EXPLORATION OF CONSENT ISSUES IN DECEASED ORGAN DONATION

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Lay Abstract

Ongoing demand for donated organs has led to legislating changes to consent for donation and conducting research trials to increase the quantity and quality of organs available for transplant. In this thesis, we explored two areas previously viewed as barriers to these strategies, consent for research and consent for donation. In study one, a systematic review, we showed that knowledge and attitudes towards opt-out consent were limited and there are important considerations that should be explored. In study two, another systematic review, we showed that jurisdictions with opt-out consent may have higher donation rates. In study three, a qualitative exploration, we concluded that views about requiring transplant recipients to have a role in consenting to donor research may not be suitable. The findings of this thesis can serve to inform consent practices in organ donor research and in healthcare systems.

Abstract

Background

It has been proposed that barriers related to consent for deceased organ donation and organ donation research have stymied efforts to advance outcomes. This thesis explores these two related, but different contexts of consent with the aim of elucidating potential impact on the organ donation and transplantation system.

Objectives

1. Assess knowledge and attitudes towards opt-out consent in deceased organ donation.
2. Assess the impact of opt-out consent on deceased organ donation.
3. Describe transplant recipients' views on organ donor research and their role in consent to this research.

Methods

Study 1: Meta-synthesis systematic review assessing knowledge and attitudes towards the opt-out model of consent in deceased organ donation.

Study 2: A systematic review assessing the effect of the opt-out model of consent in deceased organ donation on quantitative outcomes.

Study 3: A qualitative interview study to elucidate views of transplant recipients on organ donor research and their role in research consent.

Results

Study 1: We found limited knowledge and support for opt-out consent. We identified important ethical considerations about opt-out consent among members of the public, including value for

autonomy in decision-making and the right to informed consent.

Study 2: We found a weak signal that countries with the opt-out model have higher consent to donation rates and higher organ donation rates.

Study 3: Among solid organ transplant recipients, we found that while preferences varied related to the method and timing of providing consent for use of their own data, participants did not feel they had a role in research consent of a donor patient.

Conclusions

This thesis highlights that while opt-out consent may be associated with improved donation outcomes, public understanding and support for such policies remain limited. Findings from this thesis also challenge assumptions about transplant recipients' roles in donor research.

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List of Abbreviations and Symbols

LEADDR: Legislative Evaluation: Assessment of Deceased Donation Reform Consortium

SDM: Substitute decision maker

PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

CASP: Critical Appraisal Skills Programme Qualitative Research Checklist

GRADE: Grading of Recommendations Assessment, Development and Evaluation

GRADE-CERQual: Grading of Recommendations Assessment, Development and Evaluation-Confidence in the Evidence from Reviews of Qualitative Research

HCP: Healthcare provider

EPHPP: Effective Public Health Practice Project

GDP: Gross domestic product

≈ indicates more or less equal

↑ indicates improvement with opt-out

↓indicates decline with opt-out

Declaration of Academic Achievement

I declare this thesis to be my own work and that I am the primary author of all chapters included. I am responsible for study conceptualization and design, data collection, data analysis, data interpretation, and manuscript preparation. Various co-authors contributed to each of the studies. Contributions include study conceptualization and design, data collection, data analysis, data interpretation, and critical revision to the manuscript. The following individuals contributed to various components of the projects: Dr. Maureen O. Meade, Dr. Gordon Guyatt, Dr. Patricia Strachan, Dr. Matthew Weiss, Jack Young, Danica Nolette, Mackenzie Cullip, Alicia Guyard-Ruel, Dr. Frederick D'Aragon, and Dr. Aimee J Sarti

CHAPTER 1: Introduction

1.1 Background

Advancements to life-saving practices in deceased organ donation and transplantation have resulted from contributions of clinical research yielding evidence for optimal treatment of organ donors and recipients[1]. Advancements have also occurred in system-wide changes such as establishing legal practices that protect the rights of individuals that are affected by organ donation and transplantation[2].

One example of an important system-wide change is adoption of The Human Tissue Act in 1984. Under this act, each province has legislation that regulates activities related to human organ and tissue donation[2]. This includes oversight of consent practices in the clinical arena as well as oversight of consent for various research studies conducted within this milieu. The primary objective of this legislation is to ensure that donation of human organs (either for transplantation or for research), is done ethically and with permission[2]. Addressing complexities of consent procedures in organ donation and organ donation research is a shared theme of the studies within this thesis.

Members of the donation/transplantation community have identified some aspects of the Human Tissue Act as posing potential barriers to donation and one reason for limited success in this area of healthcare[3,4]. They point to the continuing demand for suitable organs and the consistently large number of people on the transplant waiting list (4000 in 2022) as evidence of poor performance[5,6]. It has been proposed that the opt-in process for consent to organ donation in place in Canada is a major contributor to the organ shortage that requires reform[7].

Other legal requirements may also be contributing to organ shortages. One challenge to the advancement of donation science, relates to the often infeasible and complicated research consent process required for large scale clinical trials[1,8]. The Human Tissue Act mandates ethical practices for research involving donated organs and tissues but defers enforcement and approval to hospital research ethics boards[2]. Since this process has potentially encumbered advancements in transplantation efforts, change has also been called for in research consent requirements[1].

This thesis explores consent practices in organ donation in two distinct contexts: the consent to donate organs and the consent to participate in clinical trials of donor management. Therefore, the three studies that comprise this thesis are independent entities that do not inform the content or methodology of the others.

1.1.1 Process of Deceased Organ Donation in Canada

With one donor, it is possible to transplant up to eight organs, including two kidneys, a liver, a heart, two lungs, a pancreas, and intestines[9]. In 2023, there were 952 deceased donors in Canada, which resulted in 3428 organs for transplantation[5]. In the Canadian deceased organ donation system, a person becomes eligible to be a donor once certain medical and legal requirements are met. The most common circumstance for organ donation occurs when an individual has suffered a catastrophic head injury and is declared neurologically deceased (NDD). While organ function may be able to be supported by mechanical life support (e.g., mechanical ventilator), there is complete and irreversible loss of brain function, including all cognitive and basic life-sustaining abilities[10]. In Canada, this represents a legal criterion for

death because recovery of function is not possible. In 2023, neurologically deceased donors accounted for approximately 67% (638) of total donors[5].

The other circumstance in Canada where a person can be eligible to donate their organs occurs once there is irreversible loss of cardiac and respiratory function (donation after circulatory death [DCD]). Occurring less frequently, a patient in this scenario has also suffered an irreversible and devastating injury or illness from which there is no chance of meaningful recovery. It is different from neurological death, in that with DCD the individual may retain brain activity[10]. This is generally considered to be a state where prognosis for meaningful recovery is poor and families have made a decision with the healthcare team to withdraw life support.

In DCD, artificial life support is withdrawn in a controlled manner and the patient's heart is allowed to stop naturally. Once the heart stops, an observation period occurs over approximately 5 minutes to confirm permanent cardiac and respiratory arrest. The brain and other vital organs are thus deprived of oxygen, which is essential to maintain normal function. As the organs will deteriorate rapidly without oxygen supply, recovery must likewise occur rapidly following the observation period. Timing and coordination in this process is essential to retain organ viability for successful transplantation[11]. In 2023, the number of donations following cardiac death accounted for about 27% (257) of donors overall[5].

Potential donors (NDD and DCD) are identified by hospital personnel usually in an emergency room or intensive care unit (ICU) environment. Some provincial organ donation organizations have mandated the referral of all potential organ donors (all hospitalized patients approaching imminent death) regardless of the patient's health status, or any

patient/family/SDM expressed wishes (Ontario, British Columbia, Alberta, Manitoba, and Nova Scotia)[12,13]. For example, in Manitoba, if a patient has been confirmed neurologically deceased (by two independent attending physicians) or is facing imminent death upon removal of life support, a representative (usually the patient's bedside nurse) contacts a specialized organ donation coordinator nurse from the provincial organ donation organization. Over the telephone, an organ donation representative asks a series of preliminary screening questions to assess donor suitability. Questions are usually related to the patient's demographic information such as age and gender, as well as health related questions around any comorbidities that would preclude them from donation[14].

If they are deemed suitable by screening questions, the representative then cross references the patient's name to the provincial donor registry to see if they have registered intent to become a donor. At this time, and regardless of pre-registered intent, the coordinator then approaches the patient's family/SDM to inform them of the possibility of donation. Knowledge of previous intent is considered helpful in consent conversations with family/SDMs, however all provincial policies require confirmation in case the pre-registration is no longer current. If family/SDM express dissent or the patient is deemed not medically suitable for donation, life support is withdrawn, and the patient passes away with comfort health measures only[14].

Other provinces (Alberta, Saskatchewan, New Brunswick, Newfoundland/Labrador, and Prince Edward Island) where a mandatory referral policy is not in place rely on clinical decision making by the medical team to identify potential donors. Referral is encouraged but not formally required[13]. And while the process from referral to procurement may vary slightly in

each province, donor identification, obtaining consent from family/SDMs, liaising with other provincial organ donation organizations to identify potential transplant recipients, and organ recovery is generally consistent[14]. Organ donor coordinators in each province lead and organize processes while medical/nursing care of the donor patient is left to ICU personnel based on national medical guidelines and best practices. Once organ recovery occurs, transplantation proceeds to matched recipients.[14]

1.1.2 Pre-registration of Donation Status in Canada

In Canada, it is possible to register as an organ donor. Some provinces have a standalone online registry (e.g., Manitoba), where an individual logs into the province's organ donor organization website (Sign up for life) and records their choice. This information is then linked to their Manitoba Health card. Other provinces also offer an additional option of the individual registering their donation choice at the time of driver's license renewal (e.g., Alberta). The information is then shared with the provincial health authority and is stored with other health information[9]. While each province has a slightly different process, registration is done in advance and before a person is even eligible to be a donor.

There are approximately only 2.5 million people on an organ donor registry across Canada[9] out of a possible 32 million Canadians over age 16. This represents less than 25% of possible donors[9]. Many reasons have been proposed for low registration rates including lack of awareness of the need for organs, lack of understanding about the donation process, and confusing registration systems[15]. Regardless of the cause (or multiple causes) for lack of registrants, it is clear there is need to increase the number of organ donors to match transplant demand.

1.1.3 Canadian Consent Models in Organ Donation

Consent in deceased donation is unique when compared to consent for other medical procedures. In most non-urgent or elective medical procedures, a patient grants explicit consent to the immediate health issue while they have capacity to do so. For example, if an individual requires chemotherapy drugs for cancer treatment (the health issue), consent is sought prior to administration of the drugs and only after all the risks and benefits have been disclosed[16]. This is different than in deceased donation, where consent occurs in advance of the health issue (i.e., death) through declaration of posthumous wishes on a formal registry.

Organ donation consent models used across the globe have demonstrated varying levels of success. The most widely used system (and the model traditionally used in Canada) is explicit consent (or informed or opt-in), where permission is granted by donor's family/SDM at the time a patient is eligible to donate[15].

The other consent model used in the province of Nova Scotia since January 18, 2021, is the opt-out model (or presumed or deemed consent). This model assumes the individual is an organ donor unless – in advance- they deny permission to donate their organs after their death[15]. involvement from family/SDM can differ.

Some jurisdictions (e.g. France) with the op-out model are more restrictive and do not involve family/SDMs in donation decisions. In this scenario, if the donor has not formally pre-registered an objection, organ recovery will proceed regardless of family/SDM views. This version of opt-out consent is referred to as "hard opt-out"[17].

Other opt-out jurisdictions, and the one legislated in Nova Scotia, are similar to the opt-in process in that they continue to require final permission for organ donation from family/SDMs.

This version of opt-out consent is referred to a "soft opt-out". In this scenario, if the family/ SDM indicate any dissent to organ donation, the potential donor is no longer considered eligible[17].

Family/SDM decision making when donor wishes have not been registered or discussed can be problematic[18]. Discussions traditionally occur shortly after the healthcare team has disclosed that further medical treatment of the potential donor is futile (or when neurological death has been declared). Learning that a loved one is nearing death can be stressful and devastating. Moreover, additional stress can occur when family/SDMs are then asked to make the important decision of whether to proceed to organ donation. This has been proposed as one reason why family/SDMs tend to align with the system default of no donation when potential donor wishes are unclear[18].

Family/SDM refusal rates for proxy decisions in Canada is estimated to be around 21% of eligible donors[3]. This contrasts with cross-sectional surveys reporting the national approval rate for organ donation lies around 70-80% amongst Canadian public[19]. It has been suggested that if the assumed default of the system is to donation (versus no donation as with the opt-in system), the pressure of decision making placed on family/SDMs is reduced[20]. Donation is more likely to proceed because family/SDMs are more likely to avoid the stress of going against the norm and they comply with the system's default[20].

It has also been suggested that changing to an opt out system would be in alignment with the afore mentioned high approval rates and result in more organ donors[15]. Proponents of this system argue that it removes barriers to pre-registration because it requires no action from individuals who would otherwise consent to donation. Meaning, those individuals who agree

with organ donation and report they would be a donor, but for various reasons have not taken steps to pre-register[15]. The opt-out model essentially capitalizes on their good intentions and removes the extra step of requiring registration.

Enacting the large-scale legislative change in Nova Scotia to allow opt-out consent catalyzed other changes to their donation system[21]. These changes included public awareness campaigns, mandatory reporting of potential donors, and added support for specialist healthcare personnel[4]. These additions to their donation processes have all been reported as measures essential for success in other high functioning systems[21]. While it is impossible to gauge which changes were responsible for any effect, there was a modest rise in donation numbers[22]. More time is needed to measure long-term impact.

Many people have been critical of the reform however, as there was little preliminary analysis of potential impact from the change (positive or negative) prior to its adoption[23,24]. Surveys of the public and exploration of attitudes toward the change from various stakeholder groups occurred afterward. This has given rise to controversy from some critics claiming government has been overly highhanded to enact large-scale change without prior public input[23,24].

Critics of the opt out system also cite incongruity reported on the effectiveness of the opt-out model[17]. Many opt-out jurisdictions report neutral or decreased donation rates following the change, while others report an increase in deceased organ donors[25.26,27].

1.1.4 Consent in Interventional Research

Interventional donor research has the potential to bridge the gap between organ supply and demand by improving the quality and quantity of donated organs. These types of studies

have met numerous hurdles, including the complexities of the research consent from transplant recipients who receive an organ from a donor who participated in a clinical trial[1,8]. A recent scoping review revealed that due to the range, frequency, and justification for consent models in neurologically deceased organ donor research, there were a lack of standards for deceased donor research. It also revealed a lack of understanding from the populations of interest, namely organ transplant recipients, and their perspective on their role in such research[8].

One issue relates to the well-being of the individuals that are involved with research consent discussions.[18] These discussions often take place at times that are emotionally charged. Whether this is with grieving substitute decision makers of deceased organ donors or with organ transplant recipients in the immediate peri-transplant period, the request for research consent can be difficult if emotional factors are not considered[18].

Another issue is the feasibility of the research consent for research teams[1,8]. For example, one organ donor participating in a clinical trial may donate a heart, two lungs, a liver, two kidneys, a pancreas etc..., each of which may, in theory, travel to different transplant programs, cities and even provinces for transplantation. With various possible methods of connecting with transplant recipients about their consent to share their data for donation research, it is difficult to coordinate discussions when different jurisdictions may have different research ethics board (REB) requirements[1,8]. Additionally there is a lack of awareness of different studies by transplant teams, allowing for missed opportunities for recruitment. And finally, research consent discussions can be time consuming, which may not be possible in high acuity environments (i.e., an intensive care unit)[18].

One solution that has been proposed for some types of low-risk research, is opting for participation without discussion – a "waiver" of research consent[7]: however, it is difficult to justify an arbitrary threshold for this 'low risk' situation. It is also possible that a more general discussion, rather than a detailed one, would appeal to research participants[28]. In an analogous situation with biobanking research, recent publications have reported that people who have donated to a biobank, or substitute decision makers who have consented on their behalf, both prefer consent models that strike a balance between some measure of control over what type of research is done with their tissues and the convenience of not having to provide consent to every individual project[29]. However, this concept has not been explored in the context of solid organ donation.

Thus, clinical trials in organ donation continue to face unique ethical challenges as uncertainty surrounds which consent models would best strike a balance between study design and preferences of the participant population of interest.

Organization of Thesis

Chapter 1 presented an introduction and background content to the thesis.

Chapter 2 presents the first study, a meta-synthesis systematic review on knowledge and attitudes towards opt-out consent. This study has been submitted for publication.

Chapter 3 presents the second systematic review. This review focuses on quantitative outcomes of opt-out consent. This study and the study in chapter 2 represent updates to a prior review published by Rithalia et al. in 2009 and has been circulated for feedback from co-authors.

Chapter 4 presents the third study, which is a qualitative exploration of transplant recipients' views on organ donor research and their preferences related to use of their data in this research. This study has already been published in a peer reviewed journal.

Chapter 5 is a discussion of these works, their methodological challenges, and conclusion for this thesis.

1.2 Summary

This chapter has highlighted some selected issues that have been identified as barriers to increasing the number of potential solid organ donors in Canada. It has outlined current understanding of the differences in research consent requirements throughout the country as well as the relative lack of evidence provided justifying large scale legislated changes to consent to donation. This thesis provides further exploration of these issues and takes steps to address knowledge gaps/ misconceptions that might affect outcomes related to consent within these different contexts.

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CHAPTER 2

A Systematic Review of Knowledge and Attitudes Towards Opt-Out Consent in Deceased Organ Donation

Chapter 2. A Systematic Review of Knowledge and Attitudes Towards Opt-Out Consent in Deceased Organ Donation

2.1 Preamble for Chapters 2 and 3

Chapters 2 and 3 are both systematic reviews. Originally, I sought to update an older review by Rithalia et al from 2009. The outcomes of the original review included knowledge and attitudes towards opt-out consent and outcomes related to quantitative metrics of success of this model. I reasoned that these outcomes were too dissimilar to be conducted as one systematic review and opted instead to conduct two reviews and present them separately. I also broadened the scope of the studies by including qualitative evidence in the first review.

The decision to conduct two separate systematic reviews occurred after the literature search was completed. Thus, the search terms and the initial body of literature identified for the two reviews were identical, as were the title and abstract screening procedures. Following full text screening, the reviews were separated. The PRISMA diagram for both reviews appear identical until this stage, but differ upon removal of studies not of interest to the individual review.

2.1.1 Opt-out consent in deceased organ donation

The opt-out model of consent has been touted as a solution to deceased organ donation rates that continue to be outpaced by their need for transplantation. Opt-out consent refers to a system in which individuals are presumed to consent to organ donation unless they have explicitly declared they do not wish to do so through a formal registry or in conversations with SDMs. Evidence illustrating the success of this system is unclear on various organ donation

outcomes, including knowledge and attitudes towards opt-out consent, and on the number of organs eventually available for transplantation.

2.1.2 Concerns about opt out consent

Presuming consent in the opt-out system has raised concerns that it ignores individuals' right to autonomy in the decision-making process. Concerns have also been raised about lack of ensuring true informed consent due to poor public knowledge of the model. In January of 2021, the Province of Nova Scotia changed legislation and adopted opt-out consent for deceased organ donation. They did so without prior assessment of public perception to this change, which could have disastrous consequences to the organ donation system overall.

These disastrous effects on the organ donation system have been observed in other countries, such as Chile and Brazil, where implementation of opt-out consent failed and resulted in fewer organ donors and high opt-out rates. Numerous studies conducted over multiple decades report varying results on organ donation rates. Thus, another concern about the opt-out system relates to its long-term effects on the number of organs available for transplantation.

2.1.3 Objectives for Chapter 2

The study described in Chapter 2 is a meta-synthesis systematic review aiming to:

1. Describe level of knowledge of different populations about opt-out consent
2. Describe attitudes of different populations towards opt-out consent

2.2 A Systematic Review of Knowledge and Attitudes Towards Opt-Out Consent in Deceased Organ Donation

2.2.1 Full citation:

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2.2.3 Abstract

Background: The opt-out consent model has been proposed as a solution for increasing the number of donated solid organs available for transplantation. In January 2021, the province of Nova Scotia changed legislation and adopted this model, being the first jurisdiction in North America to do so.

Objectives: To assess knowledge and attitudes towards the opt-out consent model in deceased organ donation.

Data Sources: Medline, Embase, CINAHL, Psychinfo, and PAIs International were searched from inception to 2019 without restrictions for language or study methodology. A second search using the same terms was conducted from 2019 to May 2023.

Study Selection: Two reviewers independently screened search results and included all qualitative and quantitative studies that reported on knowledge and attitudes towards opt-out consent.

Data Extraction: Two reviewers independently extracted data and assigned risk of bias using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) Risk of Bias in Cross-Sectional Surveys of Attitudes and Practices tool for quantitative studies and the Critical Appraisal Skills Programme Qualitative Research Checklist (CASP) tool for qualitative studies.

Data Synthesis and Analysis: To synthesize data, we used a convergent qualitative meta-integrative methodology. Two reviewers transformed quantitative data to qualitative data by conducting a content analysis of descriptive results from quantitative studies. Both reviewers used a mindful comparison process involving repeated cross-checking to confirm and develop

final themes together. A narrative synthesis presents findings according to these themes. We assessed certainty of evidence for each review finding (theme) using GRADE-CERQUAL (Confidence in the Evidence from Reviews of Qualitative Research) domains.

Results: There were 5180 titles identified for screening in the first search and 1005 for the second (total 6185). This resulted in 79 publications eligible for inclusion in the review. Among these were 60 quantitative studies and 19 qualitative studies. All age groups were represented among a range of diverse populations. Three themes emerged from the thematic analysis. These were (i) general knowledge and/or personal support for opt-out consent; (ii) the importance of societal, religious, and cultural contexts; and (iii) the need for stakeholder engagement. Certainty of evidence was low in all findings.

2.2.4 A Systematic Review of Knowledge and Attitudes Towards Opt-Out Consent in Deceased Organ Donation

Introduction

Organ donation and transplantation is an essential part of Canadian healthcare, yet national deceased organ donation rates have been relatively static, particularly in the province of Nova Scotia[1,2]. In this province, lack of donation activity has led to longer wait times and poorer outcomes for patients on a transplant waiting list when compared to other Canadian provinces[1]. To address this issue, on January 18, 2021, Nova Scotia enacted legislation to adopt opt-out consent for organ donation, becoming the first jurisdiction in North America to do so[3].

Opt-out consent is a process whereby an individual is assumed, at their death, to consent to organ donation for transplantation unless they have explicitly pre-declared their wish not to, either on an organ donation registry or by communicating wishes with substitute decision makers (SDMs) [4]. While common in certain regions, including most of Western Europe, this differs from the traditional process in Canada, in which explicit consent (from a legal SDM) must be sought when an individual is eligible to be an organ donor, at the time of brain death or prior to withdrawal of life support[4].

Survey data suggests most Canadians support organ donation[5], yet only 32% of those eligible, pre-register intent to donate upon their death[6]. As in the Canadian Province of Nova Scotia, some countries have implemented the opt-out consent to donate system as a means to increase donation rates[7-10]. However, the complexity of such systems makes it difficult to evaluate the impact of this change in isolation of other health system factors[11-15]. To illustrate this difficulty, recent systematic reviews evaluating different metrics of success of the opt-out

model, like donation rates and knowledge and attitudes toward the donation system, are inconclusive[7-10]. Critics of this system offer views that regardless of its potential to increase donation rates, opt-out consent ignores autonomy of individuals and is unethical[16-22].

As part of a group of studies aimed at evaluating the impact, potential or actual, of opt-out consent in Nova Scotia by members of the Legislative Evaluation: Assessment of Deceased Donation Reform Consortium[1], we sought to understand various populations' knowledge and attitudes toward opt-out consent. To this end, we conducted a mixed methods systematic review of the global literature.

Methods

The study protocol is registered with Prospero[23] (CRD4202013922) and follows PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines[24]. This review represents an update to a similar systematic review from Rithalia et al[9]. Our intended outcome was to synthesize the data on knowledge and attitudes towards the opt-out consent model in organ donation.

Literature Search. A medical librarian (JY) assisted with a systematic search of multiple search engines (Embase, MEDLINE, CINAHL, PsycINFO), duplicating the search terms of Rithalia et al.[9] (Appendix A). We also examined reference lists of included studies and other relevant systematic reviews to find titles previously overlooked. A second search to update this work includes studies published up to May, 2023.

Study Selection. This review includes studies from all jurisdictions and languages that assessed knowledge about and/or attitudes toward opt-out consent. We considered any quantitative

(e.g., cross-sectional surveys) and qualitative (e.g., interview, focus group) methodologies, as well as mixed methodologies.

Following calibration exercises, pairs of reviewers (AL with MC, AG, or MW) conducted title and abstract screening, full article selection, data abstraction, and quality assessments. Disagreements during calibration exercises underwent a third independent review, as needed.

Data Extraction and Quality Assessments. The data extraction sheet included sections for both quantitative and qualitative data. Abstracted data included study identification, objectives, countries involved, design and methodology, population demographics, and findings.

We used the Critical Appraisal Skills Programme Qualitative Research Checklist (CASP) to appraise qualitative studies[25]. This is a widely accepted qualitative evidence assessment for international guideline processes[26]. The instrument assesses research aims, appropriateness of qualitative methodology, research design, recruitment strategy, data collection, relationship between the participants and the researcher, ethical considerations, data analysis, findings, and research value[25]. We rated studies as having serious methodological limitations if there were concerns with more than two items and we rated studies as having moderate methodological limitations if there were concerns with two or less items.

We used the GRADE (Grading of Recommendations Assessment, Development and Evaluation) Risk of Bias in Cross-Sectional Surveys of Attitudes and Practices tool to evaluate risk of bias of individual quantitative studies[27]. This assesses the representativeness of a study, adequacy of response rate, amount of missing data, clinical sensibility, and evidence of reliability and validity of survey instruments. Reviewers rated studies as having a high risk of bias if there was no or unclear evidence that a survey instrument had been tested for validity or

reliability. We rated studies at a moderate risk of bias if the instrument was validated but had two or more items with high risk of bias.

Data Synthesis and Analysis. We conducted a data-based convergent qualitative synthesis as described in Frantzen and Fetters, 2015[28] and Pluye and Hong, 2017[29] (figure 1). This process began with categorizing studies into sources of data (quantitative and qualitative) to provide an overview of the research[28].

Next to transform data from quantitative studies into qualitative data, we performed a qualitative content analysis. Analysis and integration of newly qualitized data (formerly quantitative data) and data from qualitative studies occurred in parallel through mindful comparison, a "process of conscious and intentional consideration of the findings, commonalities, and differences" (p. 2265)[28]. Two reviewers (AL and AG or DL) implemented this process through continuous "cross-checking, connecting, and co-informing each other" (p2267)[28] to produce an integrated final qualitative synthesis based on results from all eligible studies. Reviewers organized and reported the evidence narratively, beginning with an overview of the data followed by themes with concordant findings from the integrated synthesis[28,30]. This type of qualitative synthesis does not include a statistical analysis of the quantitative findings. We do not provide a quantitative synthesis of the quantitative data. Figure 1 provides a graphical representation of the data synthesis and analysis.

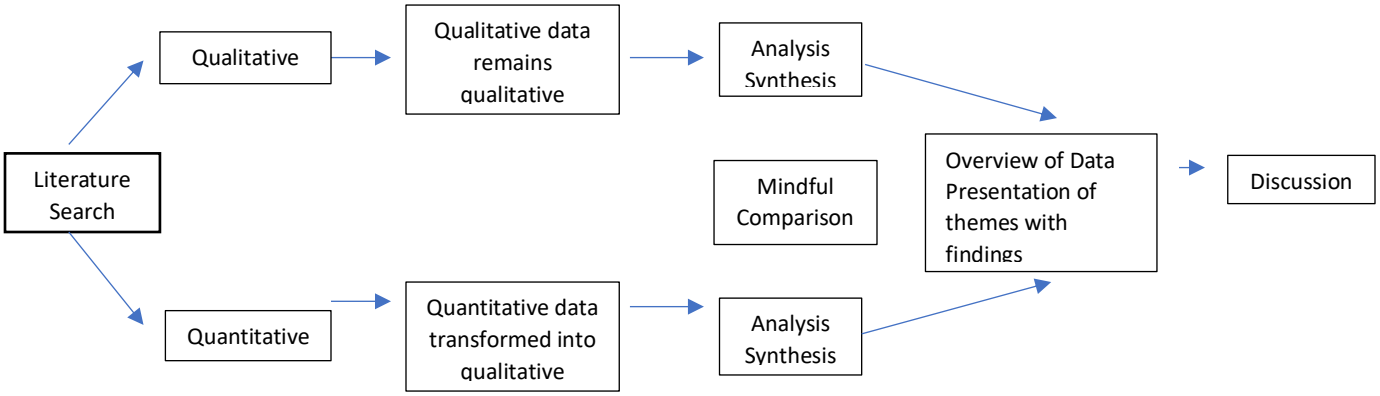

Figure 1: Methodology graphic (adapted from Frantzen and Fetters, 2015[28] and Pluye and Hong, 2014)

As a new and final step, we evaluated the certainty of evidence for each of our findings in this review. Certainty of evidence relates to the confidence in our findings that derive from all of the studies contributing to that finding. Specifically, we used the GRADE-CERQual approach (Confidence in the Evidence from Reviews of Qualitative Research) based on the domains of methodological limitations (concerns about study design)[31]; relevance (applicability of the evidence)[32]; coherence (degree of fit of the evidence to the review finding)[33]; and adequacy (degree of richness and quantity of the data supporting a review finding)[34],[35,36]. Confidence was rated from very high to low, with rating down occurring by one or more levels if there were serious or more than one minor or moderate methodological concern identified in at least one domain.

While assessing confidence in the findings, we identified a limitation of the GRADE CERQual instrument. Specifically, there exists overlap between the domains, particularly in findings that included evidence from quantitative studies in which risk of bias assessments had identified issues that fell within the methodological limitations domain and also fell within the

coherence, relevance, and adequacy domains. To avoid rating down confidence level twice from overlap of similar concerns, we did not rate down in the methodological limitations domain based on factors related to population representativeness or indirectness (relevance), cohesiveness or inconsistency of the data (coherence), or degree of richness or imprecision of the data (adequacy).

Results

There were 5180 titles identified for screening in the first search and 1005 for the second. This resulted in 79 publications eligible for inclusion in the review (Figure 2).

