative or conceptual argument?
5. What empirical research is proposed to address/inform ethical concerns?
6. What policy/pragmatic proposals are advanced to address ethical concerns?
7. What ethical issues do stakeholders identify as important?

Identifying relevant studies

The review will consider all types of literature that may be relevant to ethical issues in NRP. These include qualitative

studies, normative argument-based articles, biomedical publications, reviews, reports, working papers and policy documents.

Using known relevant articles (n=20) for validation, a search string using controlled vocabulary and keywords in Ovid Medline was developed by a clinical research librarian (online supplemental material A). We will apply a common search string across Medline, PubMed (other than Medline) and Embase. No date limits will be applied. To identify articles not captured by the searches, we will hand-search selected articles' reference lists. To identify relevant grey literature, we will consult with our research networks, conduct a web search via Google and review the websites of organ donation organisations.

Study selection

All identified references will be uploaded to Covidence by a clinical research librarian. Two researchers (NM and CW) will screen all article titles and abstracts (or full text for articles lacking abstract) against inclusion criteria (online supplemental material B). All peer-reviewed publications, commentaries, editorials or documents that engage with ethical issues in NRP (or conceptual and empirical issues as they relate to these ethical issues) will be included. News articles, conference abstracts and publications not in English will be excluded. Reasons for exclusion will be recorded. If the relevance of the article is unclear from the abstract, the full text will be reviewed against inclusion criteria. Reviewers will meet at the beginning, midpoint and end of abstract screening to discuss any challenges or uncertainties related to study selection.

Charting the data

Data from all included articles will be collected in a chart with fields relevant to the purposes of the inquiry. A preliminary data chart has been created (online supplemental material C). Two reviewers (NM and CW) will extract data from the first 5–10 articles and meet to discuss and refine the chart in advance of further extraction. Once the chart has been finalised, one reviewer (NM) will extract data from the remaining articles.

Collating, summarising and reporting results

The final stage of the review comprises four steps: (1) descriptive numerical summary; (2) thematic analysis; (3) reporting results and (4) description of the review's implications for future research, practice and policy.

A descriptive numerical summary (step 1) will describe the characteristics of included articles, including publication type, context, methods, main findings or arguments and suggestions for policy or further research. Thematic analysis (step 2) will be conducted iteratively using conventional qualitative content analysis, a method appropriate for phenomena that are undertheorised or for which the literature is underdeveloped.³¹ One researcher (NM) in regular discussion with the research team will iteratively code the entirety of the data set. The researcher will then reassess the data to inductively develop broader categories

by merging codes under overarching themes that capture more than one related key concept or argument. Categories will then be merged with others to develop thematic categories, the final output of the analysis. Results (step 3) will be reported in the manuscript by theme. Where necessary, key concepts will be repeated to describe their relationship to the theme under discussion. The review's findings will be contextualised by describing their implications for future research, policy and practice (step 4). The contents of this section of the manuscript will be discussed and agreed on by the research team.

Workstream 2: interviews and focus groups

CGT will guide workstream 2's data collection and analysis. CGT is a rigorous methodology designed to capture multiple and divergent perspectives through the systematic collection of qualitative data through purposive sampling from information-rich participants.³² The methodology allows researchers to explore stakeholder experiences to model the factors that create social processes like the social construction of trust.²⁶ Constructivist grounded theory is particularly useful for understanding undertheorised phenomena like the impact of NRP on stakeholder trust, and provides clear guidance for how to build explanatory frameworks from participants' experiences.^{33 34}

Semi-structured individual interviews

To elicit respondents' perspectives, interpretations and understanding of NRP and its ethical implications, and to explore the influence of these on the social construction of trust in organ donation, a researcher (MO) trained in constructivist grounded theory methodology will conduct semi-structured individual interviews with stakeholders. Consistent with our methodology, sampling will be purposeful, seeking participants who are well-positioned to offer insights into our research questions, and theoretical, seeking participants who can help us to elaborate, refine or disconfirm patterns identified as data analysis proceeds.²⁶

Sampling and recruitment

We will purposively recruit members of groups who have intimate knowledge of, or close association with, organ donation and transplantation (n=24–36). We have identified three groups of interest:

1. Deceased donors' family members and organ recipients (n=8–12).
2. Representatives of Trillium Gift of Life Network, Canadian Blood Services and Transplant Québec (institutions with a mandate to preserve trust in organ donation and promote donation and transplantation) (n=8–12).
3. Healthcare providers directly involved in donation and transplantation (eg, critical care physicians, donation coordinators, hepatologists, nephrologists; nurse practitioners, social workers, transplant surgeons) (n=8–12).

The recruitment strategy is multimodal, consisting of guest presentations at regularly scheduled institutional meetings and mass emails inviting potential participants to contact the research coordinator for further information.

Data collection and analysis will proceed iteratively and continue until thematic sufficiency is achieved. Thematic sufficiency will be reached when interviews are no longer providing additional insight into the dominant themes we have identified. In our experience, thematic sufficiency can be achieved with 8–12 interviews in a homogenous group, particularly when the information power of the sample is maximised through targeted sampling and interview quality.³⁵ Recognising that our participant population comprises three distinct subgroups, we anticipate 8–12 interviews with each, for a total of 24–36 interviews.

