



# Preventable harm in the Canadian organ donation and transplantation system: a descriptive study of missed organ donor identification and referral

## Préjudices évitables dans le système canadien de don et de transplantation d'organes : une étude descriptive des cas d'échecs d'identification et d'aiguillage des donneurs d'organes

Samara Zavalkoff, MD · Shauna O'Donnell, MSc · Jehan Lalani, MHA ·  
Isabela F. Karam, BSc · Lee James, MN · Sam D. Shemie, MD

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### Abstract

**Purpose** Deceased organ donation is predicated on timely identification and referral (IDR) of potential organ donors. Many Canadian provinces have legislated mandatory referral of potential deceased donors. Untimely or missed IDRs are safety events where best or expected practice has not occurred causing preventable harm to patients and denying families the opportunity of donation at end of life (EOL) as well as denying transplant waitlist patients access to lifesaving organs.

**Methods** We requested donor definitions and data to calculate IDR, consent, and approach rates from all Canadian organ donation organizations (ODOs) for 2016–2018. We then estimated the number of missed IDR patients who were eligible for approach (safety events) and the associated preventable harm to patients at EOL and on transplant waitlists.

**Results** Annually, there were 63–76 missed IDR patients eligible for approach (3.6–4.5 per million population [PMP]) from four ODOs—three with mandatory referral legislation. Applying each ODO's approach and consent rates for the corresponding year, there were 37–41 missed donors (2.4 donor PMP) annually. Assuming three transplants per donor, the theoretical number of missed transplants would be 111–123 (6.4–7.3 transplants PMP) annually.

**Conclusions** Data from four Canadian ODOs show that missed IDR safety events resulted in important preventable harm measured by a lost opportunity for donation of 2.4 donors PMP annually and 354 potentially missed transplants between 2016 and 2018. Given that 223 patients died on Canada's waitlist in 2018, national donor audits and quality improvement initiatives to optimize IDR are essential to reduce preventable harm to these vulnerable populations.

S. Zavalkoff, MD (✉)

Division of Critical Care, Department of Pediatrics, McGill University, Montreal, QC, Canada  
e-mail: samara.zavalkoff@mcgill.ca

The Research Institute of the McGill University Health Centre,  
2155 Guy St., Suite 500, Montreal, QC H3H 2R9, Canada

S. O'Donnell, MSc · I. F. Karam, BSc

The Research Institute of the McGill University Health Centre,  
2155 Guy St., Suite 500, Montreal, QC H3H 2R9, Canada

J. Lalani, MHA · L. James, MN

Canadian Blood Services, 1800 Alta Vista Drive, Ottawa, ON  
K1G 4J5, Canada

S. D. Shemie, MD

Division of Critical Care, Department of Pediatrics, McGill University, Montreal, QC, Canada

The Research Institute of the McGill University Health Centre,  
2155 Guy St., Suite 500, Montreal, QC H3H 2R9, Canada

Canadian Blood Services, 1800 Alta Vista Drive, Ottawa, ON  
K1G 4J5, Canada

### Résumé

**Objectif** Le don d'organes provenant de personnes décédées repose sur l'identification et l'aiguillage en temps opportun des donneurs d'organes potentiels. De nombreuses provinces canadiennes ont légiféré sur l'aiguillage obligatoire des donneurs potentiels décédés.

*Les identifications et aiguillages inopportuns ou manqués constituent des événements liés à la sécurité pour lesquels la meilleure pratique ou la pratique attendue n'a pas eu lieu, causant des préjudices évitables aux patients et privant les familles de la possibilité de faire un don en fin de vie, tout en refusant aux patients inscrits sur une liste d'attente de greffe un accès à des organes vitaux.*

**Méthode** Nous avons demandé les définitions et les données sur les donneurs pour calculer les taux d'identification et d'aiguillage, de consentement et d'approche de tous les organismes canadiens de don d'organes (ODO) pour la période de 2016-2018. Nous avons ensuite estimé le nombre de patients n'ayant pas été identifiés et aiguillés mais qui étaient admis à être approchés (événements liés à la sécurité) et les préjudices évitables aux patients en fin de vie et sur les listes d'attente pour une greffe.