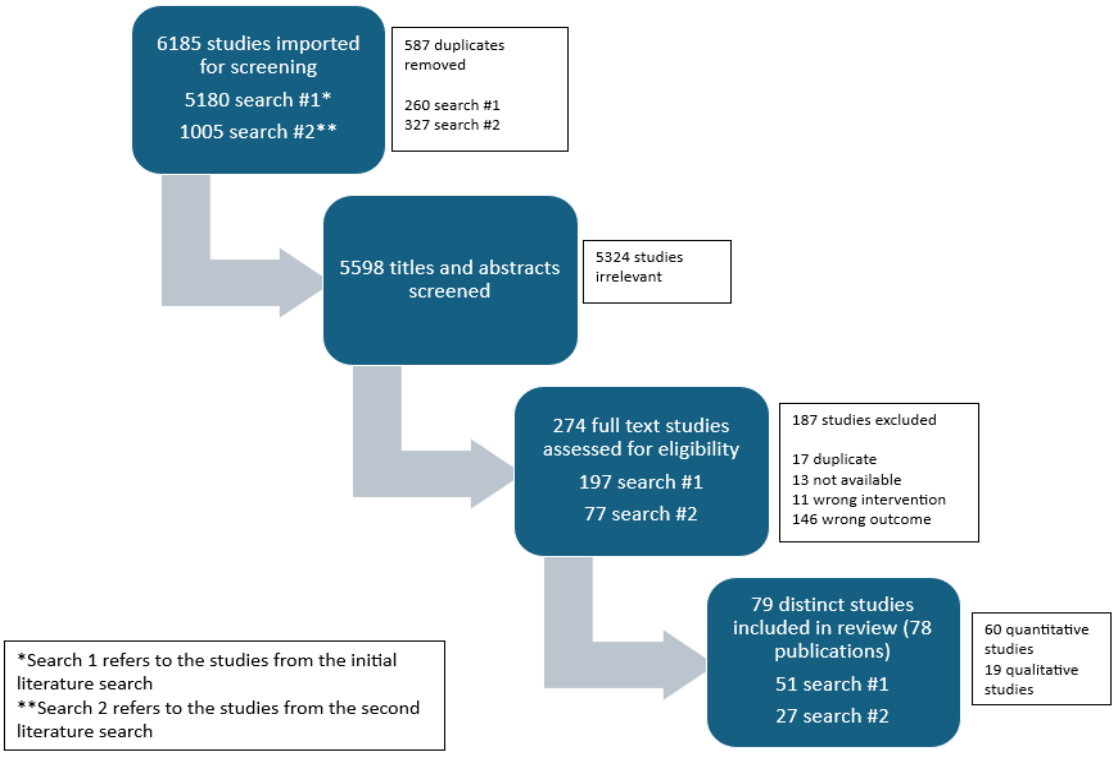

Figure 2. PRISMA diagram

Overview of the studies. Table 1 provides a detailed description of the 19 qualitative[15,20-22,37-51] and 60 quantitative studies[17-19,37,52-107] included in this review. One study includes a quantitative analysis of survey responses and a qualitative analysis of responses to free-text responses, which was treated as two separate studies[37]. Three studies were available as conference or poster abstracts only[55,56,57].

First Author Year (N)	Country	Primary Focus	Data Methods	Sampling	Analysis	Main Results	Risk of Bias/ Methodologic Limitations
Studies of the Public							
Qualitative designs							
Bailey[28] 2021 (33)	United Kingdom	Views on opt-out legislation	Semi-structured interviews	Purposive, convenience	Thematic analysis	Need to ensure public aware of evidence of impact of opt-out consent, media campaigns should focus on impact of organ donation	Moderate
Irving[39] 2012 (114)	Australia	Attitudes and perspectives on deceased organ donation consent systems	Focus groups	Convenience sample of participants registered with market research company	Qualitative analysis with grounded theory approach	Participants held beliefs that encouraged donation and discouraged donation, these were influenced by many factors, there is need for a simpler consent system	Moderate
Kurzen[20] 2021 (15)	Switzerland	Perceptions of different organ donation policies	Semi-structured telephone interviews	Convenience sample of people in public spaces	Thematic analysis	Participants concerned with individual rights and no consent system is perfect	Serious
Miller[40] 2019 (1202)	Scotland, England, Ireland	Reasons for donor choices for different consent actions	Online questionnaire with free-test responses	Convenience sample from online invitations on university website and social media	Thematic analysis	Explicit choice is important, opt-out consent may be ambiguous but may be more pragmatic	Serious
Miller[21] 2020 (15)	Scotland, England	Attitudes towards opt-out consent amongst people who plan to opt-out	Semi-structured telephone interviews	Purposive sample of those who would register opposition to organ donation	Thematic analysis	Barriers to organ donation under opt-out consent are related to government mistrust and threat to personal autonomy	Moderate
Hyde[37]* 2021 (509)	Australia	Knowledge on perspectives on consent systems	Online survey with free-text responses	Convenience sample through crowdsourcing platform and University faculty distribution list	Thematic analysis	Individual choice is important, family override should not be permitted, family involvement is important if donor decisions unknown, maintaining a donation registry is important and should be convenient	Serious
Media Content Reviews (Qualitative)							
Dallimore[46] 2018 (60 texts)	Wales	Influence of media on public attitudes toward presumed consent	Media content analysis	Purposive	Summative content analysis	The media and the state are interdependent, media is not uncritical and can influence policy. This may reflect public attitudes, which were more positive toward opt-out over time	Serious
Faherty[47] 2022 (286 stories)	England	Responses to media about presumed consent in year prior to change in legislation and year afterwards	Media content analysis	Purposive	Summative content analysis and thematic analysis	Portrayal in media of organ donors as special unlikely to normalize donation, undermining public concerns can alienate underrepresented groups. There is lack of trust from public.	Serious

Fox[48] 2022 (35 stories)	Canada	Viewpoints on opt-out consent	Media content analysis	Purposive	Qualitative description	There were positive and negative perceptions about opt-out, improving government transparency and communication of evidence for proposed changes is essential	Serious
Grigoras[49] 2010 (8572 posts)	Romania	Opinions of opt-out consent	Media content analysis	Purposive	Lists of pros and cons of proposed opt-out initiative	The list of cons related to opt-out prevailed	Serious
Marcon[51] 2022 (2337 comments)	Canada	Response to legislative changes on Facebook in Nova Scotia	Media content analysis	Purposive	Thematic content analysis	New legislation was controversial, topics included power, autonomy, government authority, religion, altruism, policy options	Serious
Marcon[50] 2021 (2663 comments)	Canada	Comments on articles published on a national network on deemed consent	Media content analysis	Purposive	Directed content analysis with descriptive qualitative analysis	Substantial issues of trust in government and healthcare system were evident, more negative comments than positive	Serious
Quantitative designs							
Al-Qerem[58] 2022 (404)	Jordan	Knowledge and attitudes towards organ donation	Online questionnaire	Convenience through social media and public website invitation	Exploratory factor analysis	15% aware of opt-out system	Moderate
Asai[56] 2018 (1500)	Japan	Attitudes towards different social incentive models	Internet survey	NR	Frequency/proportions of responses	23% supported opt-out system	High
Bacusca[95] 2022 (440)	Romania	Predictors of organ donation and transplantation rates	Survey	3-stage probability sampling technique (source not reported)	Tests of association, tests to assess differences between groups	23% supported opt-out system	Moderate
Chan[59] 2013 (802)	Hong Kong	Impact of presumed consent on kidney donation	Telephone survey	Random digit dialing of every residential telephone number in Hong Kong	Frequency/proportions of responses	73% would donate under an opt-out system	High
Cheung[96] 2018 (203)	Hong Kong	Willingness to donate organs under different consent systems	Telephone survey	Computerized random-digit dialing	Tests to assess differences between groups, tests of prediction	Opt-in system with priority allocation was preferred, willingness to donate decreased under a proposed opt-out system	Moderate
Conesa[17] 2003 (2000)	Spain	Public attitudes to organ donation and impact of presumed consent law	Questionnaire	Stratified random sampling according to sex, age, region (Source not reported)	Tests to assess differences between groups, tests of prediction	24% of agreed with opt-put law	High
Costa-Font[52] 2021 (51313)	28 countries of the European Union (Malta not included)	Effects of presumed consent with family consent on willingness to donate	Secondary analysis of pooled samples from 3 years serial surveys	Multi-stage random sampling	Tests of association, tests of prediction	Opt-out consent increases willingness to donate in countries where no family consent required	High
Dundes[18] 1999 (358)	USA	Public support for different models of consent	Telephone survey	Random selection, (Source not reported), convenience	Frequency/proportions of responses	41% supported opt-out consent, 37% supported financial compensation for organ donation	High
Diaz-Cobacho[97] 2022 (813)	Spain	Awareness and attitudes regarding organ donation and transplantation policies	Telephone and internet survey	Convenience sample from existing survey panel, stratified by sex and age	Frequency/proportions of responses	28% of respondents aware of opt-out law, 27% agree with opt-out law, 40% prefer opt-out consent over other models	Moderate

Hammami[98] 2012 (698)	Saudi Arabia	Public attitudes toward various organ donation consent systems	Self-administered questionnaire	Convenience sample of patients attending outpatient clinic in a hospital	Frequency/proportions of responses, tests to assess differences between groups	54% preferred mandated choice model of consent over 11 consent options	Moderate
Hyde[37] 2021* (509)	Australia	Knowledge and perspectives on consent systems	Online survey	Convenience sample through crowdsourcing platform and University faculty distribution list	Tests to assess differences between groups, tests of prediction	52% and 34% designated soft opt-out and hard opt-out respectively as most effective system (14% explicit consent)	High
Jafri[65] 2001 (1556)	USA	Views toward different issues in organ donation	Questionnaire	Convenience sample of high-school students, professionals clergy,	Frequency/proportions of responses	94% professionals, 41% students, 37% clergy favoured opt-out consent	High
Kanyari[69] 2021 (487)	Hungary	Knowledge and attitudes toward different concepts in organ donation	Paper questionnaire	Convenience sample of hospital employees and patients	Frequency/proportions of responses, tests to assess differences between groups	25% and 60% of general practitioners and patients unaware of opt-out system	High
Klenow[71] 1995 (414)	USA	Level of support for different consent models	Postal survey	Systematic random sample using telephone directory as sampling frame	Frequency/proportions of responses, tests to assess differences between groups	13% favored soft opt-out system	High
Lauri[72] 2006 (1200)	Malta	Support for organ donation	Serial survey done at 4 time points	Convenience sample of residents from randomly selected regions	Frequency/proportions of responses, tests to assess differences between groups	18%, 30%, 20%, 22% of respondents supported opt-out in surveys 1,2,3,4 respectively	High
Li[19] 2001 (1018)	Hong Kong	Current attitudes and knowledge about organ donation	Telephone questionnaire	Convenience sample of consecutive blood donors and random telephone numbers of public	Tests to assess differences between groups, tests of prediction	67% disagree with opt-out law	High
Metwally[75] 2020 (2743)	Egypt	Preferences regarding consent options in organ donation	Survey	Convenience sample of patients, staff, and students at 2 healthcare facilities	Frequency/proportions of responses	Opt-out consent was least preferred consent model among 11 options	High
Manninen[73] 1985 (2056)	United States of America	Knowledge, attitudes, and behaviours concerning organ donation	Telephone survey	NR	Frequency/proportions of responses	7% supported opt-out consent, 58% opposed family override	High
Muthiah[101] 2021 (799)	Singapore	Opinions and knowledge of presumed consent	In-person interview survey	Purposive two-stage cluster (based on location) convenience sample	Frequency/proportions of responses, tests of association, tests of prediction	38% and 43% aware of opt-out law and incentives available under law respectively. Awareness associated with willingness to donate	Moderate
Nordfalk[76] 2016 (1195)	Denmark	Attitudes to organ donation	Telephone questionnaire	Convenience sample using market research company	Frequency/proportions of responses	30% supported opt-out consent compared to financial incentives (6%) and mandated choice (64%)	High
Rockloff[80] 2014 (1289)	Australia	Support for opt-out system of consent.	Telephone survey	Convenience sample of randomly selected telephone numbers from previous survey	Frequency/proportions of responses, tests of prediction	59% favour opt-out consent, support of opt-out consent predictive of willingness to donate	High
Roels[83] 1997 (1306)	Belgium	Knowledge and attitudes toward organ donation	Postal survey	Convenience sample of patients in health clinic and their family	Frequency/proportions of responses, tests to assess differences between groups	76% and 88% of young and older respondents respectively would not register opposition under opt-out law	High
Runarsdottir[105] 2014 (880)	Iceland	Attitude toward organ donation and presumed consent	Online survey	Convenience sample of randomly selected individuals on a national polling list	Frequency/proportions of responses, tests to assess differences between groups	80% support opt-out consent	High

Shepherd[53] 2013 (29288)	29 countries of the European Union	How knowledge of opt-out consent affects attitudes towards it	Secondary analysis of survey	Multi-stage random sampling	Frequency/proportions of responses, tests to assess differences between groups	Proportion of people willing to donate organs did not differ between countries with opt-in or opt out consent. When people aware of legislation, willingness to donate was greater in opt-out countries	Low
Singh[54] 2021 (724)	Qatar	Opinions about organ donation	Secondary analysis of in-person survey	Stratified (geographical location and household) random convenience sample	Frequency/proportions of responses, tests to assess differences between groups, tests of association, tests of prediction	The majority supported opt-out consent, which was associated with willingness to donate	Moderate
Symvoulakis[87] 2013 (156)	Greece	Awareness and opinions of opt-out legislation	In-person questionnaire	Convenience sample of patients in 2 healthcare practices	Frequency/proportions of responses, tests of association	10% aware of opt-out legislation, 22% intended to register opposition	High
Symvoulakis[106] 2019 (203)	Greece	Role of self-efficacy in relation to knowledge and attitudes toward organ donation	Prospective survey	Convenience sample of patients in a primary care facility	Frequency/proportions of responses, tests of association, tests of prediction	34% had discussed opt-out law with family, 27% intended to register opposition, self-efficacy not associated with awareness of law	Low
Tumin[91] 2015 (775)	Malaysia	Attitudes toward different models of consent models	Self-administered questionnaire	Convenience sample of public in 4 public spaces	Frequency/proportions of responses, tests of association, tests of prediction	64% would object under opt-out law,	High
Studies of Different Cultural Groups and Other Misc. Populations							
Qualitative Designs							
Noyes[15] 2019 (107)	Wales	Experiences with new organ donation practices and legislation	Interviews and focus groups, questionnaires	Purposive sample of family member of potential deceased donors and organ donor coordinator nurses and managers	Framework approach	Organ donor coordinator role valued by families, media campaign had gaps, opt-out system found to be complex	Serious
Randhawa[22] 2010 (26)	England	Views toward organ donation and opt-out	Qualitative interviews	Purposive sample of faith and belief leaders	NR	The majority supported opt-in consent and felt there is scope to improve the current system rather than changing legislation	Moderate
Urquhart[45] 2023 (11)	Canada	Views on organ donation including presumed consent	Interviews and focus groups	Purposive sample of leaders of under-represented and equity-denied communities in Nova Scotia	Thematic analysis	Leaders of under-served groups are highly supportive of opt-out consent, there is need for cultural competence when implementing this system	Moderate
Studies of Different Cultural Groups and Other Misc. Populations							
Quantitative Designs							
Jindal[67] 2003 (80)	Scotland	Attitudes and knowledge about organ donation and transplantation	Self-administered survey	Convenience sample of Asians recruited via posters and letters (to Asian patients awaiting a kidney transplant)	Frequency/proportions of responses	61% agreed with opt-out consent	High

Johal[68] 2018 (268)	England	Knowledge and opinions about organ donation and consent system	In-person and web-based survey	Convenience sample of Sikhs recruited at local gurdwaras and online via community organizations	Frequency/proportions of responses, tests of prediction	29% had heard of opt-out, 49% understood opt-out, 37% agreed with opt-out, 6% would override wishes	High
Orlic[78] 2001 (114)	Croatia	Attitudes toward kidney donation	Questionnaire	Convenience sample of children recruited at a lecture	Frequency/proportions of responses, tests to assess differences between groups	90%-99% believe it is obligatory to ask for consent	High
Rodrigue[81] 2006 (561)	USA	Attitudes toward different models of consent and predictors of attitudes.	Telephone survey	Non-random, convenience sample of families of potential organ donors recruited at time of donation and on a national website	Frequency/proportions of responses, tests to assess differences between groups, tests of prediction	25% favor opt-out consent, 54% believe family consent not required when wishes documented	High
Siminoff[107] 2000 (453)	USA	Attitudes and beliefs about organ donation systems	United States of America	Convenience sample of white American (WA) and African Americans (AA) through random-digit dialing (Source not reported)	Frequency/proportions of responses, tests to assess differences between groups	28% AA and 21% WA agree with opt-out consent, 43% AA and 13% WA agree with an incentive model	Low
Tumin[72] 2016 (829)	Malaysia	Perspectives on organ donation and opt-out consent	Self-administered questionnaire	Convenience sample of Muslims recruited in 3 public spaces	Frequency/proportions of responses	43% were not willing to donate, 17% would register an objection under opt-out system	High
Studies of Healthcare Professionals							
Qualitative Designs							
Becker[41] 2020 (17)	Austria, Germany, Spain, United Kingdom	Opinions on organ donation concepts	Semi-structured interviews	Purposive sample of experts in national organ donation systems	Qualitative content analysis	An opt-out system alone is insufficient to increase donation rates	Serious
Boyarsky[42] 2012 (15)	Poland, Hungary, Sweden, Slovenia, Cyprus, Czech Republic, Norway, Austria, Italy, France, Belgium, Portugal, Spain	How different organ donation practices affect organ donation rates	Semi-structured telephone interviews	Purposive and snowball sample of medical experts in European countries	Thematic content analysis	Since donation practices do not differ dramatically between countries, opt-out alone is unlikely to increase donation rates	Moderate
Lauri[43] 2010 (5)	Malta	Attitudes toward the opting-out system.	Interviews	Purposive sample of physicians	Thematic analysis	Since refusal rate for donation is low in Malta, opt-in policy should be retained	Moderate
Neades[44] 2009 (42)	Portugal, Norway, Belgium	Experiences with opt-out legislation.	Semi-structured interviews	Purposive sample of healthcare workers	Phenomenology	Frequent public education is vital to achieving sufficient donation, exclusion of families in the process could be detrimental	Moderate
Quantitative Designs							
Grenier[63] 2011 (889)	USA	Perceptions, attitudes, and ethical values regarding organ donation	Postal questionnaire	Convenience sample of medical personnel from a professional association	Frequency/proportions of responses	50%, 46%, 45%, 37% of emergency room physicians, neurosurgeons,	High

				membership list and nursing staff lists		registered nurses, medical doctors respectively support opt-out consent	
Janssens[66] 2018 (1019)	Germany	Level of support for different models of consent.	Online survey	Convenience sample of healthcare personnel via online invitation	Frequency/proportions of responses	76% supported opt-out consent	High
Kiel-Puslecka[70] 2022 (69)	Poland	Knowledge of legal concepts in organ donation	Questionnaire	Convenience sample of 50 lawyers and 50 physicians (source not reported)	Frequency/proportions of responses, tests of association, tests of prediction	Knowledge of the opt-out law was average in both groups	High
Mar Lomero[99] 2017 (146)	Spain	Knowledge and attitudes about organ donation	Survey	Convenience sample of healthcare staff at one institution	Frequency/proportions of responses, tests of association, tests to assess differences between groups, tests of prediction	56% of respondents demonstrated knowledge of the opt-out law, willingness to donate was associated with favour of the opt-out law	Moderate
Sah[84] 2022 (221)	Nepal	Perception of presumed consent	Descriptive paper-based questionnaire	Purposive sample of healthcare professionals	Frequency/proportions of responses	Frequency of responses expressed as 91% of respondents support opt-out consent	High
Seetharaman [85] 2020 (532)	India	Knowledge, attitudes, and beliefs on concepts in organ donation.	Survey	Convenience sample of medical doctors and medical interns at one facility	Frequency/proportions of responses, tests to assess differences between groups	30% and 50% of doctors and students respectively are aware of the law, 41% and 51% of doctors and students respectively agree with opt-out law	High
Siddiqui[86] 2019 (120)	Singapore	Opinions about issues in an opt-out system	Online survey	Convenience sample of intensivists recruited from medical association list	Frequency/proportions of responses	63% of respondents have knowledge of the law, 51% believe it has been successful, 78% believe it is a practical law	High
Smulda[89] 2012 (282)	Hungary	Attitudes and knowledge of organ donation and transplantation	Self-administered survey	Convenience sample of healthcare staff in university hospitals at an education course	Frequency/proportions of responses, tests to assess differences between groups, tests of prediction	Most respondents knew about opt-out legislation, 91% of respondents agreed with opt-out consent	High
Tumin[93] 2019 (382)	Malaysia	Knowledge and attitudes toward presumed consent and potential influencing factors	Self-administered questionnaire	Convenience sample of healthcare personnel in a medical center	Frequency/proportions of responses, tests to assess differences between groups, tests of prediction	46% of respondents would register opposition under opt-out consent	High
Urquhart[57] 2023 (211)	Canada	Knowledge, attitudes, and experiences with organ donation and transplantation	Online survey	Convenience sample of primary care providers in Nova Scotia	Frequency/proportions of responses	84% supported opt-out legislation	High
Urquhart[94] 2023 (194)	Canada	Views of opt-out consent for organ donation	Electronic survey	Convenience sample of nurses in Nova Scotia	Frequency/proportions of responses	89% supported opt-out consent, 13% viewed opt-out as a violation of freedom and autonomy	High
Weiss[102] 2020 (249)	Canada	Attitudes and knowledge towards opt-out consent and other organ donation concepts	Online survey	Convenience sample of intensivists from national membership list	Frequency/proportions of responses	61% supported opt-out legislation, 77% believed it would increase donation rates	Moderate
Studies of Students							
Quantitative							

Alderman[55] 2018 (749)	England	Views regarding opt-out consent	Online questionnaire	Convenience sample through email university list	Bar graphs and tests of association	Registered organ donors more favourable towards opt-out system	High
Connelly[60] 2013 (263)	Scotland	Attitudes on current organ donation system	Online survey	Convenience sample of students in one institution	Frequency/proportions of responses, tests to assess differences between groups	79% of respondents support implementation of opt-out consent	High
Cornwall[61] 2015 (180)	New Zealand	Knowledge of organ donation	Paper and online questionnaire	Stratified random convenience sample of students in public spaces	Frequency/proportions of responses	72% of respondents believe consent should be opt-in, 42% of respondents believe consent should be opt-out	High
Goh[62] 2013 (294)	Singapore	Knowledge and attitudes toward organ donation	Self-administered paper-based questionnaire	Convenience sample of students in a lecture hall	Frequency/proportions of responses	91% of respondents aware of opt-out law, 45% of respondents aware of processes of law	High
Healy[64] 2009 (1103)	Ireland	Opinions on potential changes in organ donation consent regulation	Serial survey over 3 years	Convenience sample of university students	Frequency/proportions of responses, tests of association	62% of respondents in favour of opt-in consent, 32% of respondents in favour of opt-out consent	High
Martinez-Alarcon[74] 2010 (129)	Spain	Knowledge of organ donation concepts	Self-administered questionnaire	Convenience sample of journalism students in class	Frequency/proportions of responses, tests of association	75% of students opposed opt-out law	High
Martinez-Alarcon[104] 2020 (17786)	Spain	Attitudes toward the opt-out law	Self-administered questionnaire	Convenience sample of medical and nursing students from a multisite database	Frequency/proportions of responses, tests of association	66% of respondents were against the law, 48% saw it as an abuse of power	Low
Martinez-Alarcon[103] 2019 (2558)	Spain	Attitudes toward opt-out law	Self-administered questionnaire	Convenience sample of veterinary students from a multisite database stratified by geographic area and year of study	Frequency/proportions of responses, tests of association	63% of respondents opposed opt-out law	Low
Molina-Perez[100] 2022 (2193)	Austria, Belgium, Denmark, Germany, Greece, Romania, Slovenia, Spain	Awareness and attitudes towards organ donation	Comparative survey	Convenience sample of students	Frequency/proportions of responses, tests of association, tests to assess differences between groups	Participants in favour of harmonization of opt-out system (across countries in study), awareness of role of family better in opt-in countries	Moderate
Nowak[77] 2014 (800)	Poland	Knowledge and attitudes toward consent models	Questionnaire	Convenience sample of medical and non-medical students in 4 universities	Frequency/proportions of responses	73% of medical students and 30% of non-medical students aware of opt-out consent, 82% of medical students and 69% of non-medical students support opt-out consent	High
Qian[79] 2022 (523)	USA	Support for opt-out and priority consent systems	Web-based survey	Convenience sample of healthcare students in one center recruited through email, posters, social media, and verbal announcements	Frequency of responses expressed as proportions of sample, tests of association	98% of respondents supported opt-out consent, which was associated with higher knowledge of opt-out	High

Rodrigues-Arias[82] 2021 (2006)	Austria, Belgium, Denmark, Germany, Greece, Slovenia, Spain	Beliefs and views on consent policies	Online survey	Convenience sample of students recruited via emailed invitation, flyers displayed in public spaces	Frequency/proportions of responses, tests of association, tests of prediction	High rates of willingness to donate and preference for opt-out consent, higher awareness in opt-in countries	High
Spital[90] 1992 (208)	USA	Acceptance of different methods of consent	In-person paper-based survey	Convenience sample of university students waiting for a medical appointment on campus	Frequency/proportions of responses, tests of association	62% of respondents support opt-out consent, 90% of respondents support mandated choice, 87% of respondents opposed family override	High
Stadbauer[88] 2013 (2025)	Knowledge of the law and attitude toward legislation	Online and paper-based questionnaire	Austria	Convenience sample of students through invitations sent to university email accounts	Frequency/proportions of responses, tests to assess differences between groups	84% of respondents knew the opt-out law, 74% support the opt-out law	High

*treated as two separate studies

Table 1. Summary of studies in the review

Qualitative Studies. Of the 19 qualitative studies[15,20-22,28,37,39-51], 11 used one-on-one interviews and/or focus groups[15,20-22,28,39,41-45], two reported on analysis of free-text survey responses[37,40], and 6 undertook media content analyses[46-51] (i.e., qualitative analysis of online mass media content). Analytic approaches included inductive thematic analysis[20,21,28,37,40,42,43,45,51], qualitative content analysis[41,48,50], summative analysis[46,47], phenomenology[44], grounded theory[39], and step-by-step framework approach[15]. One interview study and one media content analysis did not report an analytic approach[22,49].

Serious methodological limitations were judged in 13 qualitative studies[15,20,22,37,40,41,43,46-51] and 6 were judged to have moderate methodological limitations[21,38,39,42,44,45]. This was primarily due to lack of reporting of a possible relationship between the researcher and study participants, lack of reporting of appropriateness of research methods, and lack of reporting of ethical considerations (Appendix B).

Quantitative Studies. All 60 quantitative studies[17-19,37,52-107] were cross-sectional surveys or questionnaires including three secondary analyses of other surveys. Analysis methods varied and included counts and/or proportions of frequency of survey responses, statistical analyses assessing associations between groups, prediction of survey responses, and reliability assessments (table 1). Very few studies reported any formal assessments of the comprehensiveness, clarity, and face validity of survey instruments. These were judged to lack clinical sensibility in the populations studied.

Based on methodological limitations of quantitative studies related to representativeness of samples, clinical sensibility, and established reliability or validity of survey

tools, we gauged a high risk of bias in 44 studies[15-19,5255-57,59-94], moderate risk of bias in 9 studies[54,58,95-102], and low risk of bias in 7 studies[53,97,103-107] (Appendix C).

Some studies report results only relevant to knowledge of opt-out consent, some report only on attitudes to opt-out consent, and some studies report both outcomes. For simplicity, we report syntheses of knowledge and attitudes separately**.**

Assessment of knowledge of opt-out consent varied between studies. Nine studies report whether respondents knew which consent system was used in their region[53,68,77,82,85,87-89,94]. Others reported whether respondents had prior knowledge or had heard of the opt-out system[58,68,86,97]. Five surveys tested understanding of the opt-out system by asking respondents to verify statements related to application of consent law[62,70,99-101].

Additional survey questions attempted to ascertain factors associated with knowledge. These included demographic traits such as age and gender[17,18,37,68,71,762,76,83,90,965,96,98,105]. Some surveys reported respondents' previous experience with organ donation activities[53,63,68,80,82,85,89,101], such as personally knowing or providing care to an organ donor or transplant recipient or whether they had formally registered their intent as an organ donor[18,19,55,56,60,65,73,79,81].

Assessments of attitudes toward opt-out consent also varied. Twenty-three of the surveys reported whether respondents were in favour of opt-out consent (and other consent models) using dichotomous response options[17,19,54,55,57,60, 67,68,70,74,80,83,84,87-89,94,95,100,102-104]. Other surveys asked respondents to compare support of consent models either through willingness to donate under different consent scenarios or by ranking models in order of preference[18,56,59,61,63,65,71,75,76,79,81,82,85,90,92,93,96,97].

A number of studies assessed factors that may contribute to support or opposition of opt-out and other consent systems[17-19,88,96,102-105]. This included attempts to identify demographic traits that may predict support of the opt-out model[17,52,57,65,71,76,79,82,83,92-94,105] and qualitative explorations of reasons underpinning support or opposition[20-22,39,40,44,48-51].

Overview of Study Samples and Designs. Sample sizes ranged between 70 and 51,313 participants in quantitative studies and between 5 and 114 participants in interviews or focus group qualitative studies. Two studies conducted qualitative analyses of responses to free-text survey responses and 6 studies conducted qualitative analyses of internet content.

All ages were represented, including children aged 15-years to the elderly. Samples were composed of the general public or cultural subgroups within the general public, healthcare professionals (HCPs), and students alone. Several studies compared populations, and most were from Europe (42), followed by North America (16), Asia (12), the Middle East (4), and Oceania (4). Appendix D lists each country's consent system included in this review.

Quantitative studies recruited samples through convenience methods, in which invitation to participate occurred electronically via email distribution lists and postings on public websites, in person in public spaces, through postal service, and/or over the telephone. Eighteen studies reported random number sampling and/or stratification techniques[17-19,52,54,59,61,71,73,74,80,95-97,101,104,105]. Response rates was not adequately reported in 32 studies[17,19,37,54-58,60-62,64-66,68-70,72,73,75,77-79,81,82,84,88,94-96,100,102] and the amount of missing data was also not adequately reported in 32 studies[17-19,37,54,56,59-65,67,69,71,73,74,76-78,80-87,95,96].

Many qualitative studies used convenience sampling, in which email invitations or internet advertisements were sent to participants to take part in interviews or focus groups.

Purposive sampling occurred in other qualitative studies, in which selection of participants was based on specific criteria.

Based on primarily European convenience and/or purposive samples, lack of adequate reporting of response rates and missing data, representativeness of samples was gauged to be poor overall.

Findings of the integrated datasets. Three themes were identified from the content analysis approach: (i) knowledge of opt-out consent; (ii) attitudes towards opt-out consent; and (iii) policy concerns and key considerations. No new themes were identified following the updated literature search and review. Themes do not reflect merely a subgrouping of studies, but rather the researchers' integrated perceptions resulting from the synthesis (figure 2). While there were more quantitative studies (all cross-sectional surveys) contributing data to findings, most did not provide detail or reasons for study participant answers (i.e., context for knowledge and attitudes). Qualitative studies filled this gap in detail and provided greater richness to findings.

Theme 1 Findings: Knowledge of opt-out consent

Knowledge and awareness of the opt-out model was limited (moderate confidence). Less than half of the studies reported that 50% or more of their respondents correctly identified the current consent model in their region, or that they had heard of the opt-out model[62,77,82,86,88,89,99]. This indicates that the majority of respondents did not have basic knowledge of opt out consent[68-70,85,87,94,97,101]. Knowledge of specific consent procedures for organ donation was also limited[62,70,77,100,101]. For example, two studies from Singapore reported respondents were unaware of incentives available in their region that grants families of organ donors who do not opt-out compensation for healthcare expenses[62,101]. Incentives were in the

form of direct monetary payment to the donor's family, medical or funeral expense compensation, or charitable donations made in the donor's name. Another study from Poland reported most respondents were unable to identify the process of pre-registering opposition to donation[77].

