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Development of the Nova Scotia Potential Donor Audit (PDA) Tool and 2020 Historic Performance Database: Lessons Learned From the First 1000 Medical Record Reviews

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Background: Legislation and accountability frameworks are key components of high-performing deceased-donation systems. In 2021, Nova Scotia (NS), Canada, became the first jurisdiction in North America to enact deemed consent legislation and concurrently implemented mandatory referral legislation similar to that found in other Canadian provinces. Frontline financial resources were provided by the government to support the development of program infrastructure, including implementation of means to evaluate system performance. **Methods:** The Organ Donation Program (ODP), in collaboration with other stakeholders, developed a Potential Donor Audit (PDA) tool and database for referral intake and manual performance audits. Medical record reviews of deaths in the year before legislative change were conducted to pilot and revise the PDA and evaluate missed donation opportunities. **Results:** The NS PDA was piloted on 1028 patient deaths. Of 518 patients (50.4%) who met clinical triggers for referral to the ODP, 72 (13.9%) were referred (86.1% missed referral rate). One hundred sixty-three patients met the NS definition of a potential donor; 53 (32.5%) were referred (110 missed potential donors). Referral consent rates reached 71.7% (n=38 of 53 approaches). The actualized donation rate reported by Canadian Blood Services was 29.9 donors per million population (n=34 donors). **Discussion:** We documented high rates of missed referrals and missed potential donors before the enactment of mandatory referral and deemed consent legislation. **Conclusions:** The ODP has intentionally broadened clinical criteria for referral to shift the responsibility of identifying medically suitable potential donors from bedside clinicians to organ donation specialists. Lessons learned from our experience developing a PDA include the importance of early involvement of multiple stakeholders and ongoing modification of fields and workflow based on data availability and utility for clinical, educational, research, and reporting purposes.

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Legislation and system accountability have been identified as key components of high-performing deceased-donation systems around the world.¹⁻³ On January 18, 2021, the provincial government in Nova Scotia (NS), Canada,

enacted the Human Organ and Tissue Donation Act,⁴ making NS the first jurisdiction in North America with deemed consent legislation. Under this new legislation, NS residents may register their decision to donate or opt out of organ

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K.K. conceptualized and drafted the initial Nova Scotia Potential Donor Audit (NS PDA) and donor definitions, collaborated with the Senior Systems Analyst to develop the electronic database, provided clinical support for medical record audits, cleaned/coded/verified data, conducted analyses, and drafted the final article. J.D. developed and maintained the standard operating procedure manual and data dictionary, directly supervised medical record audits, reviewed and revised the article, and approved the final article as submitted. J.G. drafted the initial NS PDA, developed the standard operating procedure manual and data dictionary, reviewed and revised the article, and approved the final article as submitted. J.H., L.J., K.T., and M.-J.W. provided input into the initial NS PDA, reviewed and revised the article, and approved the final article as submitted. C.I. and S.B. provided input into the initial NS PDA and donor definitions, reviewed and revised the article, and approved the final article as submitted. A.L. participated in development of the electronic database, advised

donation. Deemed consent applies to eligible residents with no registered decision. In instances where a potential donor is referred to the provincial Organ Donation Program (ODP), next of kin are approached to affirm and/or confirm the patient's previously expressed decision and may alter registered decisions or opt out of deemed consent in instances where there is reason to believe a person's wishes were no longer consistent with their last documented decision. Furthermore, Human Organ and Tissue Donation Act legislation requires that clinicians notify the ODP of all patients meeting clinical triggers for referral and that health authorities submit a report annually to the Minister of Health with the number of missed referrals and actual or proposed actions to address missed referrals.⁴ In other jurisdictions, legislation mandating referral has been a successful strategy for improving deceased organ donation system performance,⁵⁻⁷ with ODP notification rates reaching as high as 99.2% in other Canadian provinces.^{8,9}

Accompanying the legislative changes was a commitment from the NS provincial government to provide frontline financial resources to support the continued development of ODP infrastructure. A key priority for the NS ODP was the development of a Potential Donor Audit (PDA) tool for conducting medical record reviews of deceased patients and the establishment of an electronic database for referral intake and retrospective audits of missed referrals to monitor site-specific quality metrics, such as identification and referral patterns, next-of-kin approach for medically suitable patients, and reasons for potential donor loss at each stage of the donation process. The program previously recognized the importance of this system performance evaluation, but resource limitations only allowed for manual retrospective medical record reviews done months after the death of a patient and hand counts using paper-based records. As such, the program prioritized the creation of a foundation for (1) hospital benchmarking and scorecards that aid in achieving performance targets, (2) the development of initiatives for healthcare provider education, and (3) culturally sensitive campaigns directed toward historically underrepresented communities.