**Résultats** Chaque année, l'identification et l'aiguillage a échoué pour 63 à 76 patients éligibles (3,6 à 4,5 par million d'habitants [PMH]) dans quatre ODO – dont trois possédant une législation rendant l'aiguillage obligatoire. En appliquant l'approche et les taux de consentement de chaque ODO pour l'année correspondante, on a constaté qu'il y avait de 37 à 41 donneurs manqués (2,4 donneurs PMH) chaque année. En supposant trois greffes par donneur, le nombre théorique de greffes manquées serait de 111 à 123 (6,4 à 7,3 greffes PMH) par an.

**Conclusion** Les données de quatre ODO canadiens montrent que les événements de sécurité liés à une identification et un aiguillage manqués ont entraîné d'importants préjudices évitables, mesurés par une occasion perdue de donner pour 2,4 donneurs PMH chaque année et 354 greffes potentiellement manquées entre 2016 et 2018. Étant donné que 223 patients sont décédés sur la liste d'attente du Canada en 2018, les vérifications nationales des donneurs et les initiatives d'amélioration de la qualité visant à optimiser l'identification et l'aiguillage sont essentielles pour réduire les préjudices évitables causés à ces populations vulnérables.

**Keywords** deceased organ donation · donor audit · donor identification and referral · end of life care · patient safety · potential organ donor

Despite sustained improvements in deceased organ donation rates in Canada, the gap between patients on the transplant waitlist and available organs persists.<sup>1</sup> As a result, patients continue to die on, or be withdrawn due to deteriorating health, from the transplant waitlist.<sup>2</sup> Deceased organ donation is predicated on timely identification and

referral (IDR) of potential organ donors, as failure to perform this first, critical step jeopardizes the downstream donation process (Figure).<sup>3-5</sup> Furthermore, in Canada, five provinces (BC, MB, ON, NS, AB) have legislated mandatory referral/consideration of deceased donors to ensure IDR. In addition to untimely or missed IDR, *missed donation opportunities* (MDO) can occur at every step along the donation pathway. Missed donation opportunities are safety events where best or expected practice has not occurred.

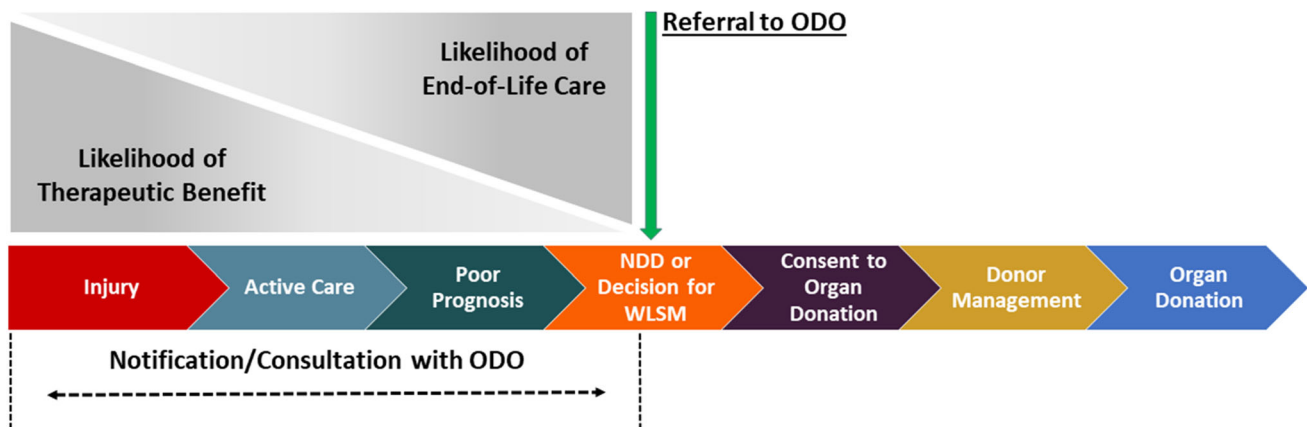
The 2016 Potential Organ Donor Identification and System Accountability expert guidance advanced missed IDR as a *preventable harm* to both patients on the transplant list, who are denied access to lifesaving organs, and to families and patients at the end of life (EOL), who are denied the opportunity to donate.<sup>3</sup> Currently, the Canadian organ donation and transplantation (ODT) system is unable to quantify this preventable harm, nor plan and monitor improvement initiatives to reduce it. Our objective was to determine the national rate of donor IDR, estimate the number of MDO from missed IDR, and quantify the consequential *preventable harm* to Canadians patients and their families at EOL and on the transplant waitlist.