Generally, greater experience with organ donation activities was associated with greater knowledge of organ donation consent models (moderate confidence). This was seen in several studies of respondents who were HCPs or families of organ donors[53,69,77,82,88,89]. Conversely, knowledge tended to be lower amongst people with less exposure to organ donation activity[69,77,82,88,97].

There were no demographic factors consistently associated with knowledge of the opt-out model (high confidence). Of studies that assessed associations of demographic traits (e.g., age, gender, income level) and knowledge, one[88] reported a statistically significant association with having completed secondary education ($p < 0.05$), another[87] reported people 58 years and older were less likely to be aware of the opt-out law ($p < 0.0028$) and people with gross incomes greater than 10,000 euros/year were more likely to be aware of the law ($p < 0.0032$). One study[89] reported no association between age or profession with knowledge of opt-out consent law.

Three studies[79,99,100] reported significant relationships between respondents' knowledge of their consent system and willingness to donate ($p = 0.013$ and $p < 0.001$ respectively). For example, in one study[53] authors concluded that opt-out consent was linked to increased willingness to donate organs when people were aware of their nation's consent system.

In summary, findings from theme 1 suggest limited knowledge and awareness of the opt-out model. People with greater exposure and experience with organ donation activities have greater knowledge of their region's consent system. There are no demographic factors, that are consistently associated with knowledge of the opt-out system (table 2).

Review finding	Explanation	Certainty assessment with GRADE CERQual					Confidence
		No of studies (quantitative: qualitative)	Coherence	Relevance	Adequacy	Methodological limitations	
Theme 1: Knowledge of Opt-Out Consent							
Knowledge and awareness of the opt-out model was limited (62, 68-70, 77, 82, 85-89, 94, 97, 99, 100, 101)	Some studies reported the majority of respondents had knowledge of opt-out consent (62, 77, 82, 86, 88, 89,99), but overall knowledge of consent was poor (68-70, 85, 87, 94, 97,101). Knowledge of consent procedures was also poor overall (62, 70, 77, 100, 101)	16 studies (16:0)	Minor concerns Findings varied. Most studies reported poor knowledge of consent system for the majority of their sample. In studies that reported greater knowledge (greater than 70% of sample), knowledge of procedures was poor.	Moderate concerns 5 studies directly relevant (represented the public), and 11 studies partially relevant (represented students and healthcare providers)	Moderate concerns Many studies had relatively superficial and/or sparse data for this descriptive finding.	Serious concerns 1 study with minor issues, 3 studies with moderate issues and 12 studies with major issues (high risk of bias due to lack of clinical sensibility and lack of reliability and validity of instruments)	Moderate ⊗⊗◯
Greater experience with organ donation activities was associated with greater knowledge of organ donation consent models (53, 69, 77, 82, 88, 89, 97).	Healthcare providers and families of organ donors had better knowledge of opt-out consent (53, 69, 77, 82, 88, 89). Knowledge was lower amongst people who lacked experience with organ donation (69, 77, 82, 88, 97)	7 studies (7:0)	No concerns	No concerns	Moderate concerns Many studies had relatively superficial and/or sparse data	Serious concerns 2 study with minor issues, 1 with moderate issues, and 5 with major issues (rationale as above)	Moderate ⊗⊗◯
There were no demographic	Age, gender, income level, and education level were generally	7 studies	No concerns	No concerns	No concerns	Serious concerns	High

factors consistently associated with knowledge of the opt-out model (53, 79, 87-89, 99, 100).	not associated with knowledge of opt-out consent, though some studies reported one or more statistically significant associations. (53, 79, 99, 100)	(7:0)				1 study with minor issues, 2 with moderate issues, and 4 with major issues (rationale as above)	⊗◯◯

Table 2. Evidence profile for findings under theme 1

Legend:
Methodological Limitations: "The extent to which there are concerns about the design or conduct of the primary studies that contributed evidence to an individual review finding" (p. 26)[31]
Coherence: "how clear and cogent the fit is between the data from the primary studies and a review finding that synthesizes the data" (p.34)[33]
Relevance: "the extent to which the body of data from the primary studies supporting a review finding is applicable to the context" (p. 52)[32]
Adequacy: "an overall determination of the degree of richness as well as the quantity of data supporting a review finding" (p. 44)[34]

⊗ indicates downgrading
◯◯◯ very high confidence in review finding
⊗◯◯ indicates high confidence in review finding
⊗⊗◯ indicates moderate confidence in review finding
⊗⊗⊗ indicates low confidence in review finding

Theme 2 Findings: Level of support for opt-out consent

Support for the opt-out model was limited (moderate confidence). Support for opt-out consent was reported in ten studies[46,57,60,66,78,84,85,89,100,105]. Another 19 studies however, reported that the majority of respondents did not support this model[17-19,61,63,67,68,71-74,81,86,87,91,95,103,104,106]. Moreover, other consent models were preferred when compared to opt-out consent[56,59,65,75,76,90,92,97,98,107]. Alternative consent models that were used in comparison studies included models that offered incentives to registered organ donors or donors that do not register opposition.

One comparison offered priority allocation of donated organs to people who pre-register as organ donors over people who do not register (in the event they need a transplant in the future). A third comparison model mandated an individual to make a choice regarding organ donation once they have capacity to do so (for example, once they were eligible to apply for a driver's license). Other comparisons were made to explicit/ informed/ opt-in consent and to mandatory/conscripted donation, where the individual is considered a donor regardless of their wishes. Among these options, participants favoured mandated choice, opt-in consent, and incentivized models over opt-out consent[56,65,75,76,90,97,98,107].

People who opposed opt-out consent, did so for ethical reasons (high confidence). In 22 studies, reasons for opposition to opt-out consent was explored. Many respondents expressed concern that opt-out consent was against human rights. This was because they viewed it as a threat to personal autonomy and the right to choose what happens to their body after death[18,19,22,45,47-49,79,83,88,94,103,104]. Other concerns included views that changing from an opt-in

model to an opt-out model diminished the altruistic nature of organ donation, which could negatively affect donation rates[15,22,40,43,47,48].

Some studies reported participants viewed the opt-out model as an abuse of government authority and shifted too much power from the individual to the state[17,18,21,22,40,44,47,49,51,96]. Individuals reported concerns of abuse of authority by the medical system (and healthcare professionals), suspecting that healthcare quality would be diminished or life-saving measures would be withheld to procure organs[19,21,41,44].

People who supported the opt-out model did so because it is practical, and benefits society (low confidence). There were 16 studies that explored reasons for support of the opt-out model. Many study participants thought it was more convenient for people who were willing to donate but had not registered their intent. It facilitated passive consent, which was less bureaucratic and more effective[20,37,40,48,49,50,79,96]. Others thought it would result in fewer wasted organs and benefited the medical system through increasing organ donation rates[22,37,39,48-50,79,102-104]. This could result in reducing costs related to supporting patients on a transplant waiting list[48,49,51].

Many supporters also thought that autonomy was preserved, and the law was fairer because it represented the wishes of a greater portion of the population who support organ donation[37,38,48,50,96]. Many believed that organ donation was a duty and opt-out consent provided an altruistic opportunity to do good for others or save lives through donation[48-50,54,82,96,103].

Those who approve of organ donation tend to also approve of the opt-out model (low confidence). There were twelve studies that reported an association between approval of organ

donation and approval of the opt out model[,54,55,74,76,79-81,93,95,96,103,104]. One study reported that more supportive attitudes were present amongst those who were registered as organ donors[55]. Other studies reported that the proportion of participants who were willing to donate were also in favour of opt-out[52,54,74,82,96,103,104]. One study reported that while 69% of the sample supported organ donation, 80% were willing to do so if under an opt-in model[95].

There were no demographic factors that were consistently associated with support or opposition to the opt-out model (moderate confidence). In three studies, opt-out was most acceptable to a greater proportion of survey respondent who were younger[18,71,91]. Conversely, one study reported participants in younger age groups in their sample were more opposed to the model[76].

Several studies assessed the association with religion and/or political ideologies, with varying results. One study reported that respondents who trusted their government (versus those who did not) were more likely to donate under and opt-out system (adjusted odds ratio=2.590; 95% confidence interval=1.02-6.55)[96]. Two studies reported that respondents who identified with liberal views preferred the opt-out model compared to those who identified with conservative or neutral political views[96,97]. Three studies reported more religious respondents opposed the opt-out model[75,77,93]. Conversely, another study reported no association between religion and support or opposition to the model[104].

Findings of theme 2 suggest that while the opt-out model is not broadly supported, those who do support it are also more supportive of organ donation overall. People that support this model tend to do so because it is convenient and good for society. People who

oppose this model, do so because they consider that it is unethical and interferes with personal autonomy (table 3).

Review finding	Explanation	Certainty assessment with GRADE CERQual					Confidence
		No of studies (quantitative: qualitative)	Coherence	Relevance	Adequacy	Additional Methodological Limitations	
Theme 2: Level of Support for Opt-Out Consent							
Support for the opt-model was limited (17-19,46, 56, 57, 59, 61, 63-69, 71-76, 78, 81, 84-87, 89-92, 94, 95, 97, 98, 100, 103-107)	Many studies reported support for opt-out consent among some participants (45, 57, 60, 66, 78, 84, 85, 89, 100, 105), but most people were opposed (17-19, 61, 63, 67 68, 71-73, 74, 81, 86, 87, 91, 95, 103, 104, 106). Other consent models were generally preferred over opt-out (56, 59, 65, 75, 76, 90, 92, 97, 98, 107) among XX that assessed for this.	40 studies (38:2)	Minor concerns Findings varied. Few studies reported that greater than 70% of the sample supported opt-out consent; the majority reported less than 50% supported opt-out.	No concerns	No concerns	Serious concerns: 5 studies with minor issues, 4 with moderate issues and 31 with major issues (high risk of bias due to lack of clinical sensibility and evidence of reliability and validity of instrument [quantitative] and/or overall methodological limitations due to lack of consideration of relationship between researcher and participants and/or other ethical concerns [qualitative])	Moderate ⊗⊗◯
People who opposed opt out consent did so for ethical reasons (15, 17-19, 21, 22,	Some were concerned that opt-out was a threat to bodily autonomy (18, 19, 22, 45, 47-49, 79, 83, 88, 94, 103, 104). Some were concerned opt-out would negatively affect donation rates (15, 22, 40, 43, 47, 48). Some viewed it as an	22 studies (12:10)	No concerns	No concerns	No concerns	Serious concerns 2 studies with minor issues, 4 with	High ⊗◯◯

40, 41, 43-45, 47-49, 51, 79, 83, 88, 94, 96, 103, 104)	abuse of government and healthcare authority (17-19,21, 22, 40, 41, 44, 47, 49, 51, 96)					moderate issues, and 16 with major issues (rationale as above)	
People that supported the opt-out model perceived that it is practical and benefits society (20, 22, 37-40, 48-51, 54, 76, 79, 82, 96, 102-104)	Some perceived opt-out facilitates organ donation (20, 37, 40, 48-50, 79, 96) and benefits the healthcare systems by increasing donation rates (22, 37, 39, 48-50, 79, 102-104) and reducing costs (48, 49, 51). Many viewed opt-out consent preserved autonomy in decision making (37, 38, 48, 50, 96) and it was a civic duty to save lives through donation (48-50, 54, 76, 82, 96, 103).	18 studies (10:8)	Moderate concerns Patterns identified based on evidence that varied across studies for this explanatory finding	No concerns	Moderate concerns Relatively superficial and sparse data for this explanatory finding	Serious concerns 2 studies with minor issues, 5 with moderate issues, and 11 with major issues (rationale as above)	Low ⊗⊗⊗
Those who support organ donation tend to support an opt-out model of consent (52, 54, 55, 74, 76, 79-82, 93, 95, 96, 103, 104).	Support was inferred through respondents who were registered donors, those who were willing to donate under the opt-out model, and those who would not register opposition under the opt-out model (52, 54, 55, 74, 76, 79-82, 93, 95, 96, 103, 104)	14 studies (14:0)	Serious concerns A pattern in the data somewhat supports the finding. Measures and definitions of support of opt-out consent were inconsistent, however, contributing to serious concerns with coherence.	No concerns	Serious concerns We judged this to be an explanatory finding, as it suggests an association between those who support organ donation and those who support opt-out consent. The data that support this finding however were superficial.	Serious concerns 2 studies with minor issues, 3 with moderate issues, and 9 with major issues (high risk of bias due to lack of clinical sensibility and lack of reliability and validity of instruments)	Low ⊗⊗⊗
No demographic factors were clearly associated with support or opposition to opt-out consent (18, 71, 76, 79, 81, 96, 97, 104)	Various demographic factors, such as age and gender, and various social factors, such as religion and political views, were not associated with support or opposition to opt-out consent (18, 71, 76, 79, 81, 96, 97, 104)	8 studies (8:0)	Moderate concerns Evidence varied and we were unable to identify consistent patterns across the studies	No concerns	Moderate concerns Superficial and sparse data provided little support for a demographic profile of individuals who support or oppose opt-out consent. Additional studies with varied designs	Serious concerns 1 study with minor concerns, 2 with moderate concerns, and 5 with major concerns (clinical sensibility and evidence of reliability and validity)	Moderate ⊗⊗◯

					may yield more definitive findings in the future.		

Table 3. Evidence profile for findings under theme 2

Legend:

Methodological Limitations: "The extent to which there are concerns about the design or conduct of the primary studies that contributed evidence to an individual review finding" (p. 26)[31]
Coherence: "how clear and cogent the fit is between the data from the primary studies and a review finding that synthesizes the data" (p.34)[33]
Relevance: "the extent to which the body of data from the primary studies supporting a review finding is applicable to the context" (p. 52)[32]
Adequacy: "an overall determination of the degree of richness as well as the quantity of data supporting a review finding" (p. 44)[34]

⊗ indicates downgrading

◯◯◯ indicates very high confidence in review finding
⊗◯◯ indicates high confidence in review finding
⊗⊗◯ indicates moderate confidence in review finding
⊗⊗⊗ indicates low confidence in review finding

Theme 3 Findings: Policy Concerns and Key Considerations

Family/substitute decision maker involvement in consent discussions should not override previously recorded donor decisions (high confidence). Several studies reported problems related to involving family in consent decisions because it could lead to vetoing previously registered donation decisions[15,18,51,60,63,85]. Family veto was seen as unethical and against an individual's right to decide what happens to their body after death[18,20,49,60,85]. Several other studies reported views that introducing opt-out consent would lead to more organ donation discussions among families[37,41,89,100]. These discussions were viewed positively and were viewed as leading to greater family acceptance of organ donation[44,52,107].

Infrastructure of an organ donation system is more important than legislation (high confidence). Several studies reported that more efforts should be directed at optimizing elements of donation systems other than the consent system[20-22,37,39,42,43,47-49,51,54,102]. Important elements included improvement of public education campaigns communicating need for organ donation, simplification of registration systems to facilitate communication of donation decisions, and implementation of operational policies aimed at identifying potential organ donors (e.g., mandatory referral of potential donors). One study reported participants questioning whether enough effort had been made to promote the existing consent system (opt-in), and if the proposed new system (opt-out) would make a difference at all[22].

Informed consent in donation decisions is required and should override medical system concerns (high confidence). Many studies reported participants' views that need for donated organs should not supersede an individual's right to informed consent, even if this resulted in fewer organs available for transplant[20,37,86]. Participants acknowledged that upholding informed

consent across an entire population could be challenging regardless of the type of consent framework. They also acknowledged that despite these perceived challenges, respecting individuals' rights through clear and thorough communication of policies is essential in an ethical system[15,22,37-39,41,44,45,47,48,86,87,94,106]. Violation of these rights would risk public backlash and result in lack of trust[15,21,86,107].

Findings related to theme three suggest respondents value upholding decisions made while alive, about what happens to their own body (organs) in death. This autonomy in informed decision making must not be jeopardized to benefit the organ donation/transplantation system. Finally, more effort should be directed to improving other elements of the system (e.g., communication around how to register intent to donate) (table 4).

Review finding	Explanation	Certainty assessment with GRADE CERQual					Confidence
		No of studies (quantitative: qualitative)	Coherence	Relevance	Adequacy	Additional methodological limitations	
Theme 3: Policy Concerns and Key Considerations							
Family/substitute decision makers should not override previously recorded donor decisions (15, 18, 20, 37, 41, 44, 49, 51, 52, 60, 63, 85, 89, 100, 107).	Many viewed soft opt-out, with potential for family to override donation decisions, as unethical (15, 18, 20, 49, 51, 60, 63, 85). Others viewed opt-out consent as a catalyst for increasing communication of donation decisions with family (37, 41, 44, 52, 89, 100, 107).	15 studies (7:8)	No concerns	No concerns	No concerns	Serious concerns 1 study with minor issues, 2 with moderate issues and 12 with major issues (high risk of bias due to lack of clinical sensibility and evidence of reliability and validity of instrument [quantitative] and/or overall methodological limitations due to lack of consideration of relationship between researcher and participants and/or other ethical concerns [qualitative])	High ⊗◯◯
Infrastructure of an organ donation system is more important than legislation (20-22, 37, 39, 42, 43, 47-49, 51, 54, 102)	Consistent finding that more efforts should be directed at optimizing elements of organ donation systems other than the consent system (20-22, 37, 39, 42, 43, 47-49, 51, 54, 102)	13 studies (11:2)	No concerns	No concerns	No concerns	Serious concerns 5 studies with moderate issues and 8 with major issues (rationale as above)	High ⊗◯◯

Informed consent in donation decisions is required and should override medical system concerns (15, 20-22, 37-39, 41, 44, 45, 47, 48, 86, 87, 94, 106, 107)	The need for organ donations should not supersede the right to informed consent (20, 37, 86). Violation of this right could be detrimental to the system (15, 21,2 2, 37-39, 41, 44, 45, 47, 48, 86, 87, 94, 106, 107).	17 studies (12:5)	No concerns	No concerns	No concerns	Serious concerns 2 studies with minor issues, 5 with moderate issues, and 10 with major issues (rationale as above)	High ⊗◯◯

Table 4. Evidence profile for findings under theme 3

Legend:

Methodological Limitations: "The extent to which there are concerns about the design or conduct of the primary studies that contributed evidence to an individual review finding" (p. 26)[31]
Coherence: "how clear and cogent the fit is between the data from the primary studies and a review finding that synthesizes the data" (p.34)[33]
Relevance: "the extent to which the body of data from the primary studies supporting a review finding is applicable to the context" (p. 52)[32]
Adequacy: "an overall determination of the degree of richness as well as the quantity of data supporting a review finding" (p. 44)[34]

⊗ indicates downgrading
◯◯◯ very high confidence in review finding
⊗◯◯ indicates high confidence in review finding
⊗⊗◯ indicates moderate confidence in review finding
⊗⊗⊗ indicates low confidence in review finding

Discussion

This review synthesizes current evidence related to knowledge and attitudes about opt-out consent models in organ donation. The key findings suggest limited knowledge and support for this model, the latter due to concerns around ethics and specifically preservation of individual autonomy. The importance of these needs may differ based on regional or social values. Our overall confidence in the findings of this review ranged from low to high, and primarily depended on concerns about risk of bias or methodological limitations in contributing studies.

Strengths and Limitations. A unique strength of this study is the breadth of research reviewed. We employed a wide search strategy and also integrated both qualitative (19 studies) and quantitative (60 studies) data in order to arrive at a comprehensive understanding of relevant research findings. Breadth in this review also refers to the geographical jurisdictions represented in the data, which implies differing cultural and religious contexts. Even though individual studies did not explicitly refer to these differences, our findings were similar across these differences and are thus generalizable across multiple settings.

Another unique strength of this review is the addition of assessments of the certainty of evidence related to each finding. Based on the widely-used GRADE methodology, we provide our degree of confidence in findings, which may help policy makers make recommendations related to opt-out consent.

This review also has limitations. Foremost, the quality of evidence in both bodies of work – qualitative and quantitative - varied, with a large proportion of studies having high risk of bias or serious methodological limitations

The findings of this review are also limited by the time elapsed since implementation of many of the studies. This is because with time comes growing exposure through experience and thus knowledge and attitudes may change.

Relation to Other Work. To our knowledge, this is the only systematic review that integrates data from qualitative and quantitative studies on knowledge and attitudes towards opt-out consent. As such, it represents an important addition to the current body of literature on this topic. The original review from 2009, which we sought to update, included data from 13 cross-sectional surveys with contextual and methodological heterogeneity[9]. Overall findings in this prior review suggest low levels of support for opt-out consent, which is consistent with some findings under theme 2 in the current study.

Findings under theme 3 illustrate differing views between the need for support of an organ donation policy that serves the greater good (i.e., by meeting the need for donated organs), and a policy that minimizes violations to individual preferences (i.e., through preservation of bodily autonomy). This finding can be compared to literature comparing societal individualism and collectivism, where collectivists are more likely to cooperate with broad spread regulations or restrictions, while individualistic people are more likely to resist[108,109], which was recently demonstrated during the COVID-19 response. The subtle balance of maintaining solidarity and ensuring individuals feel their rights are valued is essential to fostering collectivist values[108,109]. In organ donation, this contrast is akin to whether legislating a presumed consent model for organ donation respects balance between the needs of the individual and not at the expense of organ donation and transplantation rates.

Implications for Practice and Research. Our findings have important implications for health systems proposing legislative reform. Results related the *knowledge* and *awareness* of opt-out consent suggest there is a need for targeted public education, [108,109] perhaps related to both organ donation and the consent models. Education campaigns and national media coverage encouraging people to register as organ donors are associated with increases in registration rates[108,110]. In Canada however, registration of intent to donate has remained stable despite responses to periodic organ donation messaging[111]. This suggests that Canadians may be motivated to act in response to these campaigns, but motivation wanes over time. Moreover, if messaging does not correspond to a time when people can respond to it (i.e., at the time they are reviewing donation decisions), the impact of this messaging may be reduced. Insight into optimal timing and frequency of educational efforts and their effects on public knowledge of the organ donation consent system are needed.

In theme 2 (*level of support for the opt-out model*), there were differing views that contributed to support (or lack of support) of the model. This conflict demonstrates the need to create an organ donation policy that serves the greater good (i.e., by meeting the need for donated organs), while also minimizing violations to individual preferences (i.e., through preservation of bodily autonomy). Perhaps opt-out consent legislation could achieve this balance if associated with frequent or intentional public education in advance and following implementation, as was the goal in Nova Scotia, Canada. An ongoing epidemiologic study about the Nova Scotia experience is currently underway[112]. In the meantime, the current body of literature (with all its limitations) suggests that a presumed consent model does not or would not respect this balance in many jurisdictions.

Findings under theme 3 "Policy Concerns and Key Considerations" suggest that a consent policy is only one element of a successful organ donation system. Other essential components such as mandatory referral to organ donation programs close to time of death and dedicated organ donation experts working with potential donor families are just as important (or even more so) to increasing donation and transplantation rates[113,114]. While it is difficult to isolate which of these features provides the most benefit to an organ donation system, more research is needed to understand the interactions among these variables and donation consent rates.

Results of this review show that while knowledge of the opt-out consent model for organ donation is limited, it increases with exposure to organ donation processes. This review also shows there is limited support for the opt-out model and the primary sources for this opposition appear to relate to ethical values. These values are reflected in preferences for maintaining individual rights to decision-making, need for informed consent in this decision-making, and suggestions for policy changes to the organ donation system that are not related to consent.

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2.2.6 Appendix A. Search Terms

Database: OVID Medline Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) 1946 to Present

Search Strategy:

1 Presumed Consent/ (573)

2 exp Informed Consent/ (43523)

3 ((presum* or assum* or tacit or deem* or mandat*) adj3 consent*).ti,ab. (757)

4 opt out*.ti,ab. (2039)

5 opting out.ti,ab. (364)

6 opts out.ti,ab. (15)

7 1 or 2 or 3 or 4 or 5 or 6 (46089)

8 "Tissue and Organ Harvesting"/ (9782)

9 exp "Tissue and Organ Procurement"/ (25291)

10 Tissue Donors/ (43887)

11 Unrelated Donors/ (1528)

12 ((cadaver* or decease* or postmortem or "post mortem" or dead or death) adj3 (donor* or donation* or transplant* or harvest* or procur*)).ti,ab. (28837)

13 ((organ or organs or tissue*) adj3 (donor* or donation* or harvest* or procur*)).ti,ab. (32979)

14 8 or 9 or 10 or 11 or 12 or 13 (102706)

15 7 and 14 (3573)

16 (editorial or historical article or letter).pt. (2214674)

17 15 not 16 (3227)

Database: Embase <1974 to 2023 May 18>

Search Strategy:

1 informed consent/ (131513)

2 ((presum* or assum* or tacit or deem* or mandat*) adj3 consent*).ti,ab. (1045)

3 opt out*.ti,ab. (3173)

4 opts out.ti,ab. (21)

5 opting out.ti,ab. (507)

6 1 or 2 or 3 or 4 or 5 (134927)

7 exp organ donor/ (46368)

8 exp deceased donor/ (10212)

9 skin donor/ (115)

10 cornea donor/ (331)

11 ((organ or organs or tissue*) adj3 (donor* or donation* or harvest* or procur*)).ti,ab. (52503)

12 ((cadaver* or decease* or postmortem or "post mortem" or dead or death) adj3 (donor* or donation* or transplant* or harvest* or procur*)).ti,ab. (55232)

13 7 or 8 or 9 or 10 or 11 or 12 (122901)

14 6 and 13 (3218)

15 letter.mp. or editorial.pt. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword heading word, floating subheading word, candidate term word] (2070431)

16 14 not 15 (2870)

Database: APA PsycInfo <1806 to May Week 2 2023>

Search Strategy:

1 informed consent/ (4935)

2 ((presum* or assum* or tacit or deem* or mandat*) adj3 consent*).ti,ab. (190)

3 opt out*.ti,ab. (740)

4 opting out.ti,ab. (238)

5 opts out.ti,ab. (9)

6 1 or 2 or 3 or 4 or 5 (5894)

7 exp organ transplantation/ (5333)

8 ((cadaver* or decease* or postmortem or "post mortem" or dead or death) adj3 (donor* or donation* or transplant* or harvest* or procur*)).ti,ab. (582)

9 ((organ or organs or tissue*) adj3 (donor* or donation* or harvest* or procur*)).ti,ab. (1655)

10 7 or 8 or 9 (5893)

11 6 and 10 (178)

CINAHL:

☐	S15	S13 NOT S14	**Search modes** - Boolean/Phrase	View Results (1,224)
☐	S14	PT Editorial or Letter	**Search modes** - Boolean/Phrase	View Results (710,980)
☐	S13	S6 AND S12	**Search modes** - Boolean/Phrase	View Results (1,372)
☐	S12	S7 OR S8 OR S9 OR S10 OR S11	**Search modes** - Boolean/Phrase	View Results (19,851)
☐	S11	TX (organ or organs or tissue*) N3 (donor* or donation* or harvest* or procur*)	**Search modes** - Boolean/Phrase	View Results (13,676)
☐	S10	TX (cadaver* or decease* or postmortem or "post mortem" or dead or death) N3 (donor* or donation* or transplant* or harvest* or procur*)	**Search modes** - Boolean/Phrase	View Results (5,025)
☐	S9	(MH "Organ Procurement+")	**Search modes** - Boolean/Phrase	View Results (7,357)
☐	S8	(MH "Tissue and Organ Harvesting")	**Search modes** - Boolean/Phrase	View Results (2,081)
☐	S7	(MH "Transplant Donors")	**Search modes** - Boolean/Phrase	View Results (6,956)
☐	S6	S1 OR S2 OR S3 OR S4 OR S5	**Search modes** - Boolean/Phrase	View Results (21,405)
☐	S5	TX opts out	**Search modes** - Boolean/Phrase	View Results (1,442)
☐	S4	TX opting out	**Search modes** - Boolean/Phrase	View Results (252)
☐	S3	TX opt out*	**Search modes** - Boolean/Phrase	View Results (1,457)
☐	S2	TX (presum* or assum* or tacit or deem* or mandat*) N3 (consent*)	**Search modes** - Boolean/Phrase	View Results (457)
☐	S1	(MH "Consent")	**Search modes** - Boolean/Phrase	View Results (19,848)

PAIS Index:

☐	Set ▼	Search	Databases	Results
☐	S1	⊞ noft(((presum* or assum* or tacit or deem* or mandat*) NEAR/3 (consent*)) OR "opt out*" OR "opting out" OR "opts out") AND noft(((cadaver* or decease* or postmortem or "post mortem" or dead or death) NEAR/3 (donor* or donation* or transplant* or harvest* or procur*)) OR ((organ or organs or tissue*) NEAR/3 (donor* or donation* or harvest* or procur*)))	PAIS Index	46

Appendix B. Appraisal of qualitative studies

First author[ref] (year)	Was there a clear statement of the aims of the research?	Is a qualitative methodology appropriate?	Was the research design appropriate to address the aims of the research?	Was the recruitment strategy appropriate to the aims of the research?	Was the data collected in a way that addressed the research issue?	Has the relationship between the researcher and participants been adequately considered?	Have ethical issues been considered?	Was the data analysis sufficiently rigorous?	Is there a clear statement of findings?	How valuable is the research?	Overall methodologic limitations
Bailey[38] (2021)	yes	yes	can't tell	yes	yes	yes	yes	yes	yes	mod	moderate
Becker[41] (2020)	no	yes	yes	yes	yes	no	yes	can't tell	can't tell	mod	serious
Boyarsky[42] (2012)	yes	yes	yes	yes	yes	no	yes	yes	yes	very	moderate
Dallimore[46] (2018)	yes	yes	yes	can't tell	yes	no	no	yes	yes	very	serious
Faherty[47] (2022)	yes	yes	yes	can't tell	yes	no	no	yes	yes	very	serious
Fox[48] (2022)	yes	yes	yes	can't tell	yes	no	no	yes	yes	very	serious
Grigoras[49] (2010)	yes	yes	can't tell	can't tell	can't tell	no	no	can't tell	no	mod	serious
Hyde[37] (2021)*	yes	Can't tell	no	no	no	no	yes	can't tell	yes	mod	serious
Irving[39] (2012)	yes	yes	yes	can't tell	yes	no	yes	yes	yes	very	moderate
Kurzen[20] (2021)	yes	yes	can't tell	no	yes	no	yes	yes	yes	mod	serious
Lauri[41] (2010)	no	yes	yes	yes	yes	no	no	yes	yes	very	serious

Marcon[50] (2021)	yes	yes	yes	can't tell	yes	no	no	yes	yes	very	serious
Marcon[51] (2022)	yes	yes	yes	can't tell	yes	no	no	yes	yes	very	serious
Miller[40] (2019)	yes	yes	can't tell	yes	can't tell	can't tell	yes	yes	yes	mod	serious
Miller[21] (2020)	yes	yes	yes	yes	yes	can't tell	yes	yes	yes	very	moderate
Neades[44] (2009)	yes	yes	yes	yes	yes	no	yes	can't tell	yes	very	moderate
Noyes[15] (2019)	yes	yes	yes	yes	yes	can't tell	yes	can't tell	no	very	serious
Randhawa[22] (2010)	yes	yes	yes	yes	yes	no	no	can't tell	yes	very	serious
Urquhart[45] (2023)	yes	yes	yes	yes	yes	yes	yes	yes	no	very	moderate

* One publication treated as two studies. Risk of Bias related to qualitative data presented in table 2