The objectives of this study were to develop the NS PDA and, using the tool, evaluate missed potential donation opportunities in the year before legislative change.

on workflow modification, donor definitions, reviewed and revised the article, and approved the final article as submitted. A.L.-b. developed the electronic database, conducted workflow modification, reviewed and revised the article, and approved the final article as submitted.

The opinions reflected in this article are those of the authors and do not necessarily reflect the views of Health Canada, NS Health, the Nova Scotia Department of Health and Wellness, the Canadian Donation and Transplantation Research Program, Canadian Blood Services, or Transplant Québec.

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MATERIALS AND METHODS

Study Design

This mixed-methods study used an iterative design process and retrospective cohort analysis. Timelines are presented in Figure 1. This study was approved by the NS Health Research Ethics Board (REB# 1026703) with waiver of consent. A data-sharing agreement was in place between NS Health (the provincial health authority with ODP oversight) and the Legislative Evaluation: Assessment of Deceased Donation Reform (LEADDR) Program.¹⁰

Study Setting

This study was conducted in the province of NS, Canada (population: 981266),¹¹ where deceased organ donation is facilitated by the provincial ODP, Legacy of Life. At times, Legacy of Life may facilitate organ donation for the province of Prince Edward Island (population 161455).¹¹ During the study period, clinical triggers for referral to the ODP were any patient meeting "GIVE" criteria: G—grave prognosis or GCS ≤ 5 T; I—injured brain or nonrecoverable injury or illness; V—ventilated patient is intubated and ventilator-dependent; E—end-of-life discussion has been held with family, and decision has been made to withdraw life-sustaining therapy.

Study Population

We screened for inclusion of all patients who died in emergency departments (EDs), intensive care units (ICUs), or intermediate care units (IMCUs) in NS hospitals between January 1, 2020, and December 31, 2020. We subsequently applied filters to exclude patients who were not invasively ventilated within 12 h of death, those who were deemed medically unsuitable as per the organ donor coordinator in real time, and those who were retrospectively deemed medically unsuitable based on any of the following exclusion criteria documented in the medical record during the hospitalization preceding death: unsuccessful cardiopulmonary resuscitation, malignancy within 5 y (excluding primary central nervous system tumors without metastases), prematurity (<36 wk corrected gestational age), Creutzfeldt-Jakob disease, rabies, and West Nile virus. We also excluded patients meeting the following relative contraindications to donation after circulatory death in NS: age older than 70 y or younger than 16 y and weight ≤ 5 kg.

Study Definitions

Definitions were developed by clinical stakeholders at Legacy of Life based on clinical practice in NS during the study period, taking into consideration evolving national deceased-donor definitions developed as part of the National Quality Improvement in Deceased Donation Data Forum¹² and definitions described in other studies.¹³ For our study, a missed referral was defined as a patient meeting all of the GIVE clinical triggers who was not referred to the ODP. A potential donor was defined as a patient who met all of the GIVE clinical triggers and did not meet any of the exclusion criteria outlined above. A missed potential donor was defined as a potential donor who was not referred to the ODP. These definitions, including GIVE clinical triggers, were intentionally broad to capture the greatest potential for system performance with a planned shift of responsibility for identifying medically suitable potential donors from bedside clinicians to organ donation specialists under the new mandatory referral legislation.