## Methods

The Research Institute of the McGill University Health Centre, in collaboration with Canadian Blood Services, consulted with all eleven Canadian provincial organ donation organizations (ODOs) to complete the study. The study was granted an exemption letter for ethics review by The McGill University Health Centre Research Ethics Board as a quality improvement project.

### Survey and interview development

The survey and interview guide were designed using the methodology of Burns *et al.*<sup>6</sup> The research team first generated an exhaustive list of themes based on the existing literature. Themes were then drafted as survey and interview questions and divided into domains of potential donor audit practices, procedures and resources, and operational definitions. Potential survey and interview questions were then circulated to expert consultants (donor coordinators and donor physicians) for feedback. The research team and an experienced deceased donor coordinator reduced the list of potential survey questions to a target of 25 or fewer.<sup>7</sup> Our team then determined whether each item should be 1) retained, 2) retained with edits, 3) excluded, or 4) retained and moved to the interview guide.



**Figure** Sequence of care in deceased donation. Reproduced and adapted with permission from Figure 2: Sequence of care in deceased donation in relation to notification and referral. Zavalkoff S, Shemie SD, Grimshaw JM, *et al.* Potential organ donor identification and

system accountability: expert guidance from a Canadian consensus conference. *Can J Anesth* 2019; 66: 432–47. <https://doi.org/10.1007/s12630-018-1252-6>

Prior to data collection, two donor coordinators provided feedback on ease of survey completion, flow, clarity, relevance, completeness, face validity, content validity, redundancy, and time for completion. We revised the survey based on the provided feedback. The survey was created and hosted on the Interceptum (Acquiro Systems, Inc., Gatineau, QC, Canada) platform. The final survey had 21 questions.

#### Survey administration

Each ODO was invited to participate in the study as part of a larger environmental scan. A member of the research team established a point of contact and introduced the project. Subsequently, each ODO was emailed a cover letter with a link to an electronic survey. Up to three weekly reminders were sent after the initial invitation.

#### Interviews

After survey submission, the research coordinator booked a one-hour telephone interview with each ODO representative to clarify and complete submitted survey responses. Interviews were recorded for transcription with verbal consent. Data were entered and summarized in a spreadsheet. No patient level data were collected, nor did we collect information about tissue donation.

The structured interview guide included questions about donor audit objectives, frequency, scope (hospital sites and patient inclusion and exclusion criteria), methodology of data collection, human and other resources required to conduct donor audits (including training, standard operating procedures, policies), and outcomes reporting and feedback processes including accountability structures.

In addition, we sought to collect any missing data from the survey.