Appendix C. Appraisal of Quantitative studies

First author[ref] (year)	Population representativeness	Adequacy of response rate	Little missing data	Survey clinically sensible	Evidence of reliability and validity	Overall risk of bias
Alderman[54] (2018)	Probably no	Definitely no	Definitely no	Definitely yes	Definitely no	High
Al-Qerem[58] (2022)	Probably yes	Probably no	Probably yes	Probably yes	Definitely yes	Moderate
Asai[56] (2018)	Definitely no	Definitely no	Definitely no	Definitely no	Definitely no	High
Bacusca[95] (2022)	Probably yes	Definitely no	Probably no	Probably yes	Probably yes	Moderate
Chan[59] (2013)	Probably yes	Definitely yes	Definitely no	Probably no	Definitely no	High
Cheung[96] (2018)	Probably yes	Probably no	Probably no	Definitely yes	Probably yes	Moderate
Conesa[17] (2003)	Probably yes	Definitely no	Definitely no	Definitely no	Definitely no	High
Connelly[60] (2013)	Probably yes	Probably no	Definitely no	Definitely no	Definitely no	High
Cornwall[61] (2015)	Probably yes	Definitely no	Definitely no	Probably yes	Definitely no	High
Costa-Font[52] (2021)	Probably yes	Probably yes	Probably yes	Probably yes	Probably no	High
Dundes[18] (1999)	Probably yes	Probably yes	Definitely no	Probably yes	Definitely no	High
Diaz-Cobacho[97] (2022)	Definitely yes	Probably yes	Probably yes	Probably yes	Probably yes	Low
Goh[62] (2013)	Probably yes	Probably no	Definitely no	Probably yes	Definitely no	High
Grenier[63] (2011)	Probably yes	Probably yes	Definitely no	Definitely no	Definitely no	High

Hammami[98] (2012)	Probably no	Probably yes	Probably no	Probably yes	Definitely yes	Moderate
Healy[64] (2009)	Definitely no	Definitely no	Definitely no	Definitely no	Definitely no	High
Hyde[37] (2021)*	Probably no	Probably no	Probably no	Probably no	Probably no	High
Jafri[65] (2001)	Probably no	Probably no	Definitely no	Definitely no	Definitely no	High
Janssens[66] (2018)	Probably no	Definitely no	Probably yes	Definitely no	Definitely no	High
Jindal[67] (2003)	Definitely no	Definitely yes	Definitely no	Probably yes	Definitely no	High
Johal[68] (2018)	Probably yes	Definitely no	Definitely yes	Probably no	Definitely no	High
Kanyari[69] (2021)	Probably no	Probably no	Definitely no	Definitely no	Definitely no	High
Kiel-Puslecka[70] (2022)	Probably no	Probably no	Probably yes	Probably no	Definitely no	High
Klenow[71] (1995)	Probably no	Probably yes	Definitely no	Definitely no	Definitely no	High
Lauri[72] (2006)	Probably yes	Probably no	Probably yes	Definitely no	Definitely no	High
Li[19] (2001)	Probably yes	Definitely no	Definitely no	Definitely no	Definitely no	High
Mar Lomero[99] (2017)	Probably yes	Probably yes	Probably yes	Probably no	Probably yes	Moderate
Manninen[73] (1985)	Probably yes	Definitely no	Definitely no	Definitely no	Definitely no	High
Martinez-Alarcon[74] (2010)	Probably yes	Definitely yes	Definitely no	Definitely no	Definitely no	High
Martinez-Alarcon[103] (2019)	Definitely yes	Definitely yes	Definitely yes	Definitely yes	Definitely yes	Low

Martinez-Alarcon[104] (2020)	Definitely yes	Definitely yes	Definitely yes	Definitely yes	Definitely yes	Low
Metwally[75] (2020)	Probably yes	Probably no	Probably yes	Definitely no	Definitely no	High
Molina-Perez[100] (2022)	Probably yes	Probably no	Probably yes	Definitely yes	Probably yes	Moderate
Muthiah[101] (2021)	Definitely yes	Probably yes	Definitely yes	Definitely yes	Probably no	Moderate
Nordfalk[76] (2016)	Probably yes	Probably yes	Definitely no	Definitely yes	Probably yes	High
Nowak[77] (2014)	Probably yes	Definitely no	Definitely no	Definitely no	Definitely no	High
Orlic[78] (2001)	Definitely no	Definitely no	Definitely no	Definitely no	Definitely no	High
Qian[79] (2022)	Probably yes	Probably no	Definitely yes	Probably no	Definitely no	High
Rockloff[80] (2014)	Probably yes	Probably yes	Definitely no	Definitely no	Definitely no	High
Rodrigue[81] (2006)	Probably no	Probably no	Probably no	Probably yes	Probably no	High
Rodrigues-Arias[82] (2021)	Probably no	Definitely no	Probably no	Probably yes	Probably no	High
Roels[83] (1997)	Probably no	Probably yes	Probably no	Probably no	Probably no	High
Runarsdottir[104] (2014)	Definitely yes	Definitely yes	Probably yes	Definitely yes	Probably yes	Low
Sah[84] (2022)	Probably no	Probably no	Probably no	Definitely no	Definitely no	High
Seetharaman[85] (2021)	Probably no	Definitely yes	Probably no	Definitely no	Definitely no	High
Shepherd[53] (2013)	Definitely yes	Probably yes	Definitely yes	Probably yes	Probably no	Low
Siddiqui[86] (2019)	Probably yes	Probably yes	Definitely no	Definitely no	Definitely no	High

Singh[54] (2021)	Probably yes	Probably no	Probably yes	Probably yes	Probably no	Moderate
Symvoulakis[87] (2013)	Probably no	Definitely yes	Definitely no	Definitely yes	Definitely no	High
Stadbauer[88] (2013)	Probably no	Definitely no	Definitely yes	Probably yes	Definitely no	High
Smulda[89] (2012)	Definitely no	Probably yes	Probably yes	Probably no	Definitely no	High
Spital[90] (1992)	Probably no	Probably yes	Probably yes	Definitely no	Definitely no	High
Symvoulakis[106] (2019)	Probably yes	Definitely yes	Definitely yes	Probably yes	Probably yes	Low
Siminoff[107] (2000)	Probably yes	Probably yes	Definitely yes	Probably yes	Definitely yes	Low
Tumin[91] (2015)	Probably yes	Definitely yes	Definitely yes	Probably yes	Probably no	High
Tumin[92] (2016)	Probably no	Definitely yes	Probably yes	Probably yes	Probably no	High
Tumin[93] (2019)	Probably no	Probably yes	Probably yes	Definitely yes	Probably no	High
Urquhart[57] (2023)	Probably no	Definitely no	Definitely yes	Probably yes	Probably no	High
Urquhart[94] (2023)	Probably yes	Definitely no	Probably yes	Probably yes	Probably no	High
Weiss[102] (2020)	Probably yes	Probably no	Probably yes	Definitely yes	Probably yes	Moderate

*One publication treated as two studies. Methodological limitations related to qualitative data presented in table 2

Appendix D. List of countries and consent systems

Country	Consent System	Note
Australia	Opt-in	
Austria	Opt-out	Hard opt-out
Belgium	Opt-out	
Canada	Opt-in	Opt-out in province of Nova Scotia
Cyprus	Opt-in	
Croatia	Opt-out	
Czech Republic	Opt-out	
Denmark	Opt-in	
Egypt	Opt-in with or without financial or medical incentive/ Opt-out	
Estonia	Opt-in	
Finland	Opt-out	
France	Opt-out	Hard opt-out
Germany	Opt-in	
Greece	Opt-out	
Hong Kong	Opt-in	
Hungary	Opt-out	
Iceland	Opt-in	
India	Opt-in	Consent is required by Family/NOK at time of death
Ireland	Opt-in	
Italy	Opt-out	
Japan	Opt-out	
Jordan	Opt-out	
Latvia	Opt-out	
Lithuania	Opt-in	
Luxembourg	Opt-out	
Malaysia	Opt-in	
Malta	Opt-out	
Nepal	Opt-out	
The Netherlands	Opt-in	
New Zealand	Opt-in	
Norway	Opt-out	
Poland	Opt-out	
Portugal	Opt-out	
Qatar	Opt-out	
Romania	Opt-in	

Saudi Arabia	Opt-in	
Scotland	Opt-in	
Singapore	Opt-out	Hard opt-out
Slovakia	Opt-out	
Slovenia	Opt-out	
Spain	Opt-out	
Sweden	Opt-out	
Switzerland	Opt-in	
The United States of America	Opt-in	
Wales	Opt-out	

CHAPTER 3

A Systematic Review of the Effect of Opt-Out Consent on Organ Donation Outcomes

Chapter 3. A Systematic Review of the Effect of Opt-Out Consent on Organ Donation Outcomes

3.1 Preamble

As discussed in the preamble for chapter 2, chapter 3 is also a systematic review of the effects of opt-out consent on quantitative organ donation outcomes. This review focuses on quantitative metrics of success of this system. Readers may refer to chapter 2 preamble for background details related to the opt-out system of consent.

A reminder to the reader that chapters 2 and 3 were initially conducted together and were separated later. The literature search terms are identical and the PRISMA diagrams are similar.

3.1.1 Objectives for Chapter 3

The study described in Chapter 3 is a systematic review aiming to:

1. Describe the effect of opt-out consent on consent to donation rates
2. Describe the effects of opt-out consent on organ donation rates

3.2 A Systematic Review of the Effect of Opt-Out Consent on Organ Donation Outcomes

3.2.1 Full citation:

Lucas A[1,2], Weiss M[3], Cullip M[4], Strachan P[5], Young J[1], Guyatt G[1,6,7], Meade M[1]. A Systematic Review of the Effect of Opt-Out Consent for Organ Donation. manuscript in preparation for publication

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3.2.3 Abstract

Background: Consent models for organ donation, particularly opt-in versus opt-out systems, are central to ongoing debates about optimal ways to increase organ donation rates. Previous reviews have suggested a potential benefit of the opt out system, but the certainty of these effects remain unclear.

Methods: We conducted a systematic review of 26 quantitative studies comparing organ donation outcomes across different regions. Our search strategy imposed no restrictions on language, publication date, or study methodology. Risk of bias and overall certainty of evidence were assessed

Results: Studies with stronger methodological quality more consistently suggested that opt-out consent is associated with higher consent and organ donation rates. The certainty of this observational evidence was low.

Conclusions: Opt-out consent may serve as a favourable policy foundation for improving organ donation outcomes, but its success may be contingent on broader health system supports and societal and cultural contexts. Future research should examine the interplay between consent policy and system-level factors to guide more effective implementation strategies.

3.2.4 A Systematic Review of the Effect of Opt-Out Consent on Organ Donation Outcomes

Background

The impact of an opt-out consent system on rates of deceased organ donation and transplantation remains uncertain[1,2,3,4]. In an opt-out system (also referred to as presumed or deemed consent), individuals are presumed to consent to organ donation unless they have explicitly expressed their wish to not participate (opt-out), whether on a formal registry or in discussion with family members[5]. Opt-out consent differs from the opt-in consent system (also known as explicit consent), in which a person can either pre-register their intent to donate organs or have substitute decision makers (usually family) consent on their behalf. In most jurisdictions, families are offered the final decision when donation becomes a possibility for an eligible donor – always with opt-in consent, and with varying authority in opt-out consent[5].

In January 2021, the province of Nova Scotia in Canada legislated modifications to the Human Organ and Tissue Donation Act [6]. Modifications included timely mandatory referral of all potential donors to the provincial donation program and, for the first time in North America, introduction of the opt-out consent model[6]. These changes took place in light of stagnating organ donation rates and proceeded prior to a formal review of relevant literature and exploration of public reception[1,6,7]. This lack of advance exploration leaves questions about whether this change will result in the expected positive effects on the organ donation system. We therefore systematically reviewed existing literature evaluating the success of the opt-out consent model in organ donation in other jurisdictions. This review was funded by Health Canada as part of a series of studies conducted by the Legislative Evaluation: Assessment of Deceased Donation Reform Consortium (LEADDR)[1].

Methods

This review is an update of a similar systematic review conducted by Rithalia et al in 2009[8]. We registered the review protocol with Prospero[9] (CRD4202013922) and followed PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) reporting guidelines[10].

Data Sources and Searches. With the assistance of a medical librarian (JY), we conducted a literature search using multiple electronic bibliographic databases (Embase, MEDLINE, CINAHL, PsycINFO) and duplicated the search terms of Rithalia et al[8] (Appendix A) from inception to May, 2023.

Study Selection. We considered any quantitative study methodology in any language and from any region that compared outcomes of opt-out consent to other consent models. Outcomes of interest for this review include those reflecting consent rates or organ donation/transplant rates.

We performed calibration exercises at each stage of the review (title and abstract screening, full article selection, data abstraction, and quality assessments). AL, paired with one of MC, AG, or MW participated in the exercises. If there was any disagreement during the calibration exercises, a third reviewer provided clarification in order to reach consensus.

Data Extraction and Risk of Bas Assessment. A customized data extraction sheet for this review included information relevant to study identification, objectives, methodology, region of study, and as much detail as possible regarding key variables in the analysis and findings. Outcomes of interest included those that reflect the pool of potential organ donors (i.e., rates of family consent for donation, rates for consent to donation when opportunities arise at the end of life,

family refusals, and additional measures found to be of interest, such as the rate of registered opposition to donation), and those that reflect the actual number of organs available for transplant (i.e., organ donation rates, procurement rates and transplant rates). Some studies reported on combined donation rates among living and deceased donors. In these instances, we abstracted rates specific to deceased donors, if available; otherwise, we abstracted data on total donation rates. We also reviewed studies for any evaluations of interactions with the opt-out model as described by the authors. We present results related to consent to donation first, followed by results related to actual donation.

To evaluate risk of bias of each study, we used the same criteria reported in the Rithalia[8] review, which was adapted from the Effective Public Health Practice Project (EPHPP) quality assessment tool[11]. This instrument assesses the quality of individual studies in systematic reviews that address evidence in public health interventions[11,12]. Rithalia et al adapted the tool by removing components evaluating presence of blinding and whether there were withdrawals or drop-outs in the study[8]. Due to the nature of the intervention (implementing population-wide changes to legislation), these components were not applicable.

This adapted EPHPP assesses for selection bias, study design, confounders, data collection methods, intervention integrity, and analyses; thus it is an assessment of methodologic quality that is largely focused on risk of bias[11,12]. These components were assessed by asking the following questions for each study: (i) were the countries/cohorts and time periods appropriate, (ii) was there evidence that potential confounders were evaluated and adjusted for in the analysis, (iii) were data sources specified and credible (iv) were the study outcomes attributable to the intervention (opt-out consent) alone, and (v) was the

statistical analysis appropriate, with no major flaws? Each individual component of the EPHPP system is rated as strong, moderate, or low, and these component ratings are applied to a global rating of the methodologic quality for each study[11,12].

During this process, we perceived a limitation related to the global rating of study methodologic quality as suggested by the authors of the EPHPP tool. These authors suggested that all studies with no weak components were rated as high-quality studies, studies with one weak rating were rated as moderate quality studies, and studies with two or more weak ratings were rated as weak quality studies. We followed these suggestions for weak quality studies but reasoned that those studies with mostly strong components are stronger overall than those studies with mostly or all moderate components. Therefore, to determine a global rating for each study, we provided a rating of weak methodologic quality if there were two or more weak components; moderate if there was one weak component *or* if there were more moderate components than strong; and a global rating of high methodologic quality if there were no weak components and the majority of the components were strong. This approach aligns with guidance for other risk of bias tools that researchers may apply to judge the quality of individual studies[13].

Final ratings were applied by the primary author (AL) following discussion with the supervising author (MM). Ultimately, in considering the results, we focused on the difference between the high-quality studies (which we considered at low risk of bias) and the moderate and weak studies (which we considered at high risk of bias).

Data Synthesis and Analysis. Our original intent was to report a quantitative synthesis that pooled results for similar outcomes. Due to important differences across studies in their methodology, the time periods (ranging from 1990 to 2021 for periods of comparisons), the populations studied, details about the specific opt-out models, and outcomes studied, we judged that there was a high degree of variability present in the evidence. There were also important differences in the degree of bias across the studies that would affect interpretation of pooled results. Thus, we determined that a qualitative synthesis of the findings would provide a more accurate overview of the evidence. We had similar reservations about pooling data about predictors of organ donation.

Adding to the methods of the Rithalia review[8], we assessed the certainty of evidence for each finding of this review, applying GRADE (Grading of Recommendations Assessment, Development and Evaluation) methodology. Based on GRADE methodology, findings from observational studies of causal relationships started with a rating of low certainty of evidence. We then rated down for serious concerns about the risk of bias, variability in geopolitical and cultural norms across jurisdictions (in GRADE, indirectness), or imprecision in results for the body of literature reporting on that finding. This system also allows reviewers to rate up for very large effects[14].

Results

The two literature searches produced 5180 and 1005 titles, respectively. Twenty-six studies proved eligible for review (Figure 1).

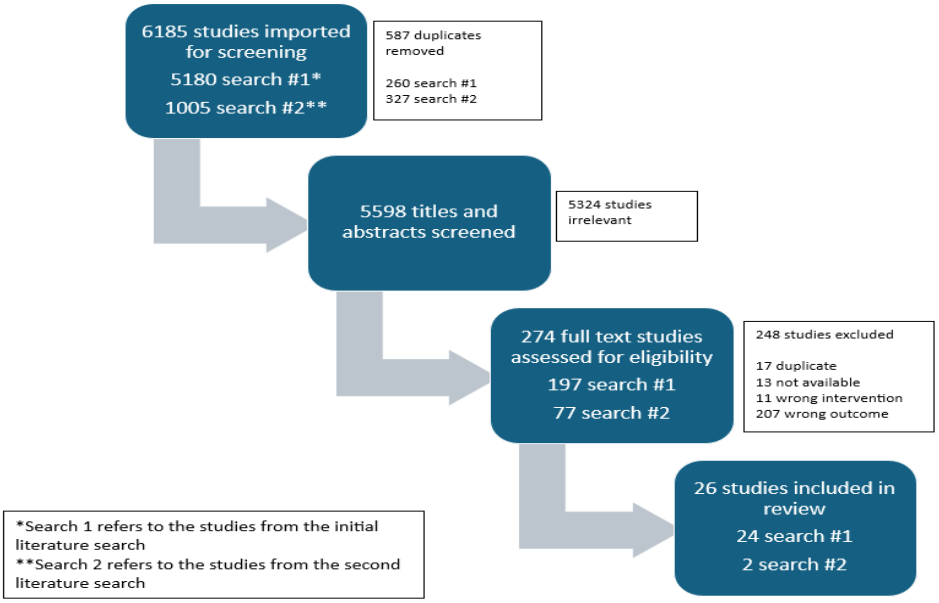

Figure 1. PRISMA diagram

Study characteristics. Table 1 describes the individual studies in this review, including four studies with high methodologic quality[15-18], twelve studies with moderate methodologic quality[19-30], and ten studies with weak methodologic quality[31-40]. Studies with high methodologic quality more frequently attempted to control for differences in predictors of donation or consent for donation. These variables included those associated with healthcare systems (e.g., the number of hospital beds[17,18] and specialist personnel[20]), population demographics (e.g., number of deaths by relevant cause like road accident of homicide[17] or religion/ethnicity[15,17,18]), and social factors (e.g., gross domestic product [GDP]/healthcare spending[17,18]). Among the studies, assessing for variables that would modify the effect of opt-out consent legislation, no compelling effect modifiers emerged. These studies also provided detailed information related to sources of data and employed sophisticated analytic approaches to data. Conversely, studies with weaker methodologic quality tended to provide

incomplete reports about data sources, presence of confounders, and presented data as counts and proportions. Table 2 describes risk of bias assessments for the studies in this review.

Among these studies, there were six with historical controls[16,31,32,34,37,38] and 17 with contemporaneous controls[15,17-20,22-30,33,35,36]. Three studies took both approaches and compared periods before and after legislative change and also compared differences between countries[21,39,40]. There was little information in any of these 26 studies regarding application of the intervention (opt-out consent) and whether there was simply a change in legislation, or if it was part of a larger bundle of changes such as education campaigns. Every region was represented, including the Americas, Europe, Asia, and Oceania. Studies took place between 1990 and 2021.

First Author; Year of Publication	Primary Study Outcome	Data Sources/ Databases	Adjustment variables Adjustment Analysis	Geographical Region Time Periods	Findings associated with use of an opt-out model of consent
Strong Methodological Quality					
Madden[15]; 2020	Organ donation consents	UK Potential Donor Audit, National organ donor Registry	Donation, registration status, ethnicity, involvement of specialist nurse in consent conversation Adjusted sequential analyses, logistic regression	Contemporaneous cohorts Wales vs England 2016/2018	↑ Organ donation in Wales (OR [95% CI] 2.1[1.26-3.41]) ↑ Consent for donation rates in Wales (OR [95% CI] 2.8 [1.58-5.03])
Noyes[16]; 2019	Family consents and organ donors	National Health Service admin and research database	None	Historical cohort study Wales 2012/15 vs 2015/17	↑ Consent rate 45.8% to 61.0% ≈ Deceased donor rate (101 vs. 104) ↑ Organ donation registrations 34% to 38% 6% registering to opt-out
Shepherd[17]; 2014	Organ donations	National transplant admin databases, World Health Organization admin databases, other global admin databases	GDP, number of road traffic accidents, number of hospital beds, % population catholic, legal system, number of organ donors Multilevel modeling and instrumental variable regression	Contemporaneous cohorts 48 countries with 3 or more years of deceased and living organ donor data 2000/2012	↑ Deceased donor rates in opt-out countries compared to opt-in countries (mean = 14.24 pmp vs mean = 9.98 pmp).
Gimbel[18]; 2003	Organ donations	Global statistical research databases	Religion, education level, number of transplant centers Ordinary least squares regression,	Contemporaneous cohorts 28 European countries 1995-1999	↑ Deceased organ donations in European countries with opt-out consent (6.14 pmp)
Moderate Methodological Quality					
Vela[19]; 2021	Organ donations and transplants	National transplant admin databases, World Health Organization admin databases, other global admin databases	None Kruskkal-Wallis test	Contemporaneous cohorts 13 European countries and the USA 2016	≈ Organ donations and transplantations in opt-out vs opt-in countries

Goldsteyn[20]; 2021	Transplants patients who died on transplant waiting list	National transplant admin databases, World Health Organization admin databases, other global admin databases	Religion, total deaths among those on transplant registry, GDP, health expenditure Ordinary least squares regression	Contemporaneous cohorts 66 countries with kidney transplant programs 2001/2014	↑ Kidney, liver, and heart transplants in opt-out countries ≈ Lung transplant rate in opt-out vs opt-in countries
Saab[21]; 2019**	Consents and organ donors	International organ donation and transplantation registry	Physician density, health expenditure % of GDP*, results of opt-out countries matched to opt-in countries based on variables listed above	Contemporaneous cohorts and historical cohort study Argentina 1999/05 vs 2005/16 Chile 1998/10 vs 2010/15 Finland 2000/07 vs 2007/16 Poland 2000/05 vs 2005/15 Slovakia 1994/04 vs 2004/13 Uruguay 2000/03 vs 2003/16	↑ Mean liver donation rate 3.23 (SD 0.97) to 6.46pmp*** (SD 1.81) ($p < 0.0001$) ↑ Mean kidney donation rate 17.94 (SD 3.34) to 26.58pmp (SD 4.23) ($p< 0.0001$) ↑ When compared to matched controls, countries with opt-out consent had higher liver and kidney transplantation rates
Arshad[22]; 2018	Organ donations and transplants	National transplant admin databases, World Health Organization admin databases, other global admin databases	GDP, legal system, religion, education level, hospital beds per 10 000 population, and 8 other demographic variables Forward stepwise multiple linear regression	Contemporaneous cohorts 35 OECD*- registered countries 2016	≈ Deceased donor rate in opt-out vs opt-in countries (20.3 vs. 15.4 respectively)
Ugur[23]; 2015	Organ donations and kidney transplants	International Registry of Organ Donation and Transplantation, Eurobarometer survey	Death by homicide, MVA, CVA, health expenditure, hospital beds per 100 000 population, religion, education, average willingness to donate Ordinary least squares regression	Contemporaneous cohorts 28 European countries 2000/2010	↑ Deceased organ donations in opt-out countries (28-32%) ↑ Kidney transplants in opt-out countries (27-31%) ↑ Benefits of opt-out consent on donation rates with families involved in ultimate decision
Bilgel[24]; 2013	Organ transplants	National transplant admin databases, World Health Organization admin	Legislative system, various procedural and managerial aspects of organ donation/transplantation	Contemporaneous cohorts 62 Christian and non-Christian countries	≈ opt-out consent does not result in higher transplant rates

		databases, other global admin databases	systems, education rates, , health expenditure per capita, income per capita, region Ordinary least squares regression	2008-2009	
Bendorf[25]; 2013	Kidney donations.	National transplant admin databases, World Health Organization admin databases, other global admin databases	Median population age, religion, region, health expenditure, education expenditure, and 5 other demographic variables Univariate and multivariate linear regression, *t* tests, F tests	Contemporaneous cohorts 53 countries in America North, America South, Asia North, Asia South, Europe East, Europe North, Europe South, Middle East, and Oceania Date range not provided	↑ Deceased kidney donations in opt-out countries (mean change 12.52; 95% CI: 6.09, 19.06; $p < 0.001$)
Bilgel[26]; 2012	Organ donations	National transplant admin databases, World Health Organization admin databases, other global admin databases	Deaths by CVA, MVA, and homicides, health expenditure Fixed Effects Vector Decomposition	Contemporaneous cohorts 28 Western Countries 1993-2006	↑ Deceased organ donations in opt-out countries The magnitude of the impact of opt-out consent, depends on whether families provide the ultimate decision
Horvat[27]; 2010	Kidneys suitable for transplant	National transplant admin databases, World Health Organization admin databases, other global admin databases	% population catholic, deaths by MVA and CVA, mean health expenditure per capita, mean physician density per 10 000 population Poisson regression	Contemporaneous cohorts 44 countries with similar deceased donor transplantation programs and other criteria 19972007	↑ Deceased kidney transplantations in opt-out countries (median 22.6 transplantations pmp [IQR, 9.3 to 33.8] vs 13.9 transplantations pmp [IQR, 3.6 to 23.1 transplantations pmp]; adjusted rate ratio, 2.0 [95% CI, 1.2 to 3.4])
Neto[28]; 2007	Organ donations	World Health Organization admin databases, other global admin databases	Number of deaths by MVA and CVA per 100 000 population, GDP per capita, % population with access to internet, religion, legal system Quantile regression	Contemporaneous cohorts 34 countries with or without opt-out consent 1998-2002	↑ Deceased organ donations in opt-out countries (21-26%)
Abadie[29]; 2006	Organ donations	National transplant admin databases, World Health Organization admin databases, other global admin databases	Health expenditure % of GDP, religion, common law legislation, number of potential donors Ordinary least squares regression	Contemporaneous cohorts 22 Western Christian countries 1993-2002	↑ Deceased donations in opt-out countries (25-30%)

Roels[30]; 1996	Organs procured	European admin database	None	Contemporaneous cohorts Austria, Belgium, Germany, the Netherlands 1992-1994	↑ Thoracic organs donations in opt-out countries Austria (18.3pmp) and Belgium (16.8pmp) vs. Germany (7.6pmp) and The Netherlands (6.2pmp)
Low Methodological Quality					
Albertsen[31]; 2018	Donor registrations, organ donations, and family refusals	National Health Service admin database	None	Historical cohort study Wales 2014/15 vs 2016/17	↓ Total number of donors in Wales 23.1 to 21.6 pmp ↑ Total number of donors in UK 19.9 to 21.6 pmp ↑ Registered organ donors in Wales 339759 to 377839 pmp ↑ Registered organ donors in UK 327853 to 361784 pmp Number of opt-out registrations in Wales 56389 pmp and in UK 3130 pmp ↑ Consent rates in Wales and UK
Dominguez[32]; 2013	Organs donated, family refusals, registered non-donors	National transplant admin database, national transplant registry	None	Historical cohort study Chile 2000/09 vs 2010/11	↓ Mean donation rates 29% ↑ Family refusals 32% to 50.4% Registered non-donors represented approximately 37% of those eligible
Coppen[33]; 2008	Organ donations	World Health Organization admin databases	National mortality rates Standard regression	Contemporaneous cohorts 10 Western European countries with similar history and health care system 1995-2005	There was no evidence that presumed consent systems perform better than explicit consent systems
Low[34]; 2006	Livers transplanted, donors referred	Clinical transplant admin database	None	Historical cohort study Singapore 2002/04 vs 2004/05	↓ 83.5 to 80 death referrals/year ↓ 35 to 34 suitable donors/year ↑ 3.5 to 5 liver transplants/year

Coppen[35]; 2005	Organ donations	National transplant admin databases, World Health Organization admin databases, other global admin databases	Average mortality rate Spearman's test	Contemporaneous cohorts 10 European countries with similar history and health care system 2000-2002	There is no correlation between consent systems and organ donation rates when controlling for relevant mortality
McCunn[36]; 2003	Organ donations and transplants	Hospital trauma database and associated transplant registry	None	Contemporaneous cohorts 1 trauma hospital in Maryland USA (opt-in consent) *vs* 1 trauma hospital in Vienna Austria (opt-out consent) 2000	≈ Number of organs transplanted (4 organs versus 3.8 organs)
Soh[37]; 1991	Kidneys suitable for transplant	NR	None	Historical cohort study Singapore 1970/87 vs 1987/90	↑ Kidneys average 4.7 to 31.3/year
Gnant[38]; 1991	Organs donated	NR	None	Historical cohort study Austria 1965/81 vs 1982/90	↑ Donor 4.6 to 42 pmp/year
Roels[39]; 1991**	Organs procured	European admin database, UK and France national transplant admin databases	None	Contemporaneous cohort and historical cohort study Opt-out: Belgium Austria France Opt-in: UK Germany Netherlands 1982/85 vs 1987/89	↑ Kidneys 18.9 to 41.3pmp ↑ Hearts 0.9 to 11.9pmp ↑ Livers 0.7 to 10.7pmp
Roels[40]; 1990**	Organs transplanted	NR	None	Contemporaneous cohort and historical cohort study Opt-out: Belgium Austria France	↑ Kidney transplants 220 to 342 ↑ All organs transplanted 234 to 561

				Opt-in: UK Germany Netherlands 1984/85 vs 1986/89	

Table 1. Profile of the studies in the review

Legend:
*Gross Domestic Product
** This study appears as both a cohort study with historical control and as a cohort study with contemporaneous control
*** per million population
≈ indicates more or less equal
↑ indicates improvement with opt-out
↓indicates decline with opt-out

Author, year, reference	Selection Bias	Confounders	Data Collection Method	Intervention Integrity	Analyses	Global Rating of Quality
Madden[22], 2020	Strong	Moderate	Strong	Moderate	Strong	Strong
Noyes[28], 2019	Strong	Moderate	Strong	Strong	Strong	Strong
Shepherd[15], 2014	Strong	Moderate	Strong	Moderate	Strong	Strong
Gimbel[36], 2003	Strong	Strong	Moderate	Moderate	Strong	Strong
Vela[37], 2021	Moderate	Moderate	Strong	Moderate	Moderate	Moderate
Golsteyn[23], 2021	Moderate	Moderate	Strong	Moderate	Strong	Moderate
Saab[18], 2019	Strong	Moderate	Strong	Moderate	Moderate	Moderate
Arshad[16], 2018	Moderate	Moderate	Strong	Moderate	Strong	Moderate
Ugur[17], 2014	Strong	Moderate	Strong	Moderate	Strong	Moderate
Bilgel[26], 2013	Moderate	Moderate	Strong	Moderate	Strong	Moderate
Bendorf[24], 2013	Moderate	Moderate	Strong	Moderate	Strong	Moderate
Bilgel[20] 2012	Moderate	Moderate	Strong	Weak	Strong	Moderate
Horvat[19], 2010	Moderate	Moderate	Strong	Moderate	Strong	Moderate
Neto[21], 2007	Moderate	Moderate	Strong	Moderate	Strong	Moderate

Abadie[25], 2006	Moderate	Moderate	Strong	Moderate	Strong	Moderate
Roels[38], 1996	Moderate	Moderate	Moderate	Moderate	Weak	Moderate
Albertsen[29], 2018	Weak	Weak	Weak	Moderate	Weak	Weak
Dominguez[30], 2013	Moderate	Weak	Strong	Moderate	Weak	Weak
Coppen[39] 2008	Weak	Weak	Strong	Weak	Moderate	Weak
Low[31], 2006	Weak	Weak	Strong	Weak	Moderate	Weak
Coppen[40], 2005	Weak	Weak	Strong	Weak	Moderate	Weak
McCunn[41], 2003	Weak	Weak	Moderate	Weak	Moderate	Weak
Soh[32], 1991	Strong	Weak	Weak	Moderate	Weak	Weak
Gnant[33], 1991	Weak	Weak	Weak	Moderate	Weak	Weak
Roels[34], 1991	Moderate	Weak	Moderate	Moderate	Weak	Weak
Roels[35], 1990	Weak	Weak	Weak	Moderate	Weak	Weak

Table2. Risk of bias assessments for the studies in the review

Findings Related to Rates of Consent for Deceased Donations. There were four studies that reported outcomes describing the eventual consent rates for deceased donation to proceed for individuals[15,16,31,32]. These include two studies with high methodologic quality[15,16] and two with weak methodologic quality[31,32].