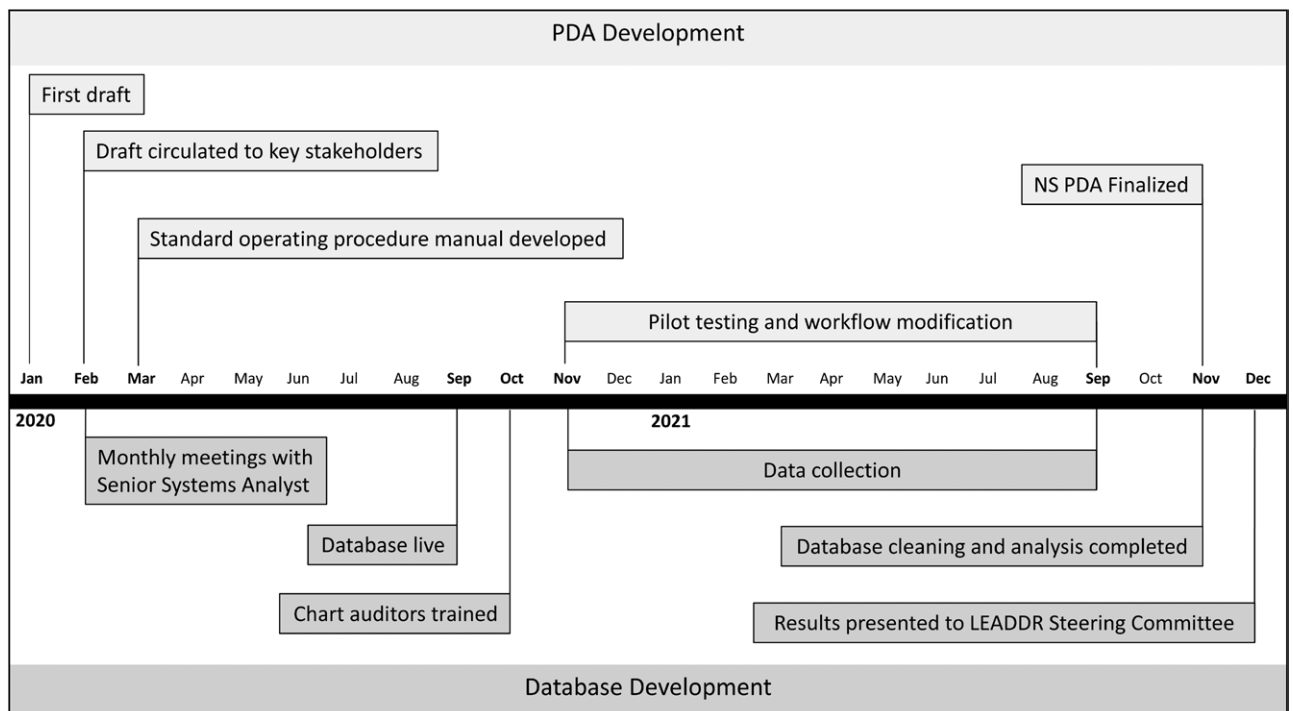


FIGURE 1. NS PDA and Database Development Timeline, January 2020–December 2021. LEADDR, Legislative Evaluation: Assessment of Deceased Donation Reform; NS PDA, Nova Scotia Potential Donor Audit.

Procedures

PDA Development (Version 1.0)

The NS PDA was initially drafted by a Legacy of Life donation physician/clinician researcher. It included 8 domains of interest, with a list of fields generated on the basis of clinical expertise and a document review of preexisting PDA tools used by the 4 Canadian ODPs known to conduct routine jurisdictional audits of ventilated patient deaths. The initial draft document included all fields in any of the audit tools. The draft document was circulated by email for review by 3 additional Legacy of Life clinical stakeholders and 2 clinical research stakeholders from the LEADDR Program.¹⁰ New fields added by any stakeholder were incorporated, and fields were removed if all reviewing stakeholders felt they were unnecessary. The 3 clinician researchers also had one subsequent virtual meeting to reach a consensus on the utility of collecting detailed information regarding relative contraindications to donation (eg, creatinine, ejection fraction, ventilator settings) and opted to exclude these fields. After the first version of the PDA was finalized, the LEADDR Program Manager and a clinical research coordinator collaborated to develop a standard operating procedure manual with data dictionary and source hierarchy to guide the conduct of medical record audits.

Database Development

The Legacy of Life donation physician/clinician researcher and clinical research coordinator had an initial in-person meeting with an Information Management/Information Technology Senior Systems Analyst at NS Health to present and discuss the intended purpose of the PDA and field-by-field requirements of an electronic, searchable database. During database development, working meetings were conducted virtually at monthly intervals. Specific values for each of 126 fields were defined, including checkboxes, radio buttons, and

pick lists, and free-text fields when “other—please specify” was an option. This exercise was key to ensuring that data capture was streamlined, clean, and consistent, with the intent of making post audit data analysis more simplified and meaningful. Virtual meetings were held quarterly and ad hoc during the electronic data entry process to address technical issues and the need for workflow modification based on beta testing of the PDA.