Interview educational content

To ensure that participants understand NRP sufficiently to reflect on its ethical implications, we developed an educational video that neutrally explains the following: (1) the rationale and aims of the pilot study; (2) the process of cDCDD; (3) the challenge of ischaemic damage in cDCDD; (4) the purpose and promise of NRP; (5) the processes of thoraco-abdominal and abdominal NRP.

The video's content was informed by an informal literature review and input from experts in ethics, education, critical care, donation and transplantation, organ recovery surgery and NRP. All investigators were consulted on the video's suitability for study purposes. The study's donor family partner (LB) co-designed the video to ensure clarity for lay participants.

To maintain consistency in educational content across interviews, all participants will be shown the educational video at the beginning of the interview regardless of their prior knowledge of NRP.

Semi-structured interview guide

We developed a preliminary semi-structured interview guide of open-ended questions and probes based on an informal literature review of ethical issues in NRP and discussions among our research team (see online supplemental material D). A qualitative methodologist (LL) supervised the development of the interview guide. All study team members reviewed the guide for clarity and resonance with the study's aims.

The interview guide explores three domains of interest: (1) participants' understanding of NRP; (2) participants' perspectives on the ethical implications of NRP; (3) participants' perspectives on the implications of NRP for trust in donation and transplantation. We anticipate that the interview guide will evolve as the study progresses. On completion of the scoping review (workstream 1), new questions and probes will be added to the guide to assess perspectives on issues not previously addressed. Moreover, because constructivist grounded theory proceeds

iteratively, new questions or probes may be added during the interview series as themes or recurring patterns emerge.

Procedures

Prior to the interview, participants will be asked to fill out an anonymous demographic survey. Anonymised demographic information will be collected to allow the research team to describe the study population and to identify groups under-represented in our participant sample. This information will enable us to develop targeted sampling strategies for future studies regarding perspectives on NRP.

Interviews will be conducted over Zoom and last 45–60 min. Before audio recording begins, the interviewer will show participants the educational video. After the video has played, the participant will be informed that audio recording will begin. The interviewer will then proceed to pose open-ended questions, follow-up questions and prompts, probing for insight into participants' perspectives.

Data analysis

Interviews will be audio-recorded and transcribed verbatim by a professional transcription service. In CGT, researchers work through iterative cycles of simultaneous data collection and analysis such that the results of ongoing data analysis inform subsequent data collection.^{26 36} The analysis process begins with line-by-line coding of the first five transcripts to identify 'codes', or key ideas evident in the data. Four study team members will participate in the initial coding and agree on a preliminary coding guide. Supported by NVivo qualitative analysis software, one qualitative researcher (MO) in regular discussion with the research team will then analyse subsequent transcripts using the constant comparison approach customary in CGT: as new data are collected, prior data will be re-analysed in light of new data.²⁶ Codes will then be grouped into thematic categories which establish patterns among ideas through a process of focused coding. The entirety of the data set will then be re-analysed using focused codes. As key themes are defined, connections between them will be determined in a process of theoretical coding.²⁶ Theoretical coding produces an understanding of overarching processes and concepts, resulting in an explanatory framework that represents the inter-relationships between them.

Focus groups with healthcare providers

While interviews explore what individuals understand and perceive, focus groups explore how groups negotiate differences in their understandings and perspectives, what tensions arise and how discrepant interpretations are resolved.³⁷ We believe these processes may be particularly important to understand in relation to healthcare providers involved in donation and transplantation, as these individuals need to collaborate for innovations such as NRP to proceed effectively. Therefore, to gain insight

into how healthcare providers negotiate the ethical implications of NRP, a researcher trained in constructivist grounded theory methodology (MO) will conduct up to four focus group sessions, each with five to eight healthcare providers.

The study's focus group sessions are designed to elaborate on themes identified in individual interviews, and to observe how perspectives of NRP are subject to change in social settings. For this reason, focus groups will begin only after the first 8–12 interviews have been completed and their transcripts analysed.

Sampling and recruitment

We will purposively recruit healthcare providers who have intimate knowledge of, or close association with, organ donation and transplantation (n=20–32). The recruitment strategy is multimodal, consisting of guest presentations at regularly scheduled institutional meetings and emails inviting potential participants to participate.

Focus group educational content

To maintain consistency in educational content across interviews and focus groups, all participants will be shown the above-described educational video at the beginning of the focus group regardless of their prior knowledge of NRP.

Semi-structured focus group guide

We developed a semi-structured focus group guide of open-ended questions and probes based on an informal literature review of ethical issues in NRP and discussions among our research team (online supplemental material D). A qualitative methodologist (LL) supervised the development of the guide, and all members of the research team assessed it for resonance with the study's aims.

As in the study's individual interviews, focus group questions and prompts concern three areas of interest: (1) participants' understanding of NRP; (2) participants' perspectives on the ethical implications of NRP; (3) participants' perspectives on the implications NRP for trust in donation and transplantation. Since the focus group guide will be further informed by the findings of individual interviews and the study's scoping review, we anticipate that the probing questions may change substantially before focus groups are undertaken. However, the broad domains of interest will not be altered.