The first study with high methodologic quality[16], showed an increase in consent rates following introduction of the opt-out model. In this study from Wales, the consent rate increased from 45.8% to 61.0% and chance proved an unlikely explanation of the finding

(p=0.009). The other high-quality study[15] compared contemporaneous consent rates between England (opt-in consent) and Wales (opt-out consent) and found that consent for donation in Wales was higher than in England (OR [95% CI] 2.8 [1.58-5.03]). This study also attempted to control for other potentially confounding differences between these two jurisdictions, lending further support to the hypothesis that an opt-out consent model is associated with higher consent rates.

Among the weak methodologic quality studies reporting consent to donation rates, a third study from Wales[31] showed improvement following adoption of the opt-out model. However, this study additionally reported increasing consent rates over the same period in the UK, which continued to employ an opt-in consent model over the time period of the Wales study. This finding mitigates the strength of influence of the opt-out consent in Wales. The fourth study (weak methodologic quality) from Chile[32], showed a decrease in consent rates following introduction of the opt-out model. In this study, family consents to move ahead with organ donation decreased from 50.4% to 32%.

Based on findings from studies with high methodologic quality, opt-out consent may improve rates of consent for organ donation. Our certainty in the evidence for this finding remains low (rather than rating down to very low).

Findings Related to Number of Donated Organs. All twenty-six studies report on the effects of opt-out consent on organ donation rates. We report findings of studies with high methodologic quality in more detail, followed by the general findings from studies with moderate and weak methodologic quality below.

One high-quality study from Wales[16] reported no change in deceased donation rates (101 donors vs 104 donors) when comparing the time period before and after implementation of the opt-out model. Another high-quality study comparing Wales and the UK[152], reported an increase in organ donation rates in Wales (OR [95% CI] 2.1[1.26-3.41]). A third study, the largest (N=48 countries)[17], reported that deceased donation rates in opt-out regions were higher per million population than in opt-in countries. Using multi-level modeling the mean was higher in opt-out countries vs opt-in (14.21 vs 9.98; p=0.029). This study also reports that despite lower living kidney donations, the total number of kidneys transplanted was also higher in opt-out countries (M =28.2 vs M = 22.43; 95%CI -11.60, -0.17, p= .044). Potential confounding variables included in the analysis included average GDP, the number of road traffic accidents, hospital beds, religion, and legal system. In addition to opt-out consent, one study observed that having a civil law legal system was also associated with higher organ donation rates[17].

The fourth high-quality study[18], reported that countries with opt-out consent have a donation rate per million population of 6.14 higher than the mean for opt-in countries. This study controlled for other variables, such as religion, education level and the number of transplant centers in the 28 European countries studied. These variables were all found to be significant predictors of deceased donation rates[18].

The remaining studies reporting on the effect of opt-out consent on organ donation rates were all moderate or weak quality. Of the twelve studies with moderate methodological quality, ten explored potential confounders in statistical analyses. Variables were similar to those used in the high-quality studies. Studies were rated down due to perceived issues with analysis methods, selection bias, and intervention integrity (table 2). Results of these studies

were varied, with four reporting little change in donation rates[19,20,22,24], and the remaining reporting improved donation rates[21,23,25-30].

Studies with weak methodologic quality also showed varied results. Three reported decreases in the number of organs available[31,32,34], three reported little change in donation rates[33,35,36], and four reported an increase in donated organs[37-40]. Many of these weaker quality studies did not explore potential confounders and many of them took place prior to the year 2010.

When assessing the overall certainty of evidence related to effects of opt-out consent on organ donation rates, our results are similar to the findings on consent rates. Considering the evidence from high-quality studies, there appears to be a signal that countries with opt-out consent have higher organ donation rates. We did not rate down for variability in methodologic quality because of the potentially important relationship between study quality and findings. However, our certainty in this finding remains low (table 3).

Outcome	Effect	Number of studies	Certainty in the Evidence
Family member consent for donation at the time of eligibility	Opt-out consent may improve the number of consents to donation at the time of donation eligibility	4 (2 high methodologic quality)	LOW ⊗⊗◯◯
Organ donation rates assessed using number of organs donated, organ donors, organs transplanted, and organs procured	Opt-out consent may improve organ donation rates	26 (4 high methodologic quality)	LOW ⊗⊗◯◯

Table 2. Evidence profile

Legend:

⊗⊗◯◯ indicates low certainty in the evidence

Discussion

This systematic review synthesizes the totality of published quantitative studies comparing organ donation outcomes in systems with opt-out versus opt-in donation consent systems. Among the studies with relatively higher methodologic quality, we observed a signal pointing to higher consent rates and possibly donation rates with the opt-out model. Our certainty in this observational data for both outcomes is low.

Strengths and Limitations. One strength of this review is the analysis with a focus on risk of bias in individual studies. Through this approach, we observed a relationship with organ donation outcomes such that the lower risk of bias studies suggested a more important role for opt-out consent than previous reviews have noted.

The focus on overall certainty of evidence constitutes another strength of this review. Certainty of evidence provides legislators and guideline developers with important information about the confidence in research findings. Thus, this review provides an important addition to the literature on this topic.

We used a broad search strategy with no limitations on date, language, or study methodology and we were able to include data from 26 studies. These studies stemmed from multiple jurisdictions and spanned over 30 years, and we were able to include data with a range of temporal and cultural influences. Ultimately, we included data from 17 studies that were not in the original Rithalia study which we sought to update, adding important new information.

This study also has limitations. The breadth of temporal and cultural influences was highly variable across study jurisdiction. For these reasons, we opted not to perform a quantitative synthesis and meta-analysis.

Findings in Context to Other Work and Implications for Practice and Research. Findings from earlier systematic reviews[8,41] suggest that countries with an opt-out system may experience higher organ donation rates when compared to regions with opt-in systems. Our findings corroborate those earlier conclusions, providing evidence that opt-out consent may have positive effects on consent to donation rates and possibly organ donation rates. These improvements may ultimately translate into more organs available for transplant.

While we observed a signal that supports the effectiveness of opt-out consent, the impact is not uniform across all settings. A key consideration emerging from our review, and consistent with previous analyses, is the role of contextual factors in shaping consent policy outcomes. For example, the rate of opposition to organ donation varies markedly between jurisdictions with opt-out systems. In Wales, only about 6% of those eligible registered their objection to organ donation, whereas in Chile, approximately 37% of those eligible opted out. These differences suggest that variations in implementation strategies may significantly influence how opt-out policies are received. Detailed comparisons of how these policies were implemented in these two settings are lacking. Such analyses may provide valuable insight into how contextual factors shape public response and, ultimately, system effectiveness.

Various studies in this review attempted to control for these factors by including covariate adjustments in statistical analyses. Variables such as religious affiliation, education level, number of transplant centers[18], and the presence of a civil law system[17] were found to be significant predictors of the effect of opt-out consent. These findings suggest that structural, legal, and cultural dimensions may mediate or amplify a consent policy's success.

Despite these insights, the scope of influence of these variables remains underexplored. For example, it is unclear how these effects intersect relative to each other or to the consent intervention itself. Moreover, most studies examining these variables have been conducted in high-income, predominantly European countries, and findings may not be relevant in regions where important cultural, religious, and healthcare system differences exist. Valuable insight may be gained by exploring why the opt-out system has underperformed in certain regions, and whether those settings are amenable to policy or systems-level change.

Further insight may also be gained through comparative evaluations of high-performing organ donation systems. These comparisons could help identify which system components, such as specialist transplant coordinators, professional education, and public awareness campaigns, contribute most meaningfully to higher donation rates. A comparative study from 2009[42] found that these infrastructure related factors were strongly associated with improved outcomes, challenging the notion that a switch to opt-out consent alone yields substantial increases in donation rates.

Thus, the findings of this review suggest that while opt-out consent may provide a favourable policy foundation, its impact may depend on the broader system within which it is implemented. Future research should focus on understanding the interplay of legal frameworks, cultural values, health system capacity, and public engagement in shaping the effectiveness of consent models. Additionally, adopting a more nuanced, context-sensitive approach to policy development and implementation may help optimize outcomes.

Conclusion

This systematic review provides updated and quality-focused evidence suggesting that opt-out consent may be associated with increased consent and organ donation rates. However, the certainty of this evidence remains low, and the observed effects appear to be influenced by various societal and cultural factors. Policymakers considering adopting the opt-out model should recognize that the success of any system likely depends on broader system supports. Future efforts should aim to clarify the interplay between these supports and explore the transferability of high-performing system component across diverse regions. Ultimately, a nuanced approach will be critical to realizing the full potential of consent policy reform to improve organ donation outcomes.

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3.2.6 Appendix A. Search Terms

Database: OVID Medline Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) 1946 to Present

Search Strategy:

1 Presumed Consent/ (573)

2 exp Informed Consent/ (43523)

3 ((presum* or assum* or tacit or deem* or mandat*) adj3 consent*).ti,ab. (757)

4 opt out*.ti,ab. (2039)

5 opting out.ti,ab. (364)

6 opts out.ti,ab. (15)

7 1 or 2 or 3 or 4 or 5 or 6 (46089)

8 "Tissue and Organ Harvesting"/ (9782)

9 exp "Tissue and Organ Procurement"/ (25291)

10 Tissue Donors/ (43887)

11 Unrelated Donors/ (1528)

12 ((cadaver* or decease* or postmortem or "post mortem" or dead or death) adj3 (donor* or donation* or transplant* or harvest* or procur*)).ti,ab. (28837)

13 ((organ or organs or tissue*) adj3 (donor* or donation* or harvest* or procur*)).ti,ab. (32979)

14 8 or 9 or 10 or 11 or 12 or 13 (102706)

15 7 and 14 (3573)

16 (editorial or historical article or letter).pt. (2214674)

17 15 not 16 (3227)

Database: Embase <1974 to 2023 May 18>

Search Strategy:

1 informed consent/ (131513)

2 ((presum* or assum* or tacit or deem* or mandat*) adj3 consent*).ti,ab. (1045)

3 opt out*.ti,ab. (3173)

4 opts out.ti,ab. (21)

5 opting out.ti,ab. (507)

6 1 or 2 or 3 or 4 or 5 (134927)

7 exp organ donor/ (46368)

8 exp deceased donor/ (10212)

9 skin donor/ (115)

10 cornea donor/ (331)

11 ((organ or organs or tissue*) adj3 (donor* or donation* or harvest* or procur*)).ti,ab. (52503)

12 ((cadaver* or decease* or postmortem or "post mortem" or dead or death) adj3 (donor* or donation* or transplant* or harvest* or procur*)).ti,ab. (55232)

13 7 or 8 or 9 or 10 or 11 or 12 (122901)

14 6 and 13 (3218)

15 letter.mp. or editorial.pt. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword heading word, floating subheading word, candidate term word] (2070431)

16 14 not 15 (2870)

Database: APA PsycInfo <1806 to May Week 2 2023>

Search Strategy:

1 informed consent/ (4935)

2 ((presum* or assum* or tacit or deem* or mandat*) adj3 consent*).ti,ab. (190)

3 opt out*.ti,ab. (740)

4 opting out.ti,ab. (238)

5 opts out.ti,ab. (9)

6 1 or 2 or 3 or 4 or 5 (5894)

7 exp organ transplantation/ (5333)

8 ((cadaver* or decease* or postmortem or "post mortem" or dead or death) adj3 (donor* or donation* or transplant* or harvest* or procur*)).ti,ab. (582)

9 ((organ or organs or tissue*) adj3 (donor* or donation* or harvest* or procur*)).ti,ab. (1655)

10 7 or 8 or 9 (5893)

11 6 and 10 (178)

CINAHL:

☐	S15	S13 NOT S14	**Search modes** - Boolean/Phrase	View Results (1,224)
☐	S14	PT Editorial or Letter	**Search modes** - Boolean/Phrase	View Results (710,980)
☐	S13	S6 AND S12	**Search modes** - Boolean/Phrase	View Results (1,372)
☐	S12	S7 OR S8 OR S9 OR S10 OR S11	**Search modes** - Boolean/Phrase	View Results (19,851)
☐	S11	TX (organ or organs or tissue*) N3 (donor* or donation* or harvest* or procur*)	**Search modes** - Boolean/Phrase	View Results (13,676)
☐	S10	TX (cadaver* or decease* or postmortem or "post mortem" or dead or death) N3 (donor* or donation* or transplant* or harvest* or procur*)	**Search modes** - Boolean/Phrase	View Results (5,025)
☐	S9	(MH "Organ Procurement+")	**Search modes** - Boolean/Phrase	View Results (7,357)
☐	S8	(MH "Tissue and Organ Harvesting")	**Search modes** - Boolean/Phrase	View Results (2,081)
☐	S7	(MH "Transplant Donors")	**Search modes** - Boolean/Phrase	View Results (6,956)
☐	S6	S1 OR S2 OR S3 OR S4 OR S5	**Search modes** - Boolean/Phrase	View Results (21,405)
☐	S5	TX opts out	**Search modes** - Boolean/Phrase	View Results (1,442)
☐	S4	TX opting out	**Search modes** - Boolean/Phrase	View Results (252)
☐	S3	TX opt out*	**Search modes** - Boolean/Phrase	View Results (1,457)
☐	S2	TX (presum* or assum* or tacit or deem* or mandat*) N3 (consent*)	**Search modes** - Boolean/Phrase	View Results (457)
☐	S1	(MH "Consent")	**Search modes** - Boolean/Phrase	View Results (19,848)

PAIS Index:

☐	Set ▼	Search	Databases	Results
☐	S1	⊞ noft(((presum* or assum* or tacit or deem* or mandat*) NEAR/3 (consent*)) OR "opt out*" OR "opting out" OR "opts out") AND noft(((cadaver* or decease* or postmortem or "post mortem" or dead or death) NEAR/3 (donor* or donation* or transplant* or harvest* or procur*)) OR ((organ or organs or tissue*) NEAR/3 (donor* or donation* or harvest* or procur*)))	PAIS Index	46

Chapter 4

Transplant Recipient Preferences Regarding Organ Donor Research: Their Role in Consent and Use of Their Data

Transplant Recipient Preferences Regarding Organ Donor Research: Their Role in Consent and Use of Their Data

4.1 Preamble

4.1.1 Research in deceased organ donation

Interventions research conducted with potential deceased organ donors is where a clinical intervention has been applied to a deceased organ donor or to their organ. This research is done with the aim of improving management of organ donors, potentially improving outcomes for transplant recipients.

4.1.2 Concerns related to research consent in deceased organ donation

With few exceptions, consent to participate in research is a requirement in interventional trials. This type of research in deceased organ donors is unique however, in that study participants may include more than one population – namely organ donor patients and transplant recipients. The need to consent multiple populations in these studies has been proposed as a barrier to conducting research in this area and broadly accepted standards guiding research consent requirements in this context is lacking.

4.1.3 Objectives

The study described in chapter 4 is a qualitative exploration using semi-structured interviews with solid organ transplant recipients, aiming to:

1. Elucidate their views on donor research
2. Elucidate their views on their role in the consent for donor research
3. Elucidate their preferences to providing their own data in organ donor research

4.2 Transplant Recipient Preferences Regarding Organ Donor Research: Their Role in Consent and Use of Their Data

4.2.1 Full citation:

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Study design and critical revisions to the manuscript

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Study design and critical revisions to the manuscript

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4.3.3 Abstract

Research on deceased organ donors has been hindered by concerns related to seeking research consent from transplant recipients. We undertook this qualitative study to elucidate solid organ transplant recipients views on organ donor research, their role in the consent for such research, and their preferences related to providing their data. We conducted interviews with 18 participants and three themes emerged from the data. The first centered around participant research literacy. The second described practical preferences of participating in research, and the third related to the connection between donor and recipient. We concluded that previously held views about the requirement for transplant recipients to have a consenting role in donor research is not always suitable.

4.2.4 Transplant Recipient Preferences Regarding Organ Donor Research: Their Role in Consent and Use of Their Data

Introduction

The gap between supply and demand remains a global concern in organ donation and transplantation (CIHI, 2014; Rey et al, 2011). Interventional research in the management of organ donors has the potential to narrow this gap by improving the quantity and quality of organs and improving outcomes for transplant recipients (CIHI, 2014; Rodrigue et al, 2016; Warrens & Lovell, 2012). Interventional or donor management research is research conducted with potential deceased organ donors, where a clinical intervention has been applied to the deceased donor patient or to their organ. The purpose of these studies is to improve viability of donated organs and reduce risks of the transplant to the recipient (Martin et al, 2021). As such, it must be noted that two populations are potentially involved in consent to this research. Namely, the deceased organ donor population and the transplant recipient population.

There is no guiding framework outlining consistent research consent requirements in prospective organ donor trials in Canada. This has created ongoing debate about which models are most suitable (D'Aragon et al, 2017). One challenging issue in this debate relates to the belief that transplant recipients should be involved in consent discussions related to research conducted with their donor (Abt & Feng, 2016; Gordon et al., 2019). Very little is known however, about recipient preferences related to donor research or use of their data post-transplant evaluating long-term outcomes (Gordon et al, 2019). Clearly, they are most directly affected by the condition of the transplanted organ any interventions, experimental or otherwise, can affect the overall health of the organ and thus, the recipient.

Another important factor relates to feasibility in obtaining consent to participate in research conducted by multiple teams. In Canada, one organ donor in a clinical trial may donate a heart, two lungs, a liver, two kidneys, a pancreas and there is potential that each organ may travel to different transplant programs, cities or provinces (D'Aragon et al., 2017). Moreover, each of these jurisdictions may have a local research ethics board (REB) that requires a different consent model. For example, one REB may require prospective informed consent, and another may allow deferred consent (D'Aragon et al, 2017). With various methods of connecting with different research teams and the broad spectrum of consent models required by different REBs, coordinating discussions across jurisdictions can be complex.

Thus, clinical trials in solid organ donation continue to face unique ethical and feasibility challenges due to uncertainty about which consent models would best strike a balance between study design and preference of stakeholders. Transplant recipients are a key stakeholder group in this field of study. They are the population that is directly affected by the condition of the organ that they receive, and any intervention has the potential to affect the success of their transplant and their health overall. We therefore undertook a qualitative study with the objective of elucidating transplant recipients' views on donor research, their role in the consent for such research, and their preferences related to providing their data.

Methods

Study design

A qualitative description design was utilized involving semi-structured interviews with transplant recipients. This methodology aims to gain knowledge of participants' first-hand personal experiences and describe their perceptions of a phenomenon (Neergaard et al, 2009).

Setting

Data collection was conducted online through the Zoom media platform (Zoom video Communications, 2022) from June 2020 to February 2021. Ethics approval was obtained from the Hamilton Integrated Research Ethics Board (HiREB; # 7517). Reporting has followed the COREQ checklist (Tong, Sainsbury, & Craig, 2007) requirements (See additional file 1).

Recruitment

We aimed to achieve a maximum variation sampling (i.e., participants with a range of experiences). In order to do this, we partnered with the Canadian Donation and Transplantation Research Program (CDTRP), a national not for profit organization that advances research in organ donation and transplantation in Canada (CDTRP, 2022). The CDTRP posted an English language invitation with information about the principal investigator (PI; name, occupation, role as PhD student) and the study (rationale, purpose, methods) via email and social media to their network of patient partners (CDTRP, 2022). Interested parties (previously unknown to the research team) contacted the PI by email and were selected based on inclusion/exclusion criteria. A ten-minute screening appointment was conducted over Zoom, where goals of the study were communicated and requirements of participants if they took part in the study. Participants were required to be 18 years or older, have received a solid organ transplant in

Canada, and have the capacity to participate in an interview with the PI, in English or language of their choice (provided an interpreter was available). All participants who met with the PI were emailed a twenty-dollar coffee voucher to compensate for their time.

Data collection

Participants who consented to the study completed a questionnaire that assessed their comfort with different research consent models. Using three-point Likert-style questions, participants answered whether they were not comfortable, comfortable, or very comfortable providing personal data for research use at different time frames. They were also asked whether they were not comfortable, comfortable, or very comfortable with a waiver of research consent, opt-out consent, advance consent with each study, and advance blanket consent (one time only). The intent of the questionnaire was to prepare them for topics arising in the interview (i.e., set the tone of the interview) and not as an additional source of data (See additional file 2).

We aimed for a sample of 20, anticipating this number would allow us to achieve 'information power' (it would be sufficiently large to elucidate information to fulfill the aims of the study) (Malterud, Siersma, & Guassora, 2016). Within this sample, we aimed to recruit individuals from across Canada with a variety of experiences.

Interviews

Semi-structured one-on-one video-interviews were carried out by the PI, a female Nurse and PhD candidate with experience in qualitative research and organ donation. Participants chose the on-line environment that was most convenient for them for virtual interviews (usually their home). Field notes were recorded by the PI.

We developed an interview guide based on a recent review of the literature pertaining to barriers to interventional research with organ donor patients (D'Aragon et al, 2017; Gordon et al, 2019; Nurs et al, 2010; Sarti et al, 2018). The interview guide (See additional file 3) was further refined with input from a patient partner in this research (a liver recipient) following a pilot interview with the PI and then review by an interdisciplinary team with expertise in qualitative and organ donation research. The interview guide explored participants' experiences at the time they were notified they would receive an organ, including perceptions about their donor and about how they would feel to learn about hypothetical scenarios involving low, moderate, and high-risk research that involved their donor (Figure 1). We also explored participants' perceptions on provision of their personal data for long-term outcomes, and their preferences for the process of consent for use of this data.

The one-hour videos were recorded and then transcribed verbatim. Three investigators (AL, MM, and PS) compared video files to transcripts to ensure data quality.

Figure 1: Description of Scenarios

Low Risk Scenario – We described placing lung donor patients in a face-down (prone) position. Participants were told that this is an intervention used safely with other critically ill patients but has not been tested in organ donor patients. Moderate Risk Scenario – We described administration of a systemic intravenous drug (heparin) to a multi-organ donor patient. Participants were told that this is a drug commonly used in the critically ill population, it carries a bleeding risk, but that it can be monitored and treated relatively easily. High Risk Scenario – We outlined a hypothetical novel intervention. In this scenario, we described administration of new and previously untested drug. Participants were told that researchers were confident that the new drug would not be harmful to the patient but it had never been used in humans.

Data analysis

Three investigators analyzed interview transcripts by hand using the analytic strategy appropriate for qualitative description methodology, content analysis. As the first few transcripts became available, we read through them independently to immerse ourselves in the data and get a sense of what was being said by the participants. Phrases or words that stood out were written into the margins of the transcripts to begin the process of identifying codes. Through this iterative process, we established the initial coding scheme (Elo & Kyngas, 2008; Hseih & Shannon, 2015).

Following completion of the first three interviews, the PI and two other investigators (MM and PS) met to discuss whether questions posed during the interviews were capturing the data that they wished to capture and any subsequent need for modifications to the interview guide. We repeated this "check-in" process after ten interviews were completed and again after fifteen interviews were completed. Additional questions were added that attempted to explore more explicitly whether participants felt providing consent for their data following intervention research with a donor at the time of their transplant was ethical (given their emotional and physical state of being) and if this potentially affected their capacity to provide truly informed consent. For example, we added a question asking if the participant was able to make legal decisions at the time of receiving news of their transplant. We also added explicit language defining research, ensuring we emphasized potential for adverse outcomes with each level of risk.

Once the coding scheme was established, we extracted generalizations based on the data and then collapsed those into themes (Neergaard et al, 2009). A synopsis of preliminary

findings was emailed to each participant for feedback and confirmation, which resulted in no further changes to findings.

Findings

Between June 2020 to February 2021, 18 interviews were conducted with individuals across Canada who had received various solid organ transplants (Table 1). Nineteen individuals consented, one participant withdrew. Interviews were 35 to 90 minutes, and all were in English.

We identified three themes regarding transplant recipients' perspectives on research consent in organ donor interventional trials. These were (1) participant research literacy, (2) practical preferences for participating in research, and (3) donor-recipient connection.

Table 1. Participant Characteristics

Characteristics of Respondents (N = 18)	N (%)
Sex	
Female Male	8 (44) 10 (56)
Age Group	
18-25 26-49 50+	1 (5) 5 (27) 12 (67)
Province	
British Columbia / Alberta Saskatchewan / Manitoba Ontario Quebec New Brunswick / Nova Scotia / Prince Edward Island / Newfoundland	6 (33) 1 (5) 10 (56) 1 (5) 0
Type of Transplant	
Heart Lung Kidney Pancreas Liver	4 (22) 2 (11) 7 (39) 2* (11) 5* (27)
Years Since Transplant	
0-5 6-10 11-15 15+	7 (39) 6 (33) 2 (11) 3**

*multi-organ transplants

**repeat transplants

Theme 1: participant research literacy

Participants reported previous experience with research studies as part of their care as a transplant recipient. We define this level of experience and understanding as research literacy, or how familiar they were with common concepts like consent, adverse outcomes, and interventions. Research literacy was composed of three dimensions; trust in research safety, perceived pressure to consent, and informed consent with an altered state of mind.

Dimension 1.1. Trust in research safety. Most participants described high levels of trust in their healthcare medical/research teams. Many described feeling that this team had the patient's best interests in mind and would not approach them to participate in research if they expected harm. They viewed research as offering benefit to them or the greater good. As one participant stated, "I trust my team enough and I trusted all of my teams enough before that if that was being presented to me, um I would feel pretty secure in the knowledge that they were pretty confident that it was gonna work, and can learn something along the way, but not that it would be something detrimental to me in order for them to find out." (male, lungs).

Some participants considered their decision to accept potential negative research outcomes as striking a balance. For them, the risk of not participating in research carried a risk in the form of lost opportunity for themselves and transplant science. As a participant stated, "there's risk with everything, and you just have to decide what risk is good with you. And I want them to keep learning new things and improve things" (male, heart). Those who experienced organ failure and treatment bridge prior to transplant, (i.e., renal transplant recipients on dialysis), were more willing to refuse hypothetical situations involving higher risk when compared to those who did not have the option (liver or lung recipients). "If I have the option of waiting, absolutely I would wait" (male, kidneys).

Dimension 1.2. Option versus pressure to consent. Participants were grateful that prior research had created more knowledge that was helpful to them. As one participant reflected, "If somebody didn't try at one time or another like (the) first heart transplant that was done in South Africa, it (there) wouldn't be transplantation now" (male, kidney). As hypothetical

moderate and high-risk research scenarios were outlined (Figure 1), some participants were unsure whether the desire to receive a transplant of a low-risk organ (i.e., one that had not undergone additional research risk) was more important than the desire to advance research (i.e., through consenting to transplantation with a higher-risk organ). "It's so hard because I know that without trying these things, we don't have the answers that we're looking for in the long run" (female, liver). While they recognized the benefits of research and identified potential for consequences, they felt a self-imposed pressure to receive higher risk organs (of potentially lower quality) as they felt they had limited options.

Dimension 1.3. Informed consent with altered state of mind. In exploring participant conflict related to personal risk/benefit in receiving a research organ, we discovered some participants reported their state of mind (at the time of transplant) was different than their baseline level. This was described as being because a state of confusion or decreased level of consciousness or feelings of euphoria at the news of receiving an organ. As one participant stated, "You know in hindsight probably my will and all that is probably not valid 'cause I… I don't really think I was kind of understanding what was going on fully at that time" (female, liver).

Theme 2: practical preferences

Practical preferences focused on aspects of consent ethics, content, and process. In this theme, there were three dimensions; the right to know, recipient role in donor consent, and options related to consent to their own research participation.

Dimension 2.1. The right to know. Most participants agreed they would like to be informed about intervention research in which their donor participated. In some cases, this was based on

a desire to preserve their autonomy in decision-making. As one participant stated, "if there's something that's going to possibly impact the health of the organ, be it experimental or whatnot, I think it's fair that that's told to the recipient so that they can make an informed decision as to whether…whether they want to accept it" (female, liver). In other cases, donor information was perceived as necessary for their post-transplantation health choices. "I adjust my risk meter. And it might tell me not so much do I want the organ, but what do I do with it after I get it in me?" (male, liver).

Dimension 2.2. Recipient role in donor consent. While participants expressed their right to know about donor intervention research, they unanimously agreed that recipients had no role in donor consent to research: those decisions should rest solely with the donor or their substitute decision maker. "It's not my body yet. I have no decision in what happens to a donor. No. Their family should have a say, if that was something that they had opted to do. Not up to me" (female, liver).

When it came to discussions about consenting to use of their own post- transplant data linked to pre-transplant interventions, preferences varied. Preferences regarding type of consent ranged from courtesy notification like "we're gonna use your lab values and we're gonna do a study on x, y, z…" (female, kidney/pancreas) to more involved discussions like "I would want to know what the intervention was, and what the implications of it were" (female, liver).

Dimension 2.3. Options related to consent. Overall, participants desired balance between control over their data with minimal disruptions– "I would appreciate less phone calls and

conversations than more" (male, kidney). Some were comfortable granting waived consent (i.e., granting advance consent once for use of data for any study), "I'm a blanket kind of girl…And I don't need to be asked along the way" (female, liver). Other participants were most comfortable being approached for consent each time a researcher wanted access to their data. As one participant stated after declaring he wanted to be informed with each study, "If my data and my information can help a patient twenty years down the road, I'm all for that. But I just want to know what this is and how it's being used" (male, kidney). Many participants were happy to receive notification through a letter or email notification versus a formal consent conversation.

While there was no consensus on the timing of consent discussions, most participants agreed that it should occur as early as possible "Well the sooner, the better" (female, Kidney), as they would like time to consider any potential additional risk "I'd like to know prior to [transplant], just to be aware, um but that wouldn't change my mind" (male, kidney). Many individuals preferred that consent to transplant and research consent should occur contemporaneously, since it would give them the opportunity to consider all risks involved and the impact on their lives post-operatively "Maybe it's actually part of the discussion before I receive the organ, right? So, if I know that this person was in a study and I received the organ in spite of that risk, that part of that was also agreeing to participate in the study, post-op" (male, heart).