Electronic Data Capture

The population of the database was a collaborative effort between Legacy of Life and the LEADDR Program. The NS Health Senior Systems Analyst queried 3 hospital systems (STAR, MEDITECH Client Server, and MEDITECH MAGIC) to identify all patients deceased in the ED, ICU, or IMCU (many capable of noninvasive and long-term invasive ventilation) of NS hospitals. After the merger and removal of duplicate entries, the following fields were loaded into the back-end database via an SQL update script: health card number, name (last, first, and middle), date of birth, date of death, age at death (calculated), sex assigned at birth, postal code, hospital zone, hospital, and hospital unit (ED, ICU, IMCU, neonatal ICU, and pediatric ICU). These fields were locked in the user interface and could not be edited during data entry. Memoranda of understanding were in place with the multi-organ transplant program to link data regarding donation outcomes for consented patients and with the NS Department of Health and Wellness to access the provincial intent-to-donate registry.

For all other fields, medical records were reviewed by 2 nonclinical auditors provided by the LEADDR Program. They maintained detailed notes pertaining to technical issues with electronic data entry workflow or fields that needed clarification. These were discussed and resolved during weekly meetings with the LEADDR Program Manager and on an ad hoc

basis with the Legacy of Life donation physician/clinician researcher. The LEADDR Program Manager maintained the data dictionary as a living document in response to queries.

Final Version of the NS PDA

Upon completion of medical record reviews for all eligible patients, the clinical data set was cleaned, free-text entries were coded, and erroneous data were verified. The proportion of data availability for each field was calculated, and field notes kept by the medical record auditors and Program Manager were reviewed. After discussion with the Legacy of Life donation physician/clinician researcher and Senior Systems Analyst, the NS PDA and workflow of the associated electronic historic performance database were finalized (Appendix 1, SDC, <http://links.lww.com/TXD/A579>). The final version of the NS PDA and results of the 2020 donor audit were presented to the LEADDR steering committee.

Statistical Analysis

Descriptive statistics were summarized using medians and interquartile ranges for continuous variables and frequencies and percentages for categorical variables. All analyses were conducted using Microsoft Excel (version 16.58 for Mac, Microsoft Corporation, 2022).

RESULTS

Data Availability

The NS PDA version 1.0 was piloted on 1028 patient deaths. Data availability for fields requiring medical record review are presented in Table 1. In addition to 10 options presented for “cause of death,” there were 586 free-text responses inputted by the nonclinical auditors that required verification and coding by clinical reviewers, ultimately yielding 17 categorical options in the final version of the PDA.

TABLE 1.
PDA field data availability obtained from medical record documentation review

Demographics (N = 1028)	Data availability, n (%)
Ethnicity	29 (2.8)
Gender identity	0 (0)
Religion	678 (66)
Ventilated within 12 h of death	1028 (100)
End-of-life discussion	988 (96.1)
Missed referrals (N = 446)	Data availability, n (%)
Reason not referred ^a	244 (54.7)
Medical examiner referral	27 (6.1)
Registered intent-to-donate decision	–
Medical suitability ^b	446 (100)
Donation discussions (N = 6)	Data availability, n (%)
Next-of-kin–initiated discussion (N = 1)	1 (100)
Which next of kin initiated? (N = 1)	1 (100)
Who did next of kin approach? (N = 1)	1 (100)
Was next of kin approached? (N = 5)	5 (100)
Which next of kin was approached? (N = 5)	5 (100)
Who approached next of kin? (N = 5)	5 (100)
Reason next of kin not approached ^c (N = 5)	1 (100)

^aReasons not referred are presented in Figure 2.

^bReasons for medical unsuitability are presented in Figure 2.

^cReason for next of kin not approached was medical unsuitability as determined by clinician. PDA, Potential Donor Audit.

Donor Potential

GIVE clinical triggers were met in 518 patients who received invasive mechanical ventilation within 12 h of death (58.5% males; median age 71 y; interquartile range, 61–79 y); 72 patients (13.9%) were referred (446 missed referrals).

We identified 163 potential donors (159/1000 patient deaths): 53 of 163 (32.5%) who were referred to the ODP and 110 of 163 (67.5%) who met the NS definition of a missed potential donor. Consent for donation was obtained for 38 of 53 referred potential donors (71.7%). At least 1 organ was recovered from each of the 34 consented patients; 112 organs were recovered.

Of 110 missed potential donors, 30 (27.3%) had medical record documentation of reasons the clinician did not approach next of kin; at least 4 missed potential donors (3.6%) were incorrectly assumed to be medically unsuitable for donation. Donor loss at each stage of the process and documented reasons for nonreferral, medical unsuitability, and next-of-kin decline are presented in Figure 2.