We collected ODO operational definitions for the following terms: potential, identified, referred, missed referral, eligible, approached, consented, and nonutilized donors. We obtained available aggregate rates for IDR, consent, and approach from the calendar years 2016, 2017, and 2018. These years were chosen as this research was initiated in 2019 but was delayed due to the COVID-19 pandemic. We accepted each ODO's local definition of a potential, eligible, approached, and consented donor. We also asked each ODO to describe how they calculated these rates based on their operational definitions and assessed whether the calculation aligned with the method outlined in Table 1. When it did not, we collaborated with the ODO to complete the calculations using their raw data. If we could not harmonize ODO data with calculations in Table 1, the data were not included. In the absence of national agreed upon definitions and metrics, we based Table 1 on work developed by the Canadian Deceased Donation Data Working Group.<sup>8</sup>

#### Calculation of preventable harm

We considered preventable harm to both potential organ donors and their families (i.e., depriving the opportunity to donate) and to patients on the transplant waitlist (i.e., depriving access to a lifesaving/life-enhancing transplant). Missed IDR patients are those who met the ODO trigger for referral but were not referred. Missed eligible IDR patients are missed IDR patients whom the ODO deemed suitable for approach (Table 1). We calculated the mean IDR, approach, and consent rates along with the 95% confidence interval. To estimate preventable harm, we applied the ODO's annual proportion of donors who were

**Table 1** Donor metrics

Metric	Definition or calculation
Missed IDR patients	Deceased patients who met the ODO's clinical triggers for referral but were not referred.
Missed eligible IDR patients	Deceased patients who met the ODO's clinical triggers for referral and were deemed suitable for approach by the ODO, but were not referred.
IDR rate	$= \frac{\text{number of IDR potential donors}}{\text{total number of potential donors (IDR+missed)}}$
Approach rate	$= \frac{\text{approached eligible donors}}{\text{eligible donors}}$
Consent rate	$= \frac{\text{consented donors}}{\text{approached eligible donors}}$

IDR = identification and referral; ODO = organ donation organization

eligible for approach (for referred donors) to the ODO's number of nonreferred donors (missed IDR). Two ODOs directly provided the proportion of referred patients who were eligible for approach. For the other two ODOs, we used the denominator of their approach rate as a surrogate for the number of potential donors who were medically eligible for approach. The other seven ODOs were unable to provide sufficient data to estimate the metrics of interest and were not included in the analysis.

We considered missed eligible IDR as patients who were harmed at EOL, as they were denied the opportunity to consider donation by not being referred. Next, we applied the ODO's actual approach and consent rates for the corresponding year, and used an average of three organs per donor,<sup>1</sup> to estimate the number of missed transplants. While a deceased organ donor may provide up to eight organs, three is the average number a donor in Canada provides.<sup>1</sup> This final number of missed transplants was then equated with the number of patients on the transplant waitlist who were harmed by missed IDR. When applied to the provincial population of the four ODOs included in this analysis, we calculated this as missed referrals per million population (PMP).<sup>9,10</sup> The denominator of PMP is the traditional metric for deceased donation, living donation, and transplantation rates and which allow interjurisdictional comparison. Analysis was carried out with Microsoft Excel (Microsoft Corporation, Redmond, WA, USA) and Stata (StataCorp, College Station, TX, USA).

## Results

Three ODOs provided definitions and metrics that aligned with those defined in Table 1. One ODO's raw data allowed the necessary data to be sourced. Together, these four ODOs provided data that could be harmonized to

calculate mean IDR, approach, and consent rates for 2016–2018 (Table 2). Both potential donors after neurologic and circulatory determination of death were included. Data were de-identified to maintain each ODO's confidentiality.

Annually, there were 75–105 missed IDR safety events in four provinces where patients who met the ODO's clinical referral triggers were not referred. Of these, 63–76 were theoretically eligible to be approached for donation (3.6–4.5 PMP),<sup>10</sup> and having not been IDR, suffered preventable harm at the EOL by not being offered the opportunity to donate. By applying each ODO's actual approach and consent rates for the corresponding year, the theoretical number of missed consented donors was 37–41 (2.4 donor PMP). The corresponding theoretical number of missed transplants was 111–123 annually (6.4–7.3 transplants PMP), and assuming three transplants per donor,<sup>1</sup> this represents preventable harm to a total of 354 waitlisted transplant patients between 2016 and 2018 (Table 3).