Theme 3: recipient connection to donor

We defined this theme as participants' descriptions of pre-existing conditions (e.g., lifestyle choices and medical interventions pre-organ procurement) that exist with their donor and potential effects on conditions related to the recipient. This theme had two dimensions; improving transplant for others and honoring the donor and family.

Dimension 3.1. Improving transplant for others. Overwhelmingly, participants agreed that tracking recipient data was essential to determining long-term outcomes of donor research. As stated by one participant, "Because if you don't have any information on the recipients, how would you know that what you're doing with the donors is worthwhile" (female, pancreas/kidney). While many recognized the benefit of monitoring of their own health, they also felt a responsibility to future recipients to improve their experience; "with this research, I want to help as many as possible" (male, kidney).

Dimension 3.2. Honoring the donor and family. In addition to improving transplant for others, participants felt obligated to contribute their data as a way to honour their organ donor. As one participant stated, "I feel like I would automatically say yes, I'm gonna be tracked for this because it's the least I could do if this person gave me their organ" (male, heart).

Discussion

In this qualitative study, participants described high levels of trust in their healthcare team when being approached about accepting research organs from deceased donors. The notion of trust in medical teams is multifaceted and involves confidence that either party will meet the other's expectations of the relationship. According to Rasiah et al (2020), "it forms a

fundamental basis in the provision of healthcare" (p.2), where the provider is expected to do the best for the patient recognizing their vulnerability and "asymmetry" in their relationship (Rasiah et al, 2020). Similar to imbalances of power in most healthcare provider to patient relationships, asymmetry between researchers and subjects also exists. Here, this trust relationship involves a new dimension where the researcher is asking the potential study participant to accept additional risk. The patient is not only consenting to the risks of treatment (transplant), but they are also consenting to the risks of treatment that strays from the standard of care (transplant with a research organ).

In spite of this risk, participants reported high levels of comfort in receiving research organs. Similarly, in Gordon et al. (2019), transplant recipients report trust in their "transplant team for vetting the intervention organ as healthy enough for transplant" (p.480). These authors propose that interventions are only one factor to consider when accepting a donor organ that needs to be reported by clinicians and researchers (Gordon et al, 2019).

Once research risk was defined for participants, they were thoughtful about implications. Meaning, how would they be personally impacted and in particular, what would it mean to refuse a 'higher risk' research organ? This emphasizes the importance and relevance of information for transplant recipients and involving them at all stages of donor research should be considered. Not involving them could create distrust, causing them to decline research organs and decline contributing their data. This could have detrimental effects on advancing research in this area, as this narrows the number of recipients willing to accept research organs. It also may have detrimental effects on the health of the potential recipient by refusing a

transplant opportunity and risk their health deteriorating while waiting for another organ (Pondrom, 2016; Rasiah et al, 2018; TCPS 2, 2018).

We characterized participants' understanding of research and its risks as research literacy. Participants required clarity relating to risks of research. This is important because it made us question whether the traditional approach to research consent is adequate. In addition to a lack of understanding of risk, many participants revealed they felt they had an altered state of mind at the time of transplant. Thus, consent discussions held at this time need to be questioned as to their validity. A recent systematic review by D'Aragon et al. discussed variability in practice relating to research consent models used in prospective studies in neurologically deceased organ donors. Due to this variability, they stress the need for clarity related to ethical standards as well as the need for further research into consent procedures, specifically into privacy laws, research governance, and cultural norms in organ donation (D'Aragon et al, 2020).

At the time of transplant, participants expressed pressure to agree to whatever organ was offered. Pressure related to their self-imposed assumption that they should accept organs that were of lower quality. In these cases, they felt they had no other choice. Informed consent in these circumstances can be challenging, because as with consent discussions with patients who may have an altered state of mind, it can be difficult to interpret whether participants fully appreciate the full scope of the study the researcher is trying to describe. For these reasons, it is clear that consent discussions related to transplant should be conducted with experts in transplant (an organ donor coordinator or transplant specialist) and consent discussions related

to research should likewise be conducted with an expert in research (a research coordinator) (D'Aragon et al, 2020; Gordon et al, 2019).

Consensus about method and timing of such discussions is also debated in the literature, ranging from prospective, deferred, and waived consent models (Gordon et al, 2019; Guedi et al, 2013; Nurs et al, 2010; Pondrom, 2016). Part of this variability exists because of lack of consistency between jurisdictions about the status of donors and recipients (D'Aragon et al, 2020; Gallin Heffernan & Glazier, 2017; Gordon et al, 2019), as well as a belief that interventional trials with donor patients also requires consent from recipients (Cooper & Gardiner, 2020; Elo & Kyngas, 2008; TCPS 2 (2018). While it was clear that individual preferences among participants varied related to the method and the timing of research consent for use of their own data, it was also clear that participants felt in no way they should have any role in the consent of a donor to any type of study. They stressed however, the importance of being informed of this research as a way of optimizing their health post-transplant.

Best Practices

Research with organ donors has been challenged with views that transplant recipients should also be required to provide research consent. Our findings suggest transplant recipients would like to be informed of such research, but do not feel they should have a role in consent unless it pertains to their own data. When it comes to providing their own data, they prefer a balance of being informed and minimizing interruption to their lives. Given the nature of qualitative research, generalizability beyond this sample cannot be broadly applied. It is possible that our findings represent commonly held beliefs amongst transplant recipients, but the context

specific methodology of our study (i.e., opinions gathered rely on the interaction of the interviewer and the interviewee and cannot be reproduced) limits inference beyond.

Research Agenda

The logistics of informed consent has historically been a barrier to conducting donor research (Gallin Heffernan & Glazier, 2017; Gordon et al, 2019; Guedi et al, 2013). Results of this study are consistent with other evidence that transplant recipients are invested in the health of their transplant and are positive about participating in research (D'Aragon et al, 2020; Gordon et al, 2019). Views from other stakeholders should also be explored, including healthcare providers, researchers, potential organ donors, and families of organ donors. Input from these groups would contribute to strategies aimed at removing barriers to interventional trials, which may translate into more transplants overall.

Educational Implications

Once further research reveals more generalizable evidence about this important topic, education around best practices will need to be conducted. Broad scope knowledge translation efforts with multiple stakeholder groups, particularly research groups, is required to communicate different views and remove barriers to conducting interventional trials in this field.

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4.2.6 Additional file 1: COREQ (COnsolidated criteria for REporting Qualitative research) Checklist

Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			
Personal characteristics			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	5
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	5
Occupation	3	What was their occupation at the time of the study?	5
Gender	4	Was the researcher male or female?	5
Experience and training	5	What experience or training did the researcher have?	5
Relationship with participants			
Relationship established	6	Was a relationship established prior to study commencement?	4
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	4
Interviewer characteristics	8	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	4
Domain 2: Study design			
Theoretical framework			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	4
Participant selection			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	4
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	4
Sample size	12	How many participants were in the study?	7
Non-participation	13	How many people refused to participate or dropped out? Reasons?	7
Setting			

Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	5
Presence of nonparticipants	15	Was anyone else present besides the participants and researchers?	5
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	Table 1
Data collection			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	6 and appendix c
Repeat interviews	18	Were repeat inter views carried out? If yes, how many?	7
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	4
Field notes	20	Were field notes made during and/or after the interview or focus group?	6
Duration	21	What was the duration of the inter views or focus group?	7
Data saturation	22	Was data saturation discussed?	5 (information power)
Transcripts returned	23	Were transcripts returned to participants for comment and/or correction	7
Topic	**Item No.**	**Guide Questions/Description**	**Reported on Page No.**
Domain 3: analysis and findings			
Data analysis			
Number of data coders	24	How many data coders coded the data?	6
Description of the coding tree	25	Did authors provide a description of the coding tree?	no
Derivation of themes	26	Were themes identified in advance or derived from the data?	7
Software	27	What software, if applicable, was used to manage the data?	N/A
Participant checking	28	Did participants provide feedback on the findings?	7
Reporting			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	7-12
Data and findings consistent	30	Was there consistency between the data presented and the findings?	7-12

Clarity of major themes	31	Were major themes clearly presented in the findings?	7
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	15-16

4.2.7 Additional file 2: Pre-Interview Survey Questions and Answers

	Not Comfortable	Comfortable	Very Comfortable (n/%)
Would you be comfortable if a researcher had access to the following information?			
• Your survival rate as a transplant recipient at 1 week, 6 months, one year.		1(7)	14(93)
• Data about how well your transplant is working, like blood tests, at different time points.		1(7)	14(93)
• Data about you, like your age, male or female, height, weight, or other health problems.		1(7)	14(93)
Below are some different situations that talk about how researcher get data. Indicate how comfortable you are with these different situations.			
• "Assumed consent" – Here, researchers would get your data (blood tests, survival rates, and data about you like age, male or female, height and weight) without telling you. They do this in a way that no one would ever know you.	1(7)	7(47)	7(47)
• "Assumed consent through opt-out advertising" (you're already part of something unless you tell someone you don't want to be) – Here, researchers get your data, but there are posters in your transplant clinic that tell you how to remover your data from the study.	2(13)	5(33)	8(53)
• "Assumed consent with a mailed letter – Here you get a letter in the mail telling you that your data has been collected and tells you how to get it taken out of the study.		5(33)	10(67)

• "Advanced consent" – Before your transplant, you are asked by a researcher to collect your data for a study after the transplant. This means that if there are many studies, you would have many people asking you and many times before your transplant.		4(27)	11(73)
• What if you provide permission once but you don't know which studies will use your information later?	3(20)	5(33)	7(47)
• What if you are asked after your transplant but BEFORE your data is collected to give permission with each study that comes up? This means you would be asked many times.		4(27)	11(73)
• What if you are asked after your transplant but BEFORE your data is collected for all studies in the future? This means you would only be asked once for data that would be used in many studies.	3(20)	2(13)	10(67)
• What if you are asked after your transplant and AFTER your data has been collected for permission to use the data in a study?	1(7)	3(20)	11(73)
• What if you are asked after your transplant and AFTER your data has been collected to give blanket permission for all the data that has been collected and is to be used in any future studies?	3(20)	4(27)	8(53)

4.2.8 Additional file 3: Interview Protocol

The following questions are for demographic purposes that I will use to describe the people who were studied overall.

What is your gender?

What is your age?

What type of transplant did you receive?

How long ago did you receive your transplant?

What province do you live in and what province did you receive your transplant?

The next series of questions will be asking you to tell me about your transplant experiences. If there is any identifiable information that you use, like your name, this will not be used to report the final results. I will just use the letter name that has been assigned to you. If there is anything that you don't want me to include in the final results, please let me know.

1. I want you to think back to the time when you got the news that you were going to receive your transplant and think about some of the things you were feeling.
   What was that like? Did you have any thoughts about the person donating and can you tell me about that?
   And, what did you think about the person who was donating?
   What did you think was happening with them (the donor) at that moment?
   ask if they were able to make legal decisions at this time

2. And when you think about what's happening with your donor and perhaps the different medical treatments they are receiving in the intensive care unit, what do (is there anything) you wonder about?

3. What if – hypothetically – I told you that some of the medical treatments were experimental, how does that make you feel about how it would affect you?

   Define experimental treatment for participant – frame very simply and as a research study. Ensure they understand before next going through risk scenarios

   What if the experimental treatments are low risk or high risk?

Let me outline an example of something low risk and something high risk (for low risk describe prone positioning intervention, moderate risk describe systemic heparin, and for high risk describe a novel or new drug treatment)
Does that change anything as I describe these levels of risk? Is there any level of risk that would be unacceptable to you? What would make you decline the transplant?
What if there is a risk to the organ itself, so that it would affects the success of the transplant or whether you could procure it or not?

4. Do you think organ donor research should be done? Why yes or why no or can you tell me more about that?
   Do you think that part of this research should involve keeping track of its effects on recipients?
   Do you think that you, as the recipient, should be informed or have any say in any research that is done with a donor patient?
   How would you imagine this would happen? For example, a letter sent out afterwards.
   And when and how often do you think this should happen? For example, do you think you should be asked every time your information was accessed or only once, or even at all?

5. What would you want out of research?

6. You've had a positive experience with your transplant. Do you think things would be different if it hadn't gone so well?

4.2.9 Appendix A. Letter to Potential Participants

Dear Recipient:

Re: Research Consent in Donation Trials

We are writing to you to tell you about a research study called "Research Consent in Organ Donation Studies". The study is being undertaken by Amanda Lucas, a clinical researcher and PhD student at McMaster University. More details and an invitation to participate are below.

This study is looking to conduct one-on-one interviews with solid organ transplant recipients to understand how they feel about organ donor research and use of their personal health data. It is also looking to understand how solid organ transplant recipients feel about how they give permission for this research. You are eligible to participate in this study if your are:

(a) A solid organ transplant recipient
(b) An adult over 18 years of age
(c) You received your transplant in Canada

This study has been reviewed by the Hamilton Integrated Research Ethics Board and by the Canadian Donation and Transplantation Research Program (CDTRP).

The CDTRP is a research network that uses research information to help increase organ and tissue donation in Canada and enhance the survival and quality of life of Canadians living with a transplant. Whenever possible, the CDTRP supports important research just like this study. To protect your privacy, the CDTRP has agreed to contact transplant recipients who might consider participating in this particular study. This way, the researcher will not know who has received this letter. No information about you, not even your name, has been shared with the researcher. She will only learn who you are if you choose to contact her, and then choose to identify yourself. It is your choice to participate or not. Any care you may be receiving related to your transplant will not be affected in any way by your decision. If you choose not to participate in the research study, you do not have to tell anyone; you may simply ignore this letter.

If you have specific questions about the study or want to participate, please contact the researcher (Amanda Lucas) directly at 204-299-8539 or lucasa5@mcmaster.ca. You do not need to reveal your identity to obtain further information.

Yours truly,

4.2.10 Appendix B. Codebook

Code and definition	Supporting quotes/data	Analysis notes
Feelings around notification of organ availability Any expression of emotions about imminent transplant or availability of donor	"It was exciting" (B, F, P+K) "Everything from um…uh relief to excitement to nervousness, right" (D, M K) "Um, well, great exhilaration. Um, relief 'cause I had waited for a year and a half in heart failure. So, at that time I was just sick of being sick. Euphoria. Um, great, great nerves" "I was more concerned form my family 'cause I was sort of at the point where I was willing to accept" "So, for me to see them go through that, you know, that was tough" (P, M, H) "It was a lot of surprise" (C, M, L) "From the time of kind of entering into hospital, the sickness to transplant was like thirteen days. So I think when I was told it was just uh…um, complete and total shock" "disbelief that…that this was happening" "I knew I was very ill and that I could die" "shocked, scared" (E, F, Lv) "I think I approached it with enormous um intellectual curiosity. I was just fascinated by what these guys were doing" (A, M, Lv) "I had very much of a renewed energy"; "Was very excited" "That was the start of starting to have hope again" "So this was the only chance that I had to live. And so, it was…it made everything exciting again. Like, there was some reason to um fight to stay awake" "it just made everything so much better knowing" (F, F, Lv)	Difference between acute illness and chronic illness…this may be an important consideration to how recipients might view research. When everything happens quickly, they have less time to think about all sorts of issues and that can be overwhelming. Some responses suggest that news of transplant is a difficult process of decisions. This may be more so with acute illness as with participant E. Lots of heavy and new information sharing, which is hard to assimilate. This person also exhibited a lack of public education with the expectation that anyone who needs a transplant gets one.

	"relief, excitement, um always a little bit of bitter-sweet, but um…understanding that somebody else had to die" (G, M, H) "it was a relief to find out that uh something might be.. be able to be done to, you know, like…{sighs} I…I could barely function, it was a that bad." (H, M, H) "by the fourth time..{pause}, you know, I wouldn't say I was jaded, but I was prepared for it to be a false alarm again. And so, as we went through all the preliminaries that you go through, you know, in the twenty-four or forty-eight hours before a… it was always in the back of my mind that, "well, you know, this…this may not be for real." And so, I don't think it ever really hit me until they were just about to put the needle in my arm {laugh\s} that is was really gonna happen. So, yeah, what…what I was thinking was just really that uh just hoping it would work out; more concerned really for my family that was with me. I think they were probably…you know, I didn't have a choice in it." "I wouldn't say I was not emotional, but I was…I was prepared for disappointment, let's put it that way." "it was all kind of routine by that point" (J, M, Lv/K) "When I received the call, I was hesitant…leading up to my transplant there was three calls in total" "I think it was a year and a half later, I got a second call, and I knew this time not to say anything to anyone um, or…Like, I kinda knew not to be as excited" "the third time…I wasn't trying to get excited or anything" (M, F, K) "So, I was so petrified when doc…when they were gonna call me" (K, M, K) "So, after so many false calls – and in those days it was a pager that went off – I basically said, you know, "This is ridiculous. When is this ever gonna happen?" And so, for me when it became a year, it was a long time. And in that regard when I got it, I was actually off from work that morning. I wasn't feeling too well, and I was sleeping. And the phone rang, and they said, Come down to the hospital as soon as you can" "So, I was a bit anxious, but I was working full-time and whatnot ,so…it wasn't like my life was put on hold waiting for that transplant" "And I find that's the hardest part for someone who's waiting for a(sic.) organ	

	and more than one organ, is the waiting part; is you get very anxious. You get, you know, "is it gonna happen? Should I go on with my life? Should I travel?" 'cause there are restrictions" (O, F, K/P) "I mean, three months was long for me, and I thought, "I am not going to be doing this for the rest of my life." This is… It was…I was going on Mondays, Wednesdays, and Fridays. And when I heard the news, well, I had… I had a bunch of people who were offering in the line. And it ended up being my sister-in-law who gave me the kidney. But I was very happy. Unbelie… Like, I can't even explain how happy I was." (I, M, K/L) "It's a bit difficult, but once again it was something that was uh…kind of coming along, like, for a while" (N, F, K)…. *Goes on to say did not want additional risk to living donor, and that's what made it difficult*	
State of mind Cognitive ability at time of transplant. May be altered level of consciousness, encephalopathy, or emotional state.	"I don't think anything totally can prepare you for what that experience is gonna be like, 'cause I mean you never know how it's gonna turn out. But man, I would have preferred to have some um time to think about it beforehand" (E, F, Lv) "You know in hindsight probably my will and all that is probably not valid 'cause I…{chuckles} I don't really think I was kind of understanding what was going on fully at that time" (E, F, Lv) "You know in hindsight probably my will and all that is probably not valid 'cause I…{chuckles} I don't really think I was kind of understanding what was going on fully at that time" (E, F, Lv) "I was lucky in the sense that I had been in hospital for a few weeks beforehand, so I had time to sort of digest the idea that somebody else had to pass away. I've met people who have been on the list for, like, a few hours and they don't have that time to…to really process what was happening, so…In a way I was kind of blessed to have that bit of a week or …or a few weeks to…to wait" "I was somewhat stable in hospital, waiting, but my condition was pretty bad" (G, M, H)	This may be different if the patient made the decision to go ahead with transplant vs the family. Liver recipients encephalopathic. With participant E, questioning decisions with validity of will. This would also bring into question the validity of consenting to research decisions

	"I could barely function so *anything* they could do I knew was going to be an improvement" (H, M, H) "In fact, you know, the whole journey that I had was, compared to a lot of people, uh not so bad. {laughs} Yeah, I didn't have the cognitive issues" (J, M, K.L) "So, I said if something's going to happen, let's happen with a transplant and we go from there on" (K, M, K) "That time I was just numb. I didn't think of anything." "At that particular moment I never thought of the donor. I was just thinking personally of myself. I start thinking about donor maybe ten years down the road when I … when everything sank in that I'm carrying somebody else's body" (K, M, K) "I was at home in bed, and they called me. But I was actually in rejection and I was exceedingly sick. I was on death's door. I was so sick. I'm surprised that I actually make it through the surgery" (L, F, L) "No, Not at that time. I was ready because I was sick. I barely could walk. Uh, I was just bones" (K, M, K) "I was so thrilled. I was so excited; I didn't know which way…which way to go" "I was thrilled again, of course, but um I think I…I had tears of joy I was so happy that they were gonna save me" "So, I was very, very happy" (L, F, L) "It's very, very complex, multi-faceted, difficult to describe that, you know, those first… or the final hours before, you know, they came in and told me, you know…told me um…you know, that they had a heart and were ready to go. And, you know, I mean, by that time I was like, "give me the paper. Let's sign it. Let's go. Let's get going." You Know?" (P, M, H)	

	"Like, I… I mean, I didn't know what the outcome was going to be, but I… I almost thought it had to be better than where I was." (I, M, K/L)	
Decision to proceed to transplant Expressions of choice to receive a transplant. Could be in advance or ahead of time.	"I was surprised that I was being asked at the age that I was. I really knew nothing about transplant, but I assumed that it was a young person's thing" (C, M, L) "I didn't know whether or not I would accept having a transplant. I hadn't decided because I had read a lot and assumed that I would have all the side effects, and…But when I got that call there was no way I was saying no" (B, F, P+K) "Because I felt that that chance would never come again" (B, F, P+K) "I don't think I would have necessarily {pause} maybe liked {laughs} what I was being told, um…but, on the other hand, I was pretty close to the end. So, I wouldn't really have had a choice. It would have been a choice between life or death, rather than a choice of "no, no. I'm gonna wait {laughs} for a while longer and see what comes up" (C, M, L) "I think if I'm at the point where I need to have an organ, I think I would accept any organ, no matter what the condition. If it was going to extend my life um…and something experimental had been tried, I think I would take the chance" (B, F, P+K). "So, they were willing to try anything, even if it meant me having {pause} like it not lasting for very long and having to get another one or I had some sort of a communicable disease from it. They…that was not even really pause for them. They…they would have gone ahead with…They would have gone ahead with anything at that point" (E, F, Lv) "I had no time to prepare for that" (E, F, Lv) "I can't imagine saying no. I just would want to be informed, I guess, of what I was going to be facing" (E, F, Lv)	As above…difference between decision made by family vs patient As above…difference between acute vs chronic illness Topic is relevant as it speaks to ability to make informed choice. If there are no other options available, is it ethical to ask about consenting to donor research at this time? The recipient may feel pressured to consent as they feel they would not be able to receive transplant and then die. There seems to be a common trend with the earlier questions about decision for transplant and then the question later, where I ask about whether there was anything that would make them not accept an organ, including

	"The way my mind works is I just ask a bunch more questions and figure out whether the risk meter {hand gesture of metronome} um works for me, and what kind of situation I'm in. And, you know, if I'm in …like, my MELD score's twenty-six, and I might not get another shot at an organ uh for six months, and by then I'm gonna be total dust, I guess I'm gonna take {chuckles} the high-risk approach." (A, M, LV) "I was never gonna turn down an opportunity to be well. Ever." (F, F, Lv) "I was my only shot at staying alive" (G, M, H) "If that was my only option, and what the medical team thinks was my best shot at…at a better outcome, then that's what I'm gonna take" (G, M, H) "But he encouraged me to put my name down, and if…when the time comes, I can always change my mind. So, when they call me, I was a little bit scared, but I look at my family and I said, "What choices do I have? If I gonna die on dialysis, on transplant; either way it will happen." So, I accept um call to go for transplant" (K, M, K) "Because I had had a successful transplant previously. So, I knew it was workable. And I was grateful that uh I was accepted and ug going to be able to breathe again" (L, F, L) "I'll take what I can get…For me, I wouldn't be picky. You know? 'Cause I was already on the transplant waiting list for, oh gosh, maybe two and a half years at that time" (M, F, K) "I didn't have anything that would have scared me away. It wasn't close" (I, M, K/L)	the hypothetical increased level of risk with research. This may have to do with the level of acuity with their illness.ie…how ill they are.
Struggle to reconcile another's loss for own gain	"it hit me all of a sudden why I was having this transplant; that someone…So, while we were rejoicing, someone else was going through probably the moment of their lives. And that really hit me hard. {with both her hands at her heart} And um…But I also understand that the person didn't die for me to get the transplant. They died anyway" (B, F, P+K)	There is a recurring theme about guilt around someone else dying for the recipient to live. Some participants choose to see

Description of realization that another died so that they could live.	"I found it difficult to…to reconcile that my family and ... and I were rejoicing {sounding choked up} while somebody else was mourning" (C, M, L) "I guess I questioned if I deserved it…Maybe somebody younger should have got it" (C, M, L) "There's guilt that's unbelievable. You know? 'Cause you think: Somebody died and…had to die because, (sighs) you know, to save you and…It's a lot to process and… and uh…um… And it still would have been hard had I …had I had a chance to think about it ahead of time, but I still would have preferred to {chuckles} have been able to kind of get a bit of a head space about that" (E, F, Lv) "So there is a cost and it's not just the cost of that person's life but the people that they are impacting" (G, M, H) "but no, they didn't die *to* save me; they were dying, but in their generosity, they saved me. And there's a huge distinction there." (H, M, H) "we're kinda hoping that that will make it easier on…on the bereaved family. Um…to know that in this, you know, worst part of their life something good might come of it. And…and it…it was kinda reassuring to me and I think to out family to know that there was that, you know, glimmer of uh…uh…of something to mitigate the grief they were going through" (J, M, K/Lv) "There was somebody up north…and had …they had had an accident. Now, I didn't know much about the situation or anything. But the young person had had an accident and uh were on life support. So, I was really sad for the …the people involved and for the person in general, I was very sad that they would have to lose somebody in order for me to…to be alive. It was very uh…it was hard to wrap around my…wrap my head around it because of the …you know, their loss and my gain." (L, F, L)	it that the person was to die anyway, so they didn't die FOR them to live, however their death allowed them to live in spite.

	"I was really worried about the family, um, the people involved, um…that…that it would be such a traumatic thing to lose somebody and to have to witness somebody , like, dying, and um…but to have the…I don't even know what...if you'd call it courage or mind...mindful enough to donate the organs that the person could still provide. You know. I was…I was really quite worried about um how they would uh take everything." (L, F, L) "My mom said to to me…she was just left all alone, and she kinda just took a deep breath, and she's like, "Somebody just died {pause} and saved my daughter's life." Like…And I'll never forget that moment" "Like I took kind of like an oath or promised myself that every year…Like, on my kidneyversary I honor…Like, every day I honour this person. But I especially highlight my kidneyversary." "I've tried to like for that other person as well" (M, F, K) "right away I thought that if I survive the transplant my family would be celebrating my rebirth, to an extent. You know, renewal of life, all of that. But the family of the…of the person donating the heart was… were going to attend a funeral that week. So, that was difficult, right, 'cause um… And that… that really kind of muted my…I mean I was euphoric that, you know, we were gonna give this a shot and a try and all that, but it… it… in … in many ways, it muted my uh… my thought about the whole thing because I'm, thinking about a family that… that are going through a terrible, terrible time." (P, M, H) "I haven't stopped thinking about that person since {chuckles} I've got my liver" "I can't let them know what it meant to me, right. So, it's… it's very {sighs} I mean, it's their wishes. They don't want to…but maybe they chose not to, but {sighs} I… I… I would… I would hope that if they knew it would maybe change their minds of what …what that gift di for me especially" "The treatment I received in that hospital and that my donor probably received were… was top notch" (I, M, K/L)	

Donor as human being and not patient Response that is framed in context of the donor. Where they connect that I am not asking about them, but about their thoughts of donor.	"I don't know if I thought about them at the moment. It was afterwards" (B, F, P+K) "Not so much um…{voice quavering} not so much pre-transplant, but certainly post" (C, M, L) "It wasn't until after the transplant" (C, M, L) "I uh… um sort of have thought about what it must have been like for the family and… and, you know, if they were on life support or, you know, if… if um… you know, the conversations and the sadness and the grief and… and um… {pause} Yeah, I mean, I think it was… would be quite similar to, you know, the experience that my family was having about, you know, facing death and… and, you know, what that looks like and, you know, what's going on. And probably shock; I'm guessing it happened very quickly for them as well. And they're facing the… you know, the death of a loved one and trying to decide what to do and… and just the overwhelming sadness and grief that, you know, that they must have been… that they must have been feeling at the time." (E, F, Lv) "There was a lot of thoughts uh because in the leadup to that there was a blood type issue and there was a size issue for me" (A, M, LV) "And so, then when you get the call and say we've got a match, you automatically think about, "oh, it must be a big young healthy guy with the same blood type." "And clearly thinking about what that would be like for a family with perhaps somebody that's under thirty that just had a bad break" "And so, I was thinking about that, but then I got back to my own mortality" "And my dire need to uh just tweak my will a bit" (A, M, LV) To be honest, I was pretty selfish. I was thinking more about what was happening to me. I knew my donor was already {pause} deceased. Um…and didn't really give a lot of thought to the family or what they were going through while I was going through what I was going through." (C, M, L)	Compartmentalizing – not thinking about donor, allows to accept organ Should they even be asked if they do not think of the donor at that time? Many participants do not answer the question about thoughts of donor directly. They speak of themselves until reminded to specifically describe donor There appears to be a moment when probed to think about the donor/family that they start to think of them as emotional human beings and not biological

	"So many thoughts now. Um…I cried pretty much all day for that family. Um they were making the hardest decision ever" That was something my dad could relate to. But this time I was going to be okay. He wasn't going to lose another child. So, it was a big thing. Um…I still think of them all the time. All the time. They're a huge part of my every day." (F, F, Lv) "I never really thought about it **at** that time" (F, F, Lv) "I guess in my mind I…I uh…um sort of have thought about what it must have been like for the family and …and, you know, if they were on life support or, you know, if…if um…you know, the conversations and the sadness and the grief and…and um…{pause} Yeah, I mean, I think it was…would be quite similar to, you know, the experience that my family was having about, you know, facing death and …and, you know, what that looks like and, you know, what's going on. And probably shock; I'm guessing it happened vary quickly for them as well. And they're facing the…you know, the death of a loved one and trying to decide what to do and…and just the overwhelming sadness and grief that, you know, that they must have been…that they must have been feeling at the time." (E, F, Lv) "I hope when somebody dies that they're an organ donor" (G, M, H) "Um, I tell people that I've been keeping my donor's heart alive for five years now. Not that their heart's keeping me alive, but I'm keeping part of them alive" (H, M, H) "his likes, his dislikes, what some of his favourite foods were such as strong black coffee, {smiles} which is how I drank mine before and especially now. I always make sure to keep …keep his heart happy by…by feeding it plenty of coffee" (H, M, H) "there's just that wondering about, you know, what was the person like? What happened to them? Um…How did they die? You know, thinking about their family. Like, with use it was a kind of a joy…It was a joyous occasion, really. Aside from the worry about whether or not I might die, {laughs} it was.. it was really the potential end of a thirty-year odyssey to…to get	

	to the transplant. Um…So, there was… Youi know, there was apprehension but here was a lot of happiness as well. Happiness and relief on out end. Meanwhile, another family somewhere is going through the worst time of their life." "it was a wave and trough kind of thing. You know, you're happy, but then "ah geez that other family" (J, M, K/Lv) "But yeah, there…there is always in the background, knowing that there's a whole other process going on someplace else. Yeah. Yeah, it…it's there and in a quiet moment you think about it" "Well. Again, we don't know what the process was. You know, we…we…we don't know how the person died. Was it an accident? Was it a long illness? We…You know, you just don't know" (J, M, K/Lv) "That time I was just numb. I didn't think of anything. I didn't even think of the donor even past transplant" (K, M, K) "I was quite young…So, I think I was just trying to mentally prepare myself; Am I really getting it this time?" " I know my mom more thought about that; her being there by herself. I think it was…For me it clicked in afterwards that someone just passed. I was just ringing emotions, and then afterwards I, like…That's when it hit me" (M, F, K) "No, not really. Yes and no. That's a hard question. The reason I say yes and no is at the time I was excited for myself. Now that's very selfish. I know somebody had to die, pass away about that. I think after I had the transplant and I was healing. I think there was a lot more reflection time um in regards to sitting back and saying, "wow! You know what? I wonder where this organ actually came from. I wonder what…" You know, "I wonder what the situation is"" (O, F, K/P) "so I watched this program and really… At that point it really hit me. Like, to the point I was actually lucky I was watching it by myself. My family was out. I was… I just burst into tears. I was just like, "Oh my god! I never…" You know. And there's …Particularly, there's this, you know, image of um …video image of the body being wheeled out and the mother just	

	howling. You know. And you're like, "Oh my god!" And *then*…I'm embarrassed to say, but *then* I really got it. Then I *really* got it." (P, M, H)	
Quest for knowledge (or not) Search for details about donor patient, about transplant in general. This could be prior to transplant or post -transplant.	"I always wondered about who they were an was there somebody missing that at that time? Were they…? Did they have a family? Were they somebody's child?" (B, F, P+K) "I tried to find out a little bit more about…about my donor…And that {trying not to get emotional} probably made it worse" (C, M, L) "I have so many questions. I wonder do I really want them answered" (B, F, P+K). "I don't know that I could even think about that. I don't think I could accept…I could handle knowing what was going on in the ICU. **I'd rather be in the dark**." (B, F, P+K). "And I just read everything I could on it" (C, M, L) "'Cause at heart I'm nosey. Um...I don't know; I've always been really interested in what was happening to me and my body." (C, M, L) "I want to know all about it. I want to know how it works and why and…Not because I want to argue against it; just because I want to know" (C, M, L) "And so, there's a number of things that they don't really tell you. And they're kind of alarming, but they're actually quite common. So, having had that knowledge ahead of time, I think, would have been beneficial as well." (E, F, Lv) "Number one. Can I have the data" "I'd still be really curious about why this individual's liver is deemed to be right for me." (A, M, LV) "I would love to find my own donor family. I wish that I could…I wish there was more openness um…to connect between them. I wish it wasn't so separate." (F, F, Lv)	There seems to be a search for information or questions about the donor as a person here, their life, their family, and also search for information or questions about the potential function of the organ….data, about the person or the organ. One seems much more humane and the other very dry or factual Speaks to link between actions pre transplant and post. While there is at times a desire not to acknowledge much about the donor until later, here there is a desire to know about things specific to pre-transplant. This might include knowledge of any research.