DISCUSSION

We describe the iterative development of a comprehensive PDA and evaluation of data availability and missed potential donation opportunities by auditing >1000 patient deaths in NS in 2020. We observed a high rate of missed referrals and identified several missed potential donors, demonstrating room for improvement in NS deceased-donation system performance. Lessons learned from our experience that may be generalizable and useful to other ODPs as they develop or modify a PDA for use as part of their own jurisdictional audits and program performance evaluation include the importance of collaborating with internal and external program stakeholders to ensure completeness of information balanced with data availability, workflow, and utility of fields for generating quality metrics, developing educational initiatives, and conducting evaluative research.

Missed Potential Donation Opportunities

Although donors per million population (dpmp) is a commonly reported metric, it is an imperfect measure for benchmarking ODP performance.¹⁴ In 2020, NS had the highest performing deceased-donation program in Canada (29.9 dpmp reported by Canadian Blood Services)²; however, our ODP was only notified of 13.9% of patients meeting GIVE clinical triggers for referral and we identified 110 missed potential donors. Applying the rates of real-time medical suitability, approach, consent, and recovery observed in referred patients in our study, early ODP notification had the theoretical potential to increase NS donation rates to 45.7 dpmp and yield as many as 171 additional organs for transplant. These findings are similar to those of studies conducted in other Canadian jurisdictions and internationally.^{8,9,15,16}

We hypothesize that our low rates of referral are partially attributable to clinician assumptions that patients are not medically suitable for donation.^{16,17} However, our study identified several missed potential donors who did not meet our exclusion criteria for medical unsuitability. This supports the need to broaden clinical criteria for referral to shift the responsibility of identifying medically suitable potential donors from bedside clinicians to organ donation specialists. In NS,