## Interpretation

We requested data on donation metrics from all Canadian ODOs. Given the lack of national consistency in conducting donor audits, only four ODOs could provide data to estimate *preventable harm*. Annually, 63–76 missed eligible IDR patients were harmed at the EOL by being denied the opportunity to donate. There were 37–41 MDO (2.4 donors PMP annually) due to missed IDR once the ODO's actual approach and consent rates were applied. This resulted in an estimated 111–123 patients on the transplant waitlist potentially harmed each year of the study by being denied a lifesaving or life-enhancing transplant (6.4–7.3 transplants PMP).

These estimations of harm are significant when considered in the context of Canada's deceased ODT

**Table 2** Mean identification and referral, approach, and consent rates (2016–2018)

Organ donor organization	95% CI
IDR rate 2016–2018	
A	84.3% (76.0 to 90.6)
B	93.7% (91.7 to 95.2)
C	83.3% (59.7 to 94.8)
D*	55.4% (41.5 to 68.6)
Approach rate 2016–2018	
A	61.6% (51.4 to 72.2)
B	81.9% (78.9 to 85.0)
C	68.3% (45.7 to 88.1)
D*	98.4% (83.8 to 99.9)
Consent rate 2016–2018	
A	47.3% (32.9 to 60.3)
B	71.7% (67.3 to 75.6)
C	48.8% (23.0 to 76.9)
D*	70.9% (51.9 to 85.8)

\*Data not available for 2016

CI = confidence interval; IDR = identification and referral

system metrics. In 2018, 4,351 patients were on the transplant waitlist and 223 patients died waiting. Given the rare scenario that allows for organ donation, in addition to these figures, the reported MDO from missed IDR are substantial. In 2018, there were 20.3 donors PMP,<sup>1</sup> so 2.4 missed donors PMP represents an unrealized increase of 12%. In addition, 7.3 missed transplants PMP represents a nearly 10% unrealized increase from the 2018 rate of 76.3 transplants PMP.<sup>1</sup> The potential harm of missed IDR is likely more significant than estimated, given calculations were only based on four ODO.

Missed and untimely IDR has been described previously in Canada and internationally. The ACCORD project found

that 35% of patients in Europe who died of devastating brain injury were never referred.<sup>11</sup> The Alberta death audit found that 18% of brain death cases were not referred.<sup>12</sup> Timely referrals entail calling the ODO when EOL conversations are planned and/or conducted to ensure sufficient time for the donation process. Untimely referral compromises the donation process by not allowing time for donor assessment, mobilizing resources, and a well-planned approach. Krmpotic *et al.* reported only 66% of medically suitable potential donors in Ontario had timely referrals before withdrawal of life-sustaining measures (WLSM), resulting in 251 MDOs over two years.<sup>13</sup> Singh *et al.* found the most common reason for not approaching a patient with donor potential in Ontario was referrals made at the time of or after WLSM.<sup>14</sup> Organ donation organization A in our study showed an improved IDR rate and a decline in approach rate for the three years reviewed, likely explained by untimely referrals. Missed and untimely referrals of potential donors are particularly problematic from the emergency department (ED). In the UK, Empson *et al.* described that 53% of potential donors failed to be referred even though 16% of these were on the donation registry.<sup>15</sup> A systematic review showed that up to 86% of patients after neurologic determination of death and 75% of donors after circulatory determination of death were not referred from the ED.<sup>16</sup> Finally, an Ontario ED donor audit found ten postmortem referrals that potentially would have increased the hospital's donation rate, had they been referred.<sup>17</sup> While the problem of IDR has been broadly described, our study is unique in quantifying its downstream preventable harm as a safety event.