Procedures

Prior to the focus group, participants will be asked to fill out an anonymous online survey that will ask for demographic information. Focus groups will last 90–120 min and take place over Zoom. Participants will first be shown the study's educational video. After the video has played, participants will be informed that audio recording will begin. The interviewer will then proceed to pose open-ended questions and follow-up questions and prompts that aim to probe for insight into participants' perspectives.



Data analysis

Focus groups will be audio-recorded and transcribed verbatim by a professional transcription service. Data will be collected and transcribed iteratively to allow each subsequent focus group session to elaborate on themes emerging from the data. NVivo will be used as a data management tool. Four researchers will independently code the focus group transcripts, agreeing to codes by consensus.

As this is a pilot study, achieving thematic sufficiency through focus group sessions is not an aim. Rather, the primary purpose of the focus groups is to gather pilot data to generate research questions for future study. Nonetheless, focus groups may contribute to the development of the study's explanatory model by elaborating and refining insights from interviews. The study's focus group sample is small, making it difficult to predict how focus group findings might be integrated with interview and scoping review findings.

Validity and methodological rigour

The rigour of our grounded theory explanatory model delineating how stakeholder perceptions of NRP's ethical implications impact trust in Canada's donation and transplantation systems will be judged using Charmaz's criteria of credibility, originality, resonance and usefulness.^{26 38} Credibility demands sufficient knowledge of the study topic to ask incisive questions regarding the phenomenon of interest. Our research team consists of experts in perfusion technologies, ethics, critical care, organ donation and transplantation. Credibility will be enhanced using three data collection methods (a scoping review, focus groups and interviews), as well as reflexive memo writing and researcher triangulation through regular discussion of emerging findings. Originality will stem from the novel conceptualisation of undertheorised aspects of the ethical implications of NRP. These concepts will facilitate an understanding of the social construction of trust in donation and transplantation and NRP's potential impacts on this process. If possible, resonance will be optimised through triangulation of interview data with focus group data, reducing the risk of misinterpretation and allowing the research team to assess the inter-relation of emerging concepts in group settings. Usefulness will be assessed through attention to the level of generality of thematic concepts, and whether these apply across participant groups and serve to make sense of participants' perspectives. Whether the findings have policy implications will be a measure of the explanatory model's usefulness. All qualitative findings from workstream 2 will be reported in accordance with the Consolidated Criteria for Reporting Qualitative Research checklist.³⁹

Confidentiality and data storage

All identifiable information collected during this study will be kept confidential and will not be shared with anyone outside the research team unless required by law. The

principal investigator will serve as data custodian. All data will be securely stored and encrypted to safeguard participant privacy. Western University's OneDrive network will be used as a secure storage site for electronic research materials. All study materials will be securely stored and destroyed 7 years after study completion.

Ethics and dissemination

The study has been approved by Western University's Health Sciences research ethics committee (Western REM; ID: 120001). All participants in this pilot study will be asked to provide written informed consent.

The findings of this study will be shared with the Canadian Donation and Transplantation Research Program, Canadian Blood Services and Trillium Gift of Life Network (Ontario's organ donation organisation). Results will be presented at academic and clinical conferences (eg, the Canadian Critical Care Forum; the Canadian Donation and Transplantation Research Program Annual Scientific Meeting). The study will result in a peer-reviewed scoping review and at least one peer-reviewed publication of qualitative findings in a national or international medical journal.

DISCUSSION

There is growing interest in adopting NRP in Canada. By selectively perfusing oxygenated blood to target organs, NRP may improve the quality and number of transplantable organs by preventing and reversing ischaemic injury, ultimately leading to better outcomes for organ recipients. Yet NRP provokes ethical controversy, hindering its adoption both in Canada and internationally. The normative questions driving ethical controversy over NRP have not been systematically explored, and gaps in our understanding of the factors influencing stakeholder perspectives remain.

Knowing how stakeholder perspectives on NRP could impact trust in donation will allow for the development of policy that responds to these perspectives. This pilot study will identify ethical issues in NRP and provide an explanatory model that will contribute to policymakers' assessment of whether the implementation of NRP in Canada will threaten trust in donation and transplantation. Ultimately, the study will help to ensure that practices in deceased donation do not exceed public perceptions of permissible organ recovery practices.

This pilot study has limitations. Since qualitative research seeks to understand participant contexts and perspectives and to interpret the data through such understanding, our study's grounded theory model will not make claims to generalisability. Instead, it will serve as a basis for generating hypotheses and questions for future, mixed-methods, national-level research. The moderate sample size, the concentration of research participants in Ontario, Canada and the fact that public and population subgroup perceptions of NRP are out of scope also entail that our findings will not capture the perspectives of all

segments of Canadian society, meaning further research will be required.

As a critical step on the way to NRP's adoption, this pilot project will help to preserve and promote stakeholder trust in donation and transplantation by informing responsible decision-making on NRP's implementation in Canada.

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