	"Um, knowledge is important, but sometime knowledge can impact your decision" (K, M, K) "Out of respect, it's just something that I…You know, I know he passed away; I don't know how. And, you know, I …I just don't want to…want to pry and find things that, for whatever reason, they didn't want to pass on or possibly weren't allowed to. I just want to follow their wishes" (H, M, H) "It's healthy to think about them, but it's not good to obsess on it." (J, M, K/Lv) "And I don't know if I was ever told by doctor that somebody gave you the kidney. It didn't seem to me to say anything at that time" (K, M, K) "Because they don't…they get to know more information about who receives the…the person's organs than I get to know about them, even though both parties want to meet." (O, F, K/P) "Sometime not knowing was better than knowing too much" (K, M, K) "I think I was so sick it took me so long to get better to get to the point where I could even think properly. I don't think I was thinking about the consequences as much as the gratitude that I was actually alive again, because I felt like I was on …like, walking…like the walking dead" (L, F, L) "Yeah. I did… I did find out, you know, sort of accidentally that the donor was a she and she was 27. I … I think she was out of province, but I've never been able to really track down who potentially it could be" "Well, it's a great mystery actually, you know, whose heat I really did get. So… And for many transplant patients that's an issue." (P, M ,H)	

Connection of donor and recipient Description of how conditions existing with donor patient, including pre-consent to donation and post-consent to donation (ICU), may have an effect on potential conditions with recipient.	"It would have a better outcome for the patient if the organs were in better condition" (B, F, P+K). "Because if you don't have any information on the recipients, how would you know that what you're doing with the donors is worthwhile" (B, F, P+K). "In the case of an opioid overdose, I don't know what effect that has on the functions of the body. What does that do to different cells in the body when that happens? Is it..? Is it something really isolated? Is it something system-wide? "(C, M, L) Do I have different dietary things? Do I have to watch for this or that or…? Can it help me manage the rest of my life better? (A, M, LV) "it adjusts my risk meter. And it might tell me not so much do I want the organ, but what do I do with it after I get it in me? Do I behave differently? Do I have different dietary things? Do I have to watch for this or that or…? Can it help me manage the rest of my life better? (A, M, LV) "Um… So, I think it was… it would be.. It would have been…I think it would have been a slightly more difficult wait because, if it was a stranger, it wouldn't have been…I wouldn't have been as informed along the process, right. And I think for many transplant patients, myself included, like this idea of a transplant is…I saw it very much as a carrot, if you will, kind of in front of me along the process; that, oh yeah, I have to do dialysis today, but a transplant is…is within reach or it's there right. And if it was a stranger, you know it… I wouldn't have had that information in the process. So, um it wouldn't have been… I think it would have been harder to wait if I hadn't known the person." (D, M, K) "She shared information with me. So, we would have had a conversation about it. Right? But that doesn't always happen. So, I think in living, there should be…if …if research is gonna take place, then I think that there should be a…an open …an open dialogue ora t least a	Speaks to realization that actions done with a donor patient may affect outcomes with recipient. Can provide rationale for seeking consent for donor research OR informing recipient of donor research. Interesting difference when living donor knows recipient. Idea of transplant as carrot. I have only seen this lack of desperation in the kidney population. Others have described transplant as an option, but in context as option against death – or really no option at all.

	conversation that has to happen between that donor and that recipient. And, you know, it's …it's complicated because ultimately the donor… the donor's body is the donor's body. But, as a recipient, you… you're receiving… {chuckling} you're receiving an organ from their body, so you should at least have um… it would be hard for me to say "consent" because...like, you…every individual has consent over what happens to their body. So… But I do think that where… where it becomes important is to um… is to be informed of it and then um I …I think it should…it would be very valuable for the recipient and the living donor to be required to have a conversation at the very least. And then…and then ultimately it's the recipients {shrugs{…it's also {chuckles} the recipient's consent for instance if a living donor u, decides to go against the wishes of the recipient, then it's also the recipient's consent on whether or not they have that transplant." (D, M, K)	
Responsibility of recipient to honor gift of transplant Expression of gratitude for donation with declaration of personal onus to reciprocate in some way. This could be as a participant in research.	"you've got to be careful. I don't think you deny yourself. You have a transplant so that you can live, and you should live your life. But I think you have to respect your donor too, and uh… you know, look after these organs the best you can. So, I think there's more than just the results themselves" (B, F, P+K). "It's important to me to continue to keep acknowledging, recognising, and um…{pause} showing my gratitude for the fact that I'm alive. "(E, F, Lv) "I'll be eternally grateful um, {pause} {voice quavering slightly} to this family and this donor. I remember after transplant I…I spoke at a symposium at the hospital, and said, "I don't know if this will last even a year, but I'm just *so* grateful to feel so well. And I had…I hadn't really realised how sick I was" (B, F, P+K). "After the fact, I think you um…(sighs) you hold your donor um…I mean, they're your saviour. They saved your life. Um… They are the salt of the earth. They are your angel. They're your everything. And so, I think I…I…They're my hero. I viewed then as such. Right? Like, as Batman or Spiderman or whatever. I mean, they're…they're… they're a superhero to me." (E, F, Lv)	Speaks to desire to contribute to body of knowledge through potentially participating in research. Strong motivation to give back, but also recognition that not all recipients feel this way.

	"And I make decisions every day on a conscious level to make him proud; to make his family proud that they are… that they did the right thing" (F, F, Lv) "Taking it ridiculously seriously. Exercising. Eating well. Kindness. Forgiveness. Generosity" "**I was given the chance to be there, so I'm going to be there**" (F, F, Lv) "I feel like I would automatically say yes, I'm gonna be tracked for this because it's the least I could do if this person gave me their organ" (G, M, H) *this is in reference to contributing own data to research* "I do everything I can. You know, I try and exercise regularly, eat health, uh…you know. {pause} There was a lot of effort, equipment, people working hard to keep me alive. I don't want to waste that. I'm doing everything to…to make it last." (H, M, H) "I participate in a bunch of stuff. I think that is um…uh…I think that's an obligation, really, as part of the stewardship of the organs that I got, to do everything that *I* can to help folks like you advance the science." (J, M, K/L) "That's why I volunteer for this study because more than ever I see importance of um knowing what is happening with someone who is transplant for so long. I think it inspire some new people who are transplant just now. And by you studying my case, um maybe can help someone else." "My personal think is in memory of my donor. I don everything that will be thankful for him, because without them there would be no me." (K, M, K) "Right now it doesn't matter who ask. When this thing came about your, I said, "Sure, I sign in" because I want to…with this research to help as many as possible" (K, M, K) "it's a positive thing to do. It's something that I should be …feel obliged to do. I think anybody who gets this gift of life should be trying to give back in some way" "You were allowed to proceed with something, a situation that was not ever going to come to anything	

	positive. You know, that you were given…you were given your life. You were given your…your breath. You know? I…I think that it's very important to give back. And I can't …I'm not the kind of person who can go out an speak to a group of people. So, I feel that um my um offering to be in studies in research studies, is…is my way of helping" (L, F, L)	
Ownership of organ Any expression of whether the participant feels the donated organ is "theirs" vs. "not theirs"	"If it's something that is going to affect me or my body, then yes." (C, M, L) "I mean, you wake up and you've got somebody else's body part in you. Some stranger has died, and you have their body…Like, it's…it's surreal." (E, F, Lv) "I still view it as somebody else's. Like, I know it's been a…been in my now for, like seven years…almost seven years, and it's mine and it's, you know, not going anywhere any time soon, hopefully, but um…you know, it…it uh…it…it's still not…You know, it's somebody else's. It's not …It's not truly mine. You know? Like, I'm kind of borrowing it or…or something like that. I mean, it's …it's uh {pause} Yeah, it's somebody else's life that...that um {pause} You, it's someone else's. I…I don't know it…I fully will ever say that it's mine, at this point" (E, F, Lv) I don't think we have a say in it; it's just the informed part of it. I think its' the family of the…of the donor that…that really this lies with. I don't think the recipient really um…{pause} it's not yours. Like, it's not your to make a input or decision about. Like, it's the family and… and what they're comfortable with. So… And I mean if it meant that something happened to the organ and that I didn't get the transplant, well then that's …that's not…I have no control over that"(E, F, Lv) "I was nervous about having somebody else's that I didn't know – organ inside of me. I wondered if it would feel different. Um…So, I was very anxious about that" (F, F, Lv) "But I was really worried that I would…it would feel like a foreign thing in my body. Like, I would just…I suffer from claustrophobia. Like, I can't sleep in a sleeping bag. And I wondered if it would be that same sort of, like, feeling like I couldn't ger something out of me that	Speaks to having the right to consent to donor research when even after transplant they still do not feel the organ belongs to them. If it is not theirs, then why would they consent to anything done pre-transplant. Is there a consent for research implications when the recipient does not see the organ as theirs anyway

	wasn't supposed to be there. Um…but it's like he was meant to be a part of my like. **We were meant to be together**." (F, F, Lv) "I borrowed it" "So, I …I really do feel like it…it's not mine; it's a gift. It's a second chance and its…and I'm not taking it for granted. Not in the least. And I…Maybe that's why I keep that thought in my head; that…that it's not mine" (F, F, Lv) "a bit of both. Like, I do often think that I'm keeping a part of him alive." (H, M, H) "when everything sank in that I'm carrying somebody else's body" (K, M, K)	
Naming organ Description of whether the organ has been named. Why? How do they refer to it?	"I gave it a name. It's called Hugh. Hugh's with me all the time." "we know that Hugh must have a sweet tooth, because I have never had a sweet tooth in my entire life." "He is a living person in our house {pause} that we honour and remember" (F, F, Lv) "you can use my kidney name, Jerry, if you want" (K, M, K) "I've named my kidney Beaner, 'cause I didn't know this person's name" (M, F, K)	I'm not sure if this is a code on its own yet. It might be more related to ownership of the organ or even connection of donor and recipient.
Right to be informed Any declaration that in order to be fully informed, they have the right to know about donor research.	"I think I would have a right to be informed" (B, F, P+K). "I think I would have been fine with it, but I…I would have liked to have been asked first. If I had been asked first, I would have said yes. So, I…Don't ask me why I have this distinction, but I think just knowing about it um…I would have appreciated" (C, M, L) "Or at least people would be, you know, conceivably given that choice. So, all of it is good. All of… all of the research, all of the knowledge, all of the data is good. There's no bad in that. When you have data, it's good. Like, you know, we're so afraid of data that's gonna tell us something we don't want to hear or believe, but it's all good. It's knowledge" (P, M, H) "I don't know that I'd want to influence it. I'd just want to know" (C, M, L)	Similar to quest for knowledge but more passive. Adds another layer to informed consent to the transplant. It appears that while they do not feel they can consent or not consent to donor research, they still feel that they should know about it. It likely wouldn't

	"You know, I think a recipient needs to be informed or a recipient's family if they're not with it. They need to be informed as to sort of the situation and what's going on."(E, F, Lv) "So, I think, you know, if…if there's something that's going to possibly impact the health of the organ, be it experimental research or whatnot, I think it's fair that that's told to the donor – or to the recipient, pardon me – so that they can make an informed decision as to whether… whether they want to accept it"(E, F, Lv) "I would love to have a big book on my donor's stuff before I receive his or her donor uh his whatever. Um… {pause and sigh} it's clearly an ethical and legal overlap kind of question here {smiling} Um…but if it were available I'd take it. I…I…Do I have a right to it? Is that the question, or do I want it?" "And I wish I had a right to it, but I'm not sure if I do have that right. It would depend on the sign off on the other side, really. You know, the other side might…The family or somebody might be willing to sign. Maybe there's a process that makes it {pause} legally and ethically…Like, there…there's the two layers there, right?" (A, M, LV) "I think if it's my organ, yes" (F, F, Lv) "I think I'm not surprised because if they have the…the generosity to donate their organs, then I think they also have the generosity to participate in research to further the field of medicine. In terms of specifically me, how I feel about it, like it's impact on me, I think it kind of depends on the research, and whether I was actually told ahead of time before my transplant whether that person was participating in a study, especially if it was something that was likely to impact my outcome" (G, M, H) "I think I'd need to be informed for any level. Um…{pause} I think the amount of information is probably gonna be less for low risk than high risk" (G, M, H)	change whether they accept the transplant or not (might be different if person is more well at time of transplant), but they might behave differently afterwards. Adjust their lifestyle depending on the potential outcomes. Participant F, referred to the organ as hers here, but above refers to it as borrowed. Interesting thought that the right to be informed or the right to information is proportional to the level of risk of the study

	"And I think one of the keys is ensuring that there is a very high level of transparency in the consent discussion" (G, M, H) "in the interest of full disclosure…"You received an organ um…and got..on this date and this date and that organ was subject to this procedure. I think that would be…I think ethically I think that's just the right thing to do; to advice the recipient. And medically, of course that that would probably be in their file anyway, I'd imagine" "I'm fine with knowing that there was…that the person was…that…that the donor was involved in a…in a research project about, you know, organs or something like that. I don't necessarily need to know the details "All I'd need to know is there might be an increased risk because of it" (J, M, K/L) "I think that you should be informed. Like, that's a…If somebody's in a study and you're taking an organ from them, I think that you should know and then make your decision, you know, based on whatever, you know, knowledge you have or…you know, what thoughts you have. Because sometimes you're so desperate that you will take anything, you know, that you can get" (L, F, L) "Um, only in the fact that if we're…I'm taking that organ. Then I think I should have the information, the knowledge of what…what's gone on. But otherwise, I don't think that…you know, if the…if the person …I don't know. Like, it's very confusing. You know? Because um…you want to…you would want to know your risks. So, I think in that case, just to have a better understanding. You know. To be able to say yes or no (to the transplant)" (L, F, L) "Um, I…I definitely think that I should, as a recipient, be informed." "Um…I don't…I…You know, ultimately as a patient you have the right to… to accept or refuse any treatment including a transplant, {pause} but… And… and part of that too is knowing all the risks and benefits, including whether research has been done on the donor." (D, M, K) "I think that as a recipient I should be informed, but then I also have the right to refuse in the event that I'm uncomfortable with that. So, whether…whether…uh, whether researchers	

	do any form of research on that donor before is purely up to those researchers and the medical system, but it's also my choice on whether I want to receive that organ" (D, M, K)	
Right to influence donor research Expression of whether the recipient has a role in whether they should provide any level of consent to donor research. This could also include an expression of not having any role in this process.	"I guess I'd come back again to it's, you know, family's decision. I mean, if they're…if they're fine with it, I'm fine with it. You know. It's …it's uh…um…{pause} You know, they're…yeah. As long as the…the family consented, I guess is…if the family was consenting to that, then I think that's totally fine. I'm not concerned with it" (E, F, Lv) "it's not my body. It's no my body yet. I have no decision in what happens to a donor. No. Their family should have a say, if that was something that they had opted to do. Not up to me" (F, F, Lv) "My initial thought is no. Um…but they should have a say in the end whether they are willing to accept an organ from that research" "I think it's key to maintain the autonomy of the patient to decline a medical service. Um…So, by being able to say no to the organ essentially on the grounds that uh it's not the standard of care. Um…{pause} because ultimately, they're consenting for...like, to participate in that research by receiving the organ. However, um…{pause} I don't think that they should…by saying no that it means that the research should not proceed, because for somebody else in a different set of circumstances they may be ok with that level of risk and they may be ok with consenting to that study" "So, I don't know that person. I don't know what their wishes were, and assuming that the …the family does, um – and even if they don't, they probably have a better sense of what they might have wanted" "I almost, like, draw a line {chuckles} where it's, like, okay, the family/donor decides whether the donor participates in the study and that's that. And the recipient doesn't get to have the discussion on that side, but the recipient does have the power to say no if the donor does end up participating in the study" (G, M, H) – *I clarifies that he meant that person has the power to decline the transplant, not the participation in the study* "you know, if…if…if I…if I was in that sit…If I was, you know in the situation of the donor, I would *hope* that my family would consent to those sorts of things. I think it is…it's kind of a	There seems to be a degree of respect for whatever the family decides to do with the donor, is up to them. This might include research, which may translate into recipient health outcomes. They feel this is not their right to consent, but that they do have the right to be informed later or even prior to transplant.

	continuation of the consent that the person has given when they agreed to an organ donor. Okay? And if the family…I…I think…Again, to…back to the family. If the family had to give consent, I would hope that if I was an organ donor and unresponsive and brain-dead or something, that uh if…that…I …I hope that they would authorize anything that would uh increase the chances of their…the donor's organs being viable" (J, M, K/L) "No, no…That's entirely…it's entirely with the uh donor family. And I might not be the…lets' face it, I might not be the only person that could use those organs, Right? I mean, uh…they could go onto someone else. So, I certainly shouldn't' have a veto on somebody else." "Um, because I have a vested interest in it. You know, I …I want an organ. I …I don't think I could be a…I'm not a detached third party and I'm not at arms' length on that one. No, I…I'm …I've got too much invested in that"(J, M, K/L) "But um just as long as families have…are. Like…are okay with it and …yeah. It's tricky" (M, F, K) "*I* don't think so. It's not um {pause} Like, I think it's the donor and the family…I guess the donor is deceased, but um I don't think *I* would have a say; um I think it's up to the family and their physicians" (M, F, K) "I believe that when you consent to something, it should be an individual decision in regards to who is making that decision" (O, F, K/P) *answered no to whether she should have a role* "I'll go back to the commitment the person makes when they… you know, when they articulate that they're willing and able to donate their organs to someone. And I think if that's part … if what you're saying is part and parcel of that process and it, you know, to a great extent doesn't endanger the person even more…" So, to me, that kind of uh, you know, is along the lines… I suppose if it's not too risky, intrusive, or harmful or endangering – and to a great deal – the potential donor, then I'm … I'm also for it " (P, M, H)	

	"I think when it comes to deceased donors, I think ultimately to me it makes most sense that the consent for that should be the family's of that person; the next of kin of that particular person. But when it comes to living, you know, again ultimately its…it's the… I mean it's living, it's obviously more complicated." (D, M, K) "I mean, for research, and if we're going forward and using that research, I… If it's going to help someone else down the road, and okay, so maybe it does something to me a little bit, but I've already… I've already assumed that risk by having the surgery. So, no, I… No, I don't feel I should be a yes or a no on the research of my donor" (I, M, K/L) "I mean, this is… {pause} difficult in the sense that you're bridging on someone else's autonomy. And one of the ethical principles is autonomy, {smiling} so that's kind of difficult to say, but {pause} I would have to diverge and go with, like, patient panels in terms of research, and see if we can outline some sort of consent form that is {pause} generally… or like research study that is generally beneficial" (N, F, K)	
Method of notification (donor research) Any method of notification of donor research.	"by a letter" (B, F, P+K). "Most times, I don't want to know." "So, maybe at that time I wouldn't have, but it would have been nice to have been given the option. You know."(P, M, H) "Um, probably just a…um…a letter" (E, F, Lv) "An opt out kind of thing" (E, F, Lv) "Would want to know what the intervention was, and what the implications of it were, and what the implications for me the recipient were." "I would want my surgeon to come to me and do something more than, you know, pat my wrist {smiles} and say, "just wanted to let you know, hey, we tried this thing out. It's part of a study" (A, M, LV)	E participant changes response somewhat in that she now wants to know in advance of transplant the potential risks of the donor research. It doesn't change the fact that she would go ahead with the transplant, and she still doesn't want any responsibility for deciding about whether a donor is involved in donor interventions research.

	"I think it's a…you know, it's a face to face conversation with a doctor that said, like, "listen, this is the situation. These are what the possible outcomes are, and, you know, we want you to know ahead of going into this" (E, F, Lv) "Basically, include it in the discussion to receive the organ in the first place" (G, M, H) They just…they verbally ask you and them um…well, some…and they'll probably slide you a form asking you to…asking you to uh to agree to it. Yeah. I don't have any problem with being asked uh…you know, being asked uh…you know, in person and, you know, that type of thing" (J, M, K/L) "I guess it would have to be just before your transplant. But to be given enough time to think about it would be much more beneficial. So, I guess that…Or, you'd have to be somebody who you've already been told, you know, that this is …this…this is something that um you may or may not encounter with your transplant. You know, just some kind of information so that you can, you know, justify it in your head one way or another" (L, F, L) "I think that somebody from the hospital. It would have to be, I would think, a doctor or a nurse practitioner or a nurse to present the study" (L, F, L) "I would want to chat with the doctors, my family to make that decision." " That would mean having to chat with the doctors to make sure…Like, nothing would happen to my future. Like, my…You know. And also depending what that donor went through itself. Like, you know, as long as making sure A) the family was okay with it. Like, knowing that this…The family was aware of their clinical trial or research type thing um, and that they were, like, honoured, I guess." "I'd probably want to make sure it's a good…{pause} a good kidney for my…where *I* am in *my* life" (M, F, K) "A meeting" "If I needed to know, like, anything major, um…and having just like a letter type thing, just to…Like, I'd have follow-up notes with my research that I was part of when I first got my transplant" (M, F, K)	

	But just let me know. It's just a sort of courtesy that, "you know what? We're gonna use your lab values and we're gonna do a study on…"x, y, z, whatever. "I just think it's a courtesy. Um I don't like a lot of presumed stuff. I like to be aware of it. I'd like to make decisions accordingly" (O, F, K/P) "I think it could be anything more formal, like a letter. Um, you know, I wouldn't have minded a phone call because at least with something like a phone call or, you know, these days a virtual meeting, you're able to ask questions on what that means, right?" (D, M, K) "I don't think I need to know about it. No. I mean, if I… if I can't know… If I'm not supposed to know the identity of my donor or their family, I definitely don't need to know that. That's…Eh, that's …That would be up to the family. If they decide they want to… Or, if they're willing to do it, I have no… I am not going to make a decision on that. Or I don't want to be part of it. I'm okay with whatever the people up the line decide." "As long as…Like you were saying, as long as I'm aware that there are those risks going in, I have no issues with that" (I, M, K/L) "I don't need to know about it all. My decision's been made already 'cause I've already been aware that there could have been a study. And I've made my decision based on that, and…No, I'm good" (I, M, K/L)	
Timing of notification (donor research) Any timeline of notification of donor research.	"I would say a year, no longer" (B, F, P+K). "But I think, you know, when I went into the hospital and started being prepped, that would have been a good time for a conversation about that" (C, M, L) "I don't' know that it could be before I went in the hospital. Um.. you know, just from a logistical standpoint" (C, M, L)	

	"Probably at that time. Like, when I got my phone call, when the doctor was in my room telling me about the Lupus and about those other things. That also would have been a really good time to let me know so that I could make a decision, yea or nay, at that point" (F, F, Lv) "Maybe it's actually part of the discussion before I receive the organ, right? So, if I know that this person was in a study and I received the organ in spite of all that risk, that part of that was also agreeing to participate in the study, post-op" (G, M, H) "But to be given enough time to think about it would be much more beneficial." "Or, you'd have to be somebody who you've already been told, you know, that this is…this…this is something that um you may or may not encounter with your transplant. You know, just some kind of information so that you can, you know, justify it in your head one way or the other" (L, F, L) "Um, well the sooner, the better, right, and, you know, if… if {pause} I… I think it would be… you know, if it's… if it's left to the last, you know say, week before the transplant, that might be a bit last minute. If it's… You know, if there's… if there's time to give that… that recipient, you know, even a couple of days to make that… to process that information, I think that would be highly valuable and important to give that patient the time to.. to better understand what it means. And I think most… you know, ultimately, I think most patients, if it's medium or low risk type of research, they probably wouldn't care. It's like, "I… I want a new organ. I want life {chuckles} to be healthy again." It's the high-risk research that I think …for me a t least, I think a lot of patients would need tome to think about." (D, M, K) "I'd like to know prior to, just to be aware, um but that wouldn't change my mind." (M, F, K) "I don't think I need to know any of the information um of maybe a study. If I'm told before my surgery that they may.. this per… this donor may have had… or if… I mean, it's gonna be a broad thing because when they tell you, it's …let's say it's three months out from when you get … you're the recipient right? If they tell me then and say, "Listen, they're…this per…	

	the person who… or the… the organ you are getting might be the result of a study that…" And then that's when you were make your decision: yes or no, right. But I mean, I…I'm not changing my mind." (I, M, K/L) "Before the transplant or even before the intervention, I mean if it's directly, like, you know that this is your donor" "Well, I think that is the earliest possible, but it would obviously be nicer to have some consideration time. But with the calling in that's obvious… Maybe even, like, before that, like you can say, like {pause} express, like, and say let's say hopefully, like first choice is like, maybe no intervention, and if that is passed its time limit or if it's like, not possible in some way, shape or form, say this is like, … Then like, okay maybe low-risk intervention. And that when you're called in, you can be like, "Oh, this is what is… was… what had happened exactly," maybe" "that you can pre-outline your acceptable risk" (N, F, K) "I think before the fact just so I have control if I decide not to do it for whatever…99% of the time…or 99.9 I would do it, but just so I know that I have that control." (O, F, K/P) "I'd be good either way" (H, M, H) *in reference to question whether would need to be informed of any donor research*	
Method of consent (own data) As above for donor research, but this is for consent for own data.	"Maybe a conversation with someone to give consent" (B, F, P+K). "I think one time's good enough. I mean, why would you give consent and then not give consent? I think it would be okay, a one time." (B, F, P+K). "I would expect that fairly early on, post-transplant, probably prior to my first annual check-up somebody at the transplant clinic would have a conversation with me about how they plan to track things" (C, M, L) "I guess it depends on the information. Just to have it in writing and for record keeping type thing" "Yeah, I think so, if it's a blanket of information, um…I'm more open to sharing if it can help the future of transplants. Uh, that's me personally. I don't know about other	There is a level of certainty that recipient data should be available for donor research. A total acceptance to sharing this data. Is there a way to quantify these responses (Maureen)? I'm not sure that quantifying will make as much of an impact as the

	people, but I think if it's explained to you and that, you know, this and this will not be shared, but these specific things will, I think that'd be totally fine." (M, F, K) "I think definitely talked again later. And if a family member, like their next of kin or whoever's there with them, just to, like, be in the same room just to talk about it" (M, F, K) *in response to question about whether this is a good time to ask and give consent at all.* "just ask me once, I'm fine" (C, M, L) "I guess I'd come back again to it's you know, family's decision. I mean, if they're…if they're fine with it, I'm fine with it. You know…It's …it's uh…um…{pause} You know, they're…yeah. As long as the…the family consented" (E, F, Lv) "I would give sort of blanket, you know, "go ahead and do it" They wouldn't need to contact me every six months to ask permission. It would be, "I'm agreeing to this. You know, **fill your boots** kind of thing"(E, F, Lv) "I'd offer blanket unless it became really irritating." (A, M, Lv) "An opt out kind of thing" (E, F, Lv) "You want it, you got it." Like, I have not problem sharing information…Personally, I think anybody can have whatever they need of mine whenever they need of it. And I feel no ownership of that. I think it's just {pause} having and altruistic view that it's for good" (F, F, Lv) "I'm a blanket kind of girl. I want to be as efficient and as easy as possible. And I don't need to be asked along the way" "I would like a heads-up that this person is being added into the list, but I don't need permission…like, an email. It doesn't have to ..Yeah, it could be a text for all I care" (F, F, Lv). *In response to different researchers and different studies.*	actual statements, especially since this is a small sample. The survey type questions would be more amenable to this type of analysis, but not powered at all.