Traditionally, we recognize safety events that cause direct harm to patients like a medication error or wrong-site surgery. In many jurisdictions, we are obligated to disclose such events to the patients.<sup>18</sup> When a potential organ donor

**Table 3** Preventable harm from missed donor identification and referral

Year	Missed IDR patients*	Missed eligible IDR patients <sup>†</sup> (preventable harm to patients/families at EOL)	Number of theoretical missed approaches <sup>‡</sup>	Number of theoretical consented donors <sup>§</sup>	Number of theoretical transplants if three organs/donor
2016	105	76	60	41	123
2017	89	74	60	40	120
2018	75	63	55	37	111
Total	269	213	175	118	354

\*Met ODO clinical triggers and were not referred

<sup>†</sup>Number obtained from applying each ODO's proportion of referred patients per corresponding year who were ultimately eligible for approach to their number of missed IDR patients

<sup>‡</sup>Specific approach rate of each ODO per corresponding year applied

<sup>§</sup>Specific consent rate for each ODO per corresponding year applied

EOL = end of life; IDR = identification and referral; ODO = organ donation organization



is not IDR this causes downstream, but disconnected, harm to a vulnerable patient awaiting transplant. There is no official accountability for this safety event; no disclosure is required. Offering donation is recommended as a standard part of high quality EOL care.<sup>3,5,19–22</sup> Moreover, it is essential we respect people's dying wishes which they may have registered or expressed to family. When standards for management of sepsis or myocardial infarction are not respected in clinical care, these are considered safety events. The same approach currently does not apply to guidelines advising routine and timely IDR of potential deceased organ donors.

The lack of available data from ODOs in our study is itself an important finding. The fact that only four of eleven ODOs could provide the requested data highlights Canada's need for a national, standardized approach to donor audits including definitions, a minimal data set, and metrics. This would allow measurement and reporting of the disconnected, downstream harm of MDOs including missed or untimely donor IDR. It would also facilitate goal setting, planning, and evaluation of quality improvement interventions.<sup>5</sup>

We acknowledge there are limitations to our study. While the lack of available data from all ODOs highlights a weakness of the Canadian ODT system, it also represents a limitation of this work. It is likely that the unmeasured harm from missed IDR is greater than reported, as our conclusions are only based on data from four ODOs. While the approach and consent rates are based on the ODOs actual rates during those years, we have made assumptions about the utilization rates and the number of organs each donor would yield. Since not all theoretically consented donors may actualize, this is a source of potential overestimation. Furthermore, ODO definitions and reporting metrics were misaligned. For example, the definition of approach (e.g., inclusive of health care provider approach vs ODO-only approach) varied by ODO, and thus the approach rate may differ. Referral rates may be impacted by a lack of standard referral criteria across jurisdictions. We attempted to mitigate these limitations by clarifying our understanding of these nuances through telephone interviews and by sourcing raw ODO data when required. In addition, data presented are a combination of both neurologic and circulatory determination of death which does not allow us to comment on specific referral patterns by donation type. We also did not weigh our results by provincial population size.

## Conclusions

Missed identification and referral of potential organ donors causes harm by denying both the opportunity to donate at end of life and access to lifesaving or life-enhancing organs

to vulnerable patients awaiting transplant. This safety event and its consequential preventable harm is unmeasured and unrecognized, so there is no accountability or disclosure of these patient safety events. Future work is needed to standardize the definition of a potential donor, clinical referral triggers, and the reporting of missed donor identification and referral to allow for accurate measurement and reporting of these patient safety events and to facilitate accountability mechanisms.

**Author contributions** Samara Zavalkoff, Shauna O'Donnell, and Jehan Lalani contributed to all aspects of this manuscript, including study conception and design; acquisition, analysis, and interpretation of data; and drafting the article. Isabela Fabri Karam contributed to the acquisition and analysis of data. Sam Shemie and Lee James contributed to the interpretation of data.

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**Prior conference presentations** Preliminary results from the environmental scan were presented by Dr. Zavalkoff at the Canadian Critical Care Forum held in Toronto, ON, Canada on 11 November 2019 in a presentation entitled, "Donor identification and referral: preventable death and disability." No abstract was published and no written material was disseminated to forum attendees.

**Editorial responsibility** This submission was handled by Dr. Stephan K. W. Schwarz, Editor-in-Chief, *Canadian Journal of Anesthesia/Journal canadien d'anesthésie*.

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