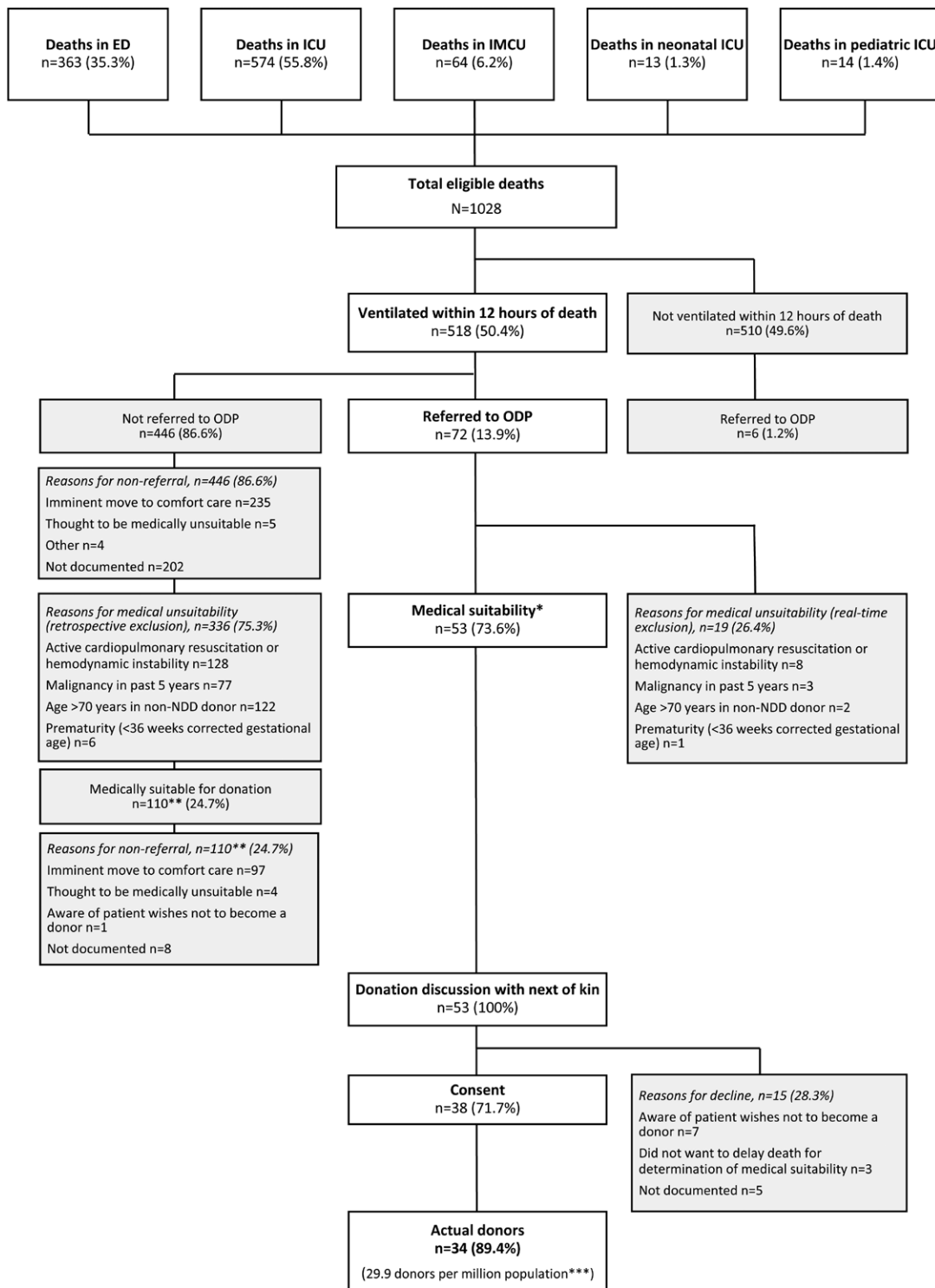


Figure 2. Overview of study population

*Total number of potential donors n=163, 31.5%

**Missed potential donors n=110, 21.2%

*** Includes patients referred from Prince Edward Island

FIGURE 2. Overview of study population. ED, emergency department; ICU, intensive care unit; IMCU, intermediate care unit; NDD, Neurological Determination of Death; ODP, Organ Donation Program.

targeted strategies to address this include mandatory referral legislation⁴ and educational initiatives directed at healthcare providers to discourage making assumptions regarding medical suitability for donation and thus not referring.

PDA Field and Workflow Modification

Early and ongoing involvement of clinical and research stakeholders ensured multiple perspectives on the potential utility and importance of data fields included in the PDA. We initially

attempted to recover data for relevant variables to develop targeted educational initiatives, conduct evaluative research,¹⁰ and generate standardized performance metrics for legislative requirements and contributions to national donor audits.^{8,12,18} We later modified the PDA during the process of data entry, cleaning, verification, and analysis. Workflow changes, including the addition and removal of fields and modification of exit points for medical record review completion, occurred in response to factors such as continually evolving clinical triggers for referral (eg, noninvasive ventilation, vasoactive support, medical assistance in dying) and medical suitability (eg, coronavirus disease 2019, type of malignancy); evaluation of donor coordinator workload (eg, capture of referrals for patients not meeting GIVE criteria); and poor data availability for low-utility variables (eg, hospital subunit, admission diagnosis).

Study Limitations

Our data completeness was limited to what the nonclinical auditors could retrospectively extract from medical records. Although we developed a data dictionary with data source hierarchy, data inconsistencies were noted even within the same patient medical record. The location of data documentation within the medical record varied by hospital and was further complicated by many hospitals still using paper-based documentation that is later scanned into the medical record. This highlights the importance of piloting the tool on patient deaths occurring in several centers and units (eg, ED, ICU).

The cumulation of multiple sources of data required a meticulous approach to data acquisition for overall completeness. In instances where collaboration with other provincial programs was required to obtain information (ie, provincial intent-to-donate registry, multiorgan transplant program), there were minor delays in completing individual patient audits. As such, we were unable to accurately determine the approximate duration of time required to perform each medical record review and were unable to ascertain whether the medical record review process would have been more efficient with clinically experienced reviewers. Furthermore, the ability to cross-reference or potentially integrate information maintained by other programs (eg, provincial ICU database, Medical Examiner records, Regional Tissue Bank referrals) may have improved accuracy of data capture. Future considerations include early involvement of key stakeholders from other organizations to collaborate on documentation of data and data linkages (including standardized patient identifiers) to ensure audits are more complete.

CONCLUSIONS

We documented a high rate of missed referrals and missed potential donors in NS in the year before the enactment of mandatory referral and deemed consent legislation. This supports the decision to intentionally broaden clinical criteria for referral to shift the responsibility of identifying medically suitable potential donors from bedside clinicians to organ donation specialists. Development of target organizational and educational initiatives is required to support these changes. Ongoing evaluation of deceased-donation system performance is required to observe the effects of legislative change. Lessons learned during our PDA development and modification process that may be generalizable to other jurisdictions include the importance of collaborating with multiple

stakeholders and ongoing evaluation of data availability and utility of fields in the context of local practices.

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