	"And I think one of the keys is ensuring that there is a very high level of transparency in the consent discussion" (G, M, H) "that's what I'm thinking, is that um assuming that, as a recipient and of sound mind and whatnot, that when I consent to the surgery, that I'm consenting to follow-up" (G, M, H) "I'd say I'd need to be notified" "when it comes to consent and stuff, it's all about transparency {pause} and understanding what my data is being used for and what's required of me; that sort of thing." "If my data was anonymized or de-identified, either one, and um…uh…what's the word? Presented in aggregate, I guess, then …then I think I'll be okay with it being used for other purposes" (G, M, H) "Anything they can find out from me. I'm all for that being shared to see, you know, how things are being done, how everything's working out and that…that…that just sort of screams out, you know, "Share this!"" (H, M, H) "I don't know if there's anything they would be able to do; like put a number to the donor and tie it with the recipient, but anonymously. If there was, I would be all for that. You know, see if anything they did differently with this heart compared to another heart-how it reacted, what worked better- you know, that…that would make an awful lot of sense to me; that they…they would or could do that" (H, M, H) "I would think that would be a pre-transplant question. You know, they…there's all sorts of um physical, mental, you know, questions that are asked. And really, that…that would fit right in there, in the pre-transplant…" (H, M, H) "To use that for research purposes. I'm *totally* fine with that. And if it was just one-time blanket consent, I'm fine with that rather than having to come to me with every project." (J, M, K/L)	

	"I think that's fine, to me. But I think everybody's different. Some people find it still too personal. I don't know. You know? But I would hope that, you know, if its gonna help others or even yourself, I think that it would be a good option to uh, you know, open up for it." (L, F, L) *in response to open consent for de-identified data* "Yeah. I guess so. They should know what happens to us. You know?" *this is in response to use of own data* "Now, I think an email" (O, F, K/P) "I would appreciate less phone calls and conversations than more. So, I'd rather it be one big meeting or tac that conversation onto another visit or appointment with someone>" "Yeah, I mean I… I …I kind of make the assumption, when I have been a part of studies, that my data's um going to be shared wo some extent. I mean, obviously, with privacy being considered, but I… I kind of make that assumption. Even if it's not stated in any of the documentation, I sort of make that assumption when I'm signing agreeing to that study." "I want to know, right, how…where my data's being used, right. You know, I ..I fully recognize and, you know, I want to be part of studies if it's …if it's useful. You know, I have a rare kidney disease. I've… I want to.. If …If my data and my information can help a patient twenty years down the road, I'm all for that. But I just want to know what.. what that is and how it's being used " (D, M, K)	
Benefit of research Description of pros (or cons) of donor research. Could be related to all stages of continuum from	"I trust my team enough and I trusted all of my teams enough before that if that was being presented to me, um I would feel pretty secure in the knowledge that they were pretty confident that it was gonna work, and can learn something along the way, but not that it would be something detrimental to me in order for them to find out." (C, M, L) "I think that's important 'cause just chatting about with me, a lot of things have come up; not at the beginning, but going now through later. If it can help future um donor or patients or recipients, kinda seeing what happens with their transplant over time, I think that's very valuable information" (M, F, K)	Speaks to whether participant values research or not. This will be biased since they are taking part in a research project by being interviewed. Need to be clear that there is a possibility of a negative

effect on donor rates, procurement, success of graft, recipient outcomes.	"because if you don't…if you don't do research, as long as you have a well-founded idea, you're not going to learn what you can be doing better." (C, M, L) "otherwise, how are you ever gonna know" (C, M, L) "I personally wouldn't have issues with being experimented on if it meant trying to save my life" (E, F, Lv) "I think…it's needed to advance the science around transplant and organ donation, so…I mean we…we {sighs} can't move forward without experimentation and research" (E, F, Lv) "if anything can be learned from my experience, I want… I want that learning to happen" "Anything that can improve the outcome for somebody else, I am 100% behind and happy to participate in" (E, F, Lv) "Donorship scientific research is an essential part of getting things better and better all the time" (A, M, Lv) "Just improving outcomes for um…improving outcomes for recipients. You know, at that point a donor…I mean, if they're a candidate for donation and …and everything has been done for them and the family consents and…and uh…you know, then we need to look at what's going to…to…to be the best for the recipient at that point, and, you know…We have to keep improving on the science to ensure the best outcomes as far as I'm concerned. You know, we're not…the field still needs more research, I guess" (E, F, Lv) "It's so hard because I know that without trying these things, we don't have the answers that we're looking for in the long run" (F, F, Lv) "Maybe it's your more people saved in the long run, more knowledge, more understanding. Um..science isn't…It's a work in progress. Medicine is a work in progress. There's always	consequence of donor research. Participant E – learning focus

	more to learn and more to understand" "I…I think it still has to be, uncomfortable as that is. I still think it's important" "Well, that's the only way you know the long-term effects of that…whatever that process had been done" (F, F, Lv) "I'm of the mindset of giving back. And so, if anything can be learned from my experience, I want…I want that learning to happen. Um…You know, if it means my liver is in a pathology lab somewhere, then, you know, hey that's great. My old liver. Um…Yeah, it's…it's…Anything that can improve the outcome for somebody else, I am 100% behind and happy to participate in" (E, F, Lv) "Ultimately, um what makes it different from any other research?" "Other research affects people's lives and can have negative outcomes. It's not always a pretty picture, but uh sometimes it does work out. And when it does, it can be huge. And I think with that lens, I think it still should be done" (G, M, H) Well, whatever they did ended up saving my life. I know for a fact that without my transplant, with how quickly I was going downhill, what was happening to me…that without that transplant, I would not be here today talking with you. So, experimental or otherwise, it worked, I'm here, I'm happy, {smiling} and um, you know, they have to try new things to…to grow" "we all grow through trial and error. And I'm good with that" "again, you've got to learn new things, otherwise we'll never move forward. And I…I'm all for it." (H, M, H) "I would hope that they would do *everything* possible to…to make the organ transplant successful. Including that." (J, M, K/L) I want um the research just to make transplantation more successful; make more organs useable; get more…get more donors, more…more organs into the system that weren't necessarily in the system before, that weren't necessarily useable before. Um…I just want everybody to have as good an experience and as good an outcomes as I did" (J, M, K/L)	

	"if it advances the field; if it advances the science in the field and if the risks are justified, I think yes" (J, M, K/L) – *this is in response to whether donor research should be done* "You know that if there was no experimental there would be no transplant. If somebody didn't try at one time or another like first heart transplant that was done in South Africa, if wouldn't be transplantation now" (K, M, K) "Well, any research…ay research, whether it's like transplant or cancer or any illness is very valuable because we learn from research" (K, M, K) "Well, I'm all for research studies. I think it's very important, and I don't think it would make the quality any different other than maybe improve it. I don't think it would be detrimental to…to me in any way" "You have to be able to research in order to be able to see what will happen; to see the outcomes. So, it's kind of like a catch-22 where you need the research to be able to get these organs to a suitable state, but it's um…it's…it's a very hard thing to…to say yes or no to, to me anyway" "The more we know, the better the outcome and…you know. It's just…The studies, the research is amazing – what they find out when they really dig in and look. Yeah, I'm all for research" (L, F, L) "Organ donor research is, I think…I think is good. Um, the more research, the better so patients can live longer and more…better outcomes. Again, I just want to make sure the donor is highlighted or honoured as much as possible" (M, F, K) "Because I think you need to do…you need to understand organ donor patients, because we're so individual and so many different cases with so many additional factors" (O, F, K/P) "And …and the also thing I've learned being on different studies, you get extra care – you're getting extra blood work; you're getting extra tests. Like, I felt like I was …{pause} Like, people were watching my numbers probably more than recipient B if they weren't on a study. You know? So, I'm kinda all for it" (M, F, K)	

	"I was really insistent that at least you learned from the experience so that the next person would be successful. Right? So, that's, you know, kind of the…my mentality going in, so…And… and I think the other aspect of all of this is um you… you… you have to be willing to sign yourself over to their expertise. You have to be willing to completely trust them" "You know, so I think it's a far greater waste to… to allow people to die, you know, with… with no… no ability to um remedy the situation. When a remedy is… is close at hand" "I think it's equally important, equally interesting, and fascinating to look at donors and their ability to… you know to have their organs transplanted successfully" (P, M, H) "I think most fundamentally if…if that research on those organ donors has… It can have impact on the overall health and outcomes of the organ recipients, and so therefore, you know, that's um… to me that's the reason right there. Right? If that research means that organ recipients are having better outcomes, shorter wait times, shorter recovery times – all those things – then.. you know, then it's worth it. And so absolutely yeah." (D, M, K) "I think it's best to understand anyway, even if… {pause} even if there might be some mild risk to it, but…I mean, it… it might help. It might help in the future of transplants because I mean it's amazing what they're doing these days. And um if… if there has to be, maybe, some research done, I'm okay… it's tough… I mean, {sighs} see, I … I might be different than other people who would say no when they say that there might be this…"You might have an issue with this." So, I think it comes back to, "Yes, go to the research if… if you need the research to be done." But then you can also tell the people or tell the recipient of the risks and let the decide" "Without research nobody would have known what happened" (I, M, K/L)	
Concerns of research This could be a report of concern of the outcomes	"Um, I'm fine with that. I don't have any issues with that. I personally wouldn't have issues with being experimented on if it meant trying to save my life. So…" "It's so hard because I know that without trying these things, we don't have the answers that we're looking for in the long run" (F, F, Lv)	Again, there is an issue with the possible negative effects of research. There is an assumption of benefit only, not risk. There is also not the realization that the

of research or even lack of concern of outcomes of research.	"I would hope that the family would be aware…and agree to those trials, and it wouldn't be um sort of un…unannounced to them" (F, F, Lv) "It's hard because you don't want to lose the organs that are given for donation. {pause} it's weighing up those risks and rewards" (F, F, Lv) "I don't …I don't know how I feel necessarily about that. Uncomfortable" "Yeah. Like, it's sort of um…it's already a bad situation, and that's making it worse, potentially." "Yeah, I wouldn't…You don't really know what the effects would be, and like you said, you can't save the person anyways. It's not like it will save the person's life, but it potentially could cost somebody else their life from those organs. So, that ripple effect is an uncomfortable feeling" "I…I think it still has to be, uncomfortable as that is. I still think it's important" (F, F, Lv) "And my answer was no because the risks were too high. I didn't want to risk developing another problem on top of the big problem that I had. But I was not willing to risk anything at that point. I feel like I had…I was putting myself in enough risk having liver disease. *Now,* I look at it as something that's so valuable that I.. I understand people's apprehensions, but now I have a different sour of perspective on the process of a need for it, I say yes as much as I can. Whenever I'm given the opportunity, I tend to say yes." (F, F, Lv) "I don't know if I would want to take the risk because I don't know what the outcome is" (G, M, H) "I mean, if I'm 65 or 70, I've had a pretty decent life um…I've even already gotten one heart. If I was to get a second, then maybe I would be a bit more inclined to take that higher risk" (G, M, H) "in that the manipulation of the organ can have a very big outcome on…on the recipient. Um…so, yes, I…I do think it changes how I feel, in terms of risk, about manipulation or, like,	purpose may not be to save their own life, but to save the life of others. Many of the participants struggle with the concept of donor intervention research. They interpret it as research to provide better outcome for donor. They are challenged to recognize that the "experimentation" occurs after the donor designation. There may be room for another code about level of risk and what is acceptable risk for that patient.

	changes to the protocol that might influence the health of the organ itself, because ultimately it would impact me in some way" (G, M, H) "because sometime the research can negatively impact your thinking. And not knowing, in my personal opinion, is always sometime better. But in the other hand, you have right to know. "(K, M, K) "Like, there's on the one end of the spectrum people are just dying waiting for a transplant or…but on the other hand, other people are dying of other things. But if then they're saving other's…saving other lives…" (M, F, K)	
Self before transplant and self after transplant Any comparison of self before and after transplant.	"Maybe if you asked me four years ago; there was no way I was gonna participate in anything. *Now*, I have a *complete* different sense of that." (F, F, Lv) "One that is going to have a better outcome for me that what I had before" (G, M, H)	I think this is relevant because we are asking them to reflect on a previous experience. Would their opinion about research have changed from pre and post?
Balance of risks Refers to weighing risk of not having a transplant with any associated risk with having transplant with that organ.	"high risk is better than…than no heart" "I would and was willing to accept what was available. Anything better" (H, M, H) "You have to be willing to sign yourself over to their expertise. You have to be willing to completely trust them" "So again, it… it goes back to trusting and understanding and accepting and signing yourself fully over to the technical expertise that is completely available to you" "So, you know, I think you would… I think you would take the risk. I think you would take the risk because you're just so tired and sick of being sick" "a ratio of risk, your surgery's a risk. Everything's a risk. The anesthesia's a risk. The recovery's a risk because you could catch a virus in your recovery. You know. You're so immune compromised like, right now especially with Covid. You know, it's all a risk. So, you know, add on. {laughs}	Participant N identifies the issue of risk associated with donor (living) and that the same implications do not apply when there are no long-term risks for a deceased donor.

	you know, like… I mean, I… I think that was, you know, my thinking too by the end of… you know, the end of it, was like, {sighs} there's so many… so many things at risk. I did know one thing. If I didn't get the new heart, I was going to die. You know. That wasn't a risk. I knew that end" (P, M, H) "There's risk with everything. I could step out my front door and get hit by a piece of space junk. You… you never know. But no, there's risk with everything, and you just have to decide what risk is good with you. And I want them to keep learning new things and improve things" (H, M, H) "There's risk in everything. You know? I…I mean… **And you can't uh expand the envelope without pushing the envelope**. You know, and every now and then you're gonna step over and make a mistake, but…but I think I have enough confidence in um, you know, medical research and medical ethics to know…to…to think that uh they're not gonna take any unnecessary risks." "I think each …each case has to be …has to be handled individually. And the ethics of it has to be handled individually. And I think we have to trust the um…trust the professionals – the researchers and the medical people – to…to do that cost/benefit analysis. Again, if I was a donor as well I'd know I'm not getting any better. And u…you know, the…Nobody's getting out of there alive. And so, whatever they have to do. And if it'll help people, you know…if it doesn't necessarily work in this case and preserve the organs in this case, but if it can help somebody else down…down the road, then…then I'm fine with it" (J, M, K/L) "well, you know, I'd…I'd take it if there was no other choice" "Um, it comes down to risk/benefit. You know? And when you're on dialysis and both your liver…your kidneys have failed and your liver is failing, you're not in a great bargaining position. And, you know, you're not getting any better. You know, each day you're just getting worse" "Each day that we delayed it decreased the chances of a successful outcome. Okay, so…so to answer your question, yeah, if it was: take the sub-optimal organs or don't so anything, then yeah, I'd take the sub-optimal ones. That's how I…that's how I justified that decision." (J, M, K/L)	

	"Well, you…you never get anywhere without taking…without taking risks." (J, M, K/L) "It doesn't change how I feel about research because um without the research, whatever level it is, they would have not know what to do. They have to have research" "At that time I was young; I didn't think of any of those things. I didn't…I didn't know" (K, M, K) "if it was in such a bad state that it really wasn't going to be helpful to me, I don't …I think that would be where I would draw the line" "you put yourself in these positions for research, but you don't know what the outcome's going to be. And um if…if the …the organ was not really up to…up to snuff then I think that um…I have faith in the…in the health care system that they wouldn't use that organ, and it wouldn't be a matter of me having to accept it or not" (L, F, L) "And I think if I can help other patients to…other future patients or other donors, I'd say why not. I was at the very beginning of my transplant journey. Now…Probably now that I've had my transplant for this long, I don't know if I'd be…depending on the study and what it entails, I'd be more cautious of what I do and don't do" "I think it's the unknown of a um…{pause} Now knowing how long my kidney has done and how well it's done, I'm cautious of what I may or may not try. Um, you know, your research project: totally fine 'cause it's just sharing my story and, you know, what I feel, and if it can help others or…But to switch me on my new m…on my medications that have been working for me for so long…Maybe if it was nearing the end of my transplant I'd say, :Sure, why not?" You know? But I know a few recipients that at forty-three years or, you know, twenty-five. I want to make it to those. You know? So, I'm still in my mid um…mid-thirties and I kind of would like to hopefully make it my fifties before I need another transplant." "Yeah, risk, um emotions. I know emotionally I couldn't handle that right now, um just the "what-ifs?" And…I think the risk. I just kinda am happy with how my life is right now, and I am a definitely low risk taker, that's for sure. **If something's working, why break it**?" (M, F, K)	

	"If it was my first transplant, I might not. If it was my third, which I will need one day most likely…Um, I may think twice because of the fact that I'm gonna be highly sensitized to begin with. And for me to chance it on a third transplant, no, I wouldn't accept it. But if it was my first, probably even my second, I would accept it. It's the high sensitization. I mean…when and if I need a kidney transplant…it's going to be a very difficult match." "Because it's my third one I'm gonna be very, very picky. Very picky" "I have to know that it is a good match. And I'm not looking at anybody with…I'm looking for a good match without testing or experiments or anything else, 'cause I need that to …basically that'll be my…probably last one. And I'm not that young. I'm…I'm not that old. So, I need it to last me. Like, lets say this one lasts me 25, 30 years, I need it to last me, let's say, the next one 30 years, right? I need to go in…by 80. I want to go to at least 80" "Um, I just think at this point in time of my life that a higher risk kidney is not what I would want because I'm looking at the longevity of that kidney "(O, F, K/P) "I mean it's the donor's consent. Um…it all comes down to the donor's consent. And if they are comfortable with it and the… the family are…is aware of what's happening, like I think it…I think for that, when it comes, if they know the risks and if they are that severe, I think the family should be aware and have that, you know option. I think it would be okay, but as long as the family and the donor are fully aware of the risks." (M, F, K) *in response to high risk research question* "certainly, the low and medium risk I wouldn't have much of a problem with; I'd be fairly comfortable with. High-risk, I would have to… I would be slightly more cautious." "If I didn't have a live donor….you know, at a certain point it's also {chuckles} you know, about "Okay, do I want to live, or do I want to not live?"…So if…you know, and there's I've thought about, you know, some day if I had to have a second transplant, you know, if… if it was from a deceased donor and it was, you know, say a high-risk scenario like you describe, um I would have to think about it, but I … You know, and honestly, It would um,… For me it would depend on where my health was at that point. Right? I know it's u, hard to explain, but I think that, to me, is a determining factor, right, Like if, I'm perfectly healthy and I don't	

	really need the transplant yet and I could wait until a medium or low risk scenario, I would. But if my function was declining really fast, I would go high risk" "Well, I think generally speaking if…if I knew that there was a probably chance of that organ not working, a) because of research or just generally not working, then… then, you know, that would be a factor. But then, you know, I think for me, again it kind of all goes back to where my health status is. Right? You know, if…if I have the option of waiting, absolutely I would wait. If it's sort of a scenario where its like do or die, {shrugs shoulders} I'll take it, and, you know, worst case scenario, I'm back to square one. Best case scenario, organ works, and life moves on." (D, M, K) "I don't think it changes anything. I mean, I'd still…I'd still want the transplant. I'm not…I'd be willing to deal with certain side effects. And I mean, there are side effects of what I … what I take now. I mean, {pause} it's… it's one of those things you're told before surgery, and you've got to deal with the side effects. So, if that were another side effect, that would be just included in the uh… in the... in the um discussion pre-surgery, right," "I think it's a little of both. I think quality…Quality of life is important to me. Well, very important to me. ….And like I said earlier, all the things that have happened since, I… I don't think I'd trade them for a risk" (I, M, K/L) "Fine, 'cause it's like low-risk and it's just…it depends on, like, the intervention, right? If it's low-risk and it's just, like, say a minor thing, then not too… there's not… If there were… Yeah, like, if the risk isn't too high then not too much concern, right." "Once again, it kinda depends on , like, why. Like, if this is, like, say a rescue kinda organ of, like, say {pause} either someone who has, like say, maybe diabetes or is a deceased donor that has kind of um maybe a health condition and you're treating it. So, sort of like ex-vivo kind of thing with lungs and stuff, then perhaps. But if it's just, like… Like, what is the parameters of this study? Right? Um, the reasoning behind like the significance. If it was just a control kind of… I mean then that's not too much. But like, {pause} I guess I need to know the why" ("I guess, if it's like a…like the reward is hopefully more than the risk, right." "With the potential being better with said intervention, then it's a roll of the dice I'm more willing	

	to take, but if it's a first transplant and I don't have like, as high in these other options, then yeah, maybe not so much" "I guess it's just the risk for both sides. So, you don't… Like, if long-term risk is established, that's one thing. But if it's a new kind of intervention, then for both the donor side with the kidney and for the recipient… So, it's going into more of a blind territory. And with most of that it would make, like… it would make me hesitate, right" (N, F, K)	

Participant code:

(letter name, gender, organ)

K = kidney

L = lung

Lv = liver

P = pancreas

H = heart

So (A, M, Lv) would = participant A, male, Liver

Research questions:

Notes:

They always assume I'm asking about whether they wonder if the donor was ethically treated. Shows concern that the decision to donate was ethical and that they have right to the organ at that time?

Understand the dimensions of central themes. One thing to think about is are there things are maximum variation in the sample.

Trust in medical community overrides the level of risk that is presented with the research.

Add specifically a question to identify personal risk re research. Add question re ok, now you don't want organ and person not in study, how does that make you feel

Look at references in the link Janice Morris, find a framework or process to guide decision making in analysis. 2-3 main Themes from collapsing codes, how are these things related. Read the stuff on saturation and the controversies. Defend that done a thorough analysis and can stand behind findings. Try to get as much depth with themes as possible.

Audit trail

Coreq criteria for qual write up. Analysis is more rigorous because it has been challenge

CHAPTER 5

Conclusions

Chapter 5. Conclusions

5.1 Summary of Findings

In the first systematic review (chapter 2), I aimed to understand current attitudes and knowledge regarding the opt-out consent model in organ donation. This review included 19 qualitative and 60 quantitative studies, and I integrated the evidence by conducting a meta-synthesis of the data. This qualitative exploration revealed three overarching themes. These were: (i) knowledge of opt-out consent, (ii) levels of support for opt-out consent, and (iii) policy concerns and key considerations. Findings across these three themes suggest that societal knowledge of the opt-out consent model is limited and increases with exposure to organ donation experiences. I also observed limited support for the opt-out model, based on ethical values of autonomy and the importance of informed consent.

This chapter adds to the literature by providing the most comprehensive synthesis to date of both qualitative and quantitative evidence on public knowledge, support, and concerns regarding opt-out consent. Unlike previous reviews, this work identifies the nuanced role of personal experience in shaping public understanding and highlights the importance of autonomy and informed consent in determining support. It moves beyond simple data about acceptability of opt-out consent and shows how contextual and value-based considerations affect public opinion. This information is critical for policymakers considering consent model changes.

Chapter 3 presents a more typical systematic review of observational data evaluating the effect of opt-out consent on quantitative outcomes in organ donation. In this study, I observed a signal towards higher organ donation rates in jurisdictions with an opt out model of

consent. Confidence in this finding is low, as the varied findings derive from observational studies.

This chapter challenges the dominant narrative that changing to an opt-out consent model may independently lead to improved donation rates. By systematically evaluating studies based on methodological quality, this review contributes a more critical and refined interpretation of the evidence than previous reviews. It introduces the clearer evidence that opt-out consent may be a marker for system investment and policy attention, rather than a singular causal factor in improved donation outcomes. This has important implications for the design of donation systems and policy evaluation frameworks.

In chapter 4, I addressed a different aspect of consent, focusing on the perspectives of 18 solid organ transplant recipients regarding donor intervention research and the use of their personal data. Through semi-structured interviews, three key themes emerged. Recipients emphasized the importance of autonomy in health-related decision, including the right to refuse organs involved in interventional research. They communicated that recipients should not have any role in determining whether organ donors participate in donor intervention research; rather; they stipulated that they'd prefer to be asked only about their own consent for research use of their personal data post-transplant. I concluded that previously held assumptions about the need for transplant recipient consent in donor intervention trials may not hold true in most cases.

This chapter fills a significant gap in the literature on the ethics of donor intervention trials. It uniquely centers the voices of transplant recipients, whose perspectives are often assumed or underrepresented. The patient values illuminated by this study provide a

foundation for a more precise ethical framework that distinguishes data governance from assumptions about consent requirements.

5.2 Methodological Limitations

A Systematic Review of Knowledge and Attitudes Towards Opt-out Consent in Deceased Organ Donation

The primary methodological challenge I faced with this study was identified while assessing the certainty of evidence related to the main findings. During this process, I noted a limitation with the GRADE-CERQual instrument. This arose in evaluating quantitative studies, in which there was overlap between risk of bias assessments that identified issues in the methodological limitations domain and also issues that fell within the coherence, relevance, and adequacy domains. I reasoned that any issue identified with coherence, relevance or adequacy would already be accounted for as a methodological limitation and to rate down in two categories for the same issue was wrong.

To overcome this issue with the GRADE-CERQual tool, we did *not* rate down in the methodological limitations domain based on factors that related to population representativeness or indirectness (relevance), cohesiveness or inconsistency of the data (coherence), or degree of richness or imprecision of the data (adequacy). I judged this accurately reflected concerns with risk of bias without over-penalizing (i.e., penalizing twice for the same concern) studies for a single concern.

A Systematic Review of the Effect of Opt-out Consent on Organ Donation Outcomes

The primary limitation in Chapter 3 related to the tool that I used to assess risk of bias, the Effective Public Health Practice Project (EPHPP) quality assessment tool. This instrument

assigns global ratings to each study for overall methodological quality following evaluation of selection bias, study design, confounders, data collection methods, intervention integrity, and appropriateness of analyses. All studies that have no weak ratings in any of these components are rated as high methodologic quality. If, however among these ratings, there are mostly strong components, we reasoned these studies are stronger than those studies that have mostly or all moderate components.

To provide a global rating for each study, a rating of low methodologic quality was assigned if there were two or more weak components; moderate if there was one weak component *or* if there were more moderate components than strong; and a global rating of strong methodologic quality if there were no weak components and the majority of the components were strong. This approach aligned with guidance from other risk of bias tools in which the researcher may make a judgement about quality assessments for individual studies.

A further challenge in this chapter was the high variability among the included studies. I initially approached the analysis through the lens of study design. Based on feedback from co-authors however, I shifted to an analysis based on methodologic quality. This change allowed for a clearer signal to emerge from the data and more refined and meaningful conclusions.

Transplant Recipient Preferences Regarding Organ Donor Research: Their Role in Consent and Use of Their Data

One methodological challenge we identified early during this qualitative study related to soliciting views from individuals who lacked research literacy. The purpose of this study was to explore transplant recipient perceptions about donor intervention research and their role in consent to this research. We were concerned that potential participants would not fully

understand questions about different consent models used in research trials and that some interviews might yield information pertinent to this topic.

To overcome this challenge, I created a questionnaire that was to be completed after the initial consent conversation to participate in the study and prior to the interview. The questionnaire assessed the participant's comfort with different research consent models with Likert-style questions and also provided explanations for research consent models with different time frames. This served to set the tone for topics that would arise during the interviews.

5.3 Implications

This thesis demonstrates that consent, while ethically central, is not the sole determinant of success of organ donation systems. Moreover, findings point to need for a more nuanced understanding of how societal values, health system structures, and ethical frameworks interact to shape organ donation and transplantation systems. In organ donation, legislative reforms such as opt-out consent may contribute to improving outcomes, but their effect is often mediated by broader system investments. Attributing improvements to consent models alone risks oversimplifying what is a complex interaction of many factors. In donor intervention research, the perspectives of transplant recipients challenge prevailing assumptions about their role in consent. Recipients emphasized that while they value autonomy over use of their own data, they do not see themselves as decision-makers in donor participation in research trials. While both forms of consent are distinct, the importance of clarifying ethical boundaries upholds individual autonomy and avoids imposing unnecessary barriers to the donation system.

This thesis provides evidence for the need for evidence-informed policy reform that positions the debate about consent into broader conditions under which donation and research in donation can occur. Qualitative inquiry has shown itself to be essential for capturing social values and individual perspectives that often remain hidden in quantitative evaluations. Incorporating these perspectives into structured environmental scans of different jurisdictions, and then convening decision-makers to collectively interpret and act on these findings, offers a pathway toward reforms that is ethically robust, context-sensitive and capable of sustaining public trust.

5.3.1 Implications for Healthcare Providers and Policy-Makers

Healthcare providers have a central role in supporting patients, families, and the organ donation system because they are the main point of communication for individuals facing consent decisions. While most hands-on clinicians (such as those providing direct care) act more as facilitators in consent processes, they have a responsibility to support patients/families by answering questions or helping to clarify how participation (in research or in organ donation) might intersect with care. For healthcare providers directly involved in consent discussions (i.e., organ donor coordinators in donation consent and researchers in research consent), the nuances of consent should be communicated early, transparently, and at decision-making moments. Since both consent contexts are very different, the timing and depth of this communication can vary broadly. However, populations under both contexts would benefit from simple, accessible resources about consent which would enhance their understanding and allow them to engage meaningfully in decisions about issues that pertain to them.

For those seeking insight through environmental scans, healthcare providers contribute by sharing front-line perspectives on workflow and best practices. Including their participation in cross-jurisdictional learning collaboratives would further strengthen system-wide approaches to education policy by including their "real-world" views.

For policymakers, there is a need to situate consent reforms within the broader system. From a consent to donation perspective, opt-out consent may provide momentum to increase donation rates in some jurisdictions. Its success depends however on the infrastructure, professional training, and community engagement that accompany it. Environmental scans could be used to compare how different jurisdictions design and implement consent frameworks, while carefully distinguishing between the presence of legislation and the depth of implementation. From a research consent perspective, policies could clarify that donor or family consent governs trial participation, while transplant recipient consent only pertains to those aspects of the research that involves them. Clear ethical delineation in this area would streamline oversight without weakening protections.

This thesis, as a kind of environmental scan of evidence and perspectives (across public attitudes, policy outcomes, and transplant recipient voices), offers policymakers a map of current evidence and a framework for interpreting it. Beyond the specific findings, policymakers can synthesize diverse forms of data about public attitudes, systems outcomes, and stakeholder perspectives to provide an interpreted perspective of where assumptions are supported, where evidence is mixed, and where gaps remain.

Finally, policy development will be most effective when decision-makers are brought together in structured forums. Dedicated groups focused on organ donation and research

policy should be created, and include members from various ministries, organ donation organizations, ethics boards, minority group leaders, patients, and clinical leaders. This concept has worked well in other contexts of organ donation and transplantation, for instance, in understanding stakeholder readiness for DCD heart donations[1], and could provide a venue for interpreting current evidence, coordinating reforms, and setting shared standards in these areas as well. Time limited improvement initiatives across jurisdictions, including different provinces, could accelerate the adoption of high-impact practices, supported by common metrics and transparent reporting. By aligning provider-level insights with coordinated policy action, these approaches can create donation and research systems that are both ethically and practically effective.

5.3.2 Future Research

While this thesis provides new insights into public knowledge, policy impacts, and transplant recipient perspectives, it also highlights areas where further research is needed to strengthen the evidence base and build public trust in organ donation and donor-intervention research. A key priority is to better understand how trust is formed, maintained, or undermined within donation systems. This requires moving beyond outcome measures such as donation rates and instead examining the conditions under which individuals and communities feel about the system.

Future research should explore how different approaches to communication affect public knowledge of consent models. Comparative and experimental studies testing the framing of donation policies – whether in terms of solidarity, autonomy, or transparency – could identify which strategies best support trust while preserving informed choice. Tailored

investigations into the needs of diverse communities, including indigenous peoples, immigrants, and minorities, would further illuminate culturally specific barriers and opportunities for engagement.

At the family and community level, more work is needed to understand how decisions are made in practice, particularly in cases where family members override a donor's wishes. Qualitative and longitudinal studies of family experiences could reveal the ethical and emotional dimensions of these decisions and how they influence broader perceptions of fairness and legitimacy.

At the policy level, cross-jurisdictional evaluations should be expanded to capture not only the presence of consent legislation but also the depth of its implementation. Environmental scans that integrate policy analysis, system investments, and outcome data would allow for more precise attribution of what drives improvements in donation and trust. Complementary policy deliberation studies, such as citizens assemblies of consensus panels, could also shed light on how structured engagement with the public and patients contributes to both policy legitimacy and system trust.

These areas of future research will help move the field beyond narrow debates about consent models toward a more comprehensive understanding of how to design donation and research systems that are ethically robust and culturally sensitive.

5.4 References

1. Honarmand, K., Parsons Leigh, J., Martin, C.M. *et al.* Acceptability of cardiac donation after circulatory determination of death: a survey of the Canadian public. *Can J Anesth/J Can Anesth* **67**, 292–300 (2020). https://doi.org/10.1007/s12630-019-01560-z