Factors associated with consent for organ donation: a retrospective population-based study

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Abstract

Background: Optimizing the approach to and consent of potential organ donors maximizes patient autonomy and the availability of organs for transplants. We set out to identify modifiable factors associated with donation consent.

Methods: We conducted a retrospective cohort study of consecutive adults (≥ 18 yr) referred for organ donation in Ontario between April 2013 and June 2019. We analyzed patient clinical data and demographics, data on substitute decision-makers and characteristics of the donation consent approach. Study outcomes were consent for organ donation and approach

rate. We evaluated independent associations between consent and approach- and system-level factors.

Results: We identified 34 837 referrals for organ donation, of which 6548 (18.8%) substitute decision-makers were approached for consent. Of these, 3927 (60.0% of approaches) consented for organ donation and 1883 (48.0% of consents) patients proceeded to be organ donors. The most common reason substitute decision-makers were not approached for consent in a case with donation potential was a late referral by the health care team (45.2%). Modifiable

factors independently associated with consent included a telephone approach for consent (adjusted odds ratio [OR] 0.46, 95% confidence interval [CI] 0.35–0.58) and a collaborative approach by a physician and donation coordinator (adjusted OR 1.26, 95% CI 1.01–1.59).

Interpretation: Consent for organ donation was associated with several modifiable factors. Organizations should target interventions to ensure timely referrals to organ donation organizations, increase in-person consent approaches and increase physician participation in the approach process.

Many people die on transplant waiting lists because the demand for organs outstrips supply. Almost 4500 people are on organ transplant waiting lists in Canada. Despite public support for organ donation across Canada,[1] donation rates vary between 8.8 and 21.2 donors per million population,[2] and a substantial pool of potential donors is not being realized.[2,3] The identification, referral and approach of potential donors can be facilitated by policy, legislation and best practices,[3,4] although the efficacy of interventions is variable across jurisdictions.[5,6] Some comprehensive interventions to increase donor numbers have not changed consent rates,[7] suggesting that the consent approach process may be a target for improvement.

Substitute decision-makers play an important role in the organ donation process, even in jurisdictions with donation consent registries or opt-out consent systems. Substitute decision-makers are almost always asked permission for organ donation, even when there is a registered donation consent,[8]

and their consent rates vary widely.[9] Substitute decision-makers faced with consent decisions often do so in emotionally charged circumstances, and many do not know the explicit wishes of the patient.[10] Given this context, the process of obtaining consent and the supports provided may have a substantial impact on the decision. Practices have been identified that improve consent rates from substitute decision-makers,[11] and these are routinely performed by large, high-performing organ donation organizations. Several epidemiological studies have identified nonmodifiable factors associated with donation consent (e.g., race, age, socioeconomic status and education).[12–15] The persistent variability in consent rates suggests that other modifiable factors may influence a substitute decision-maker's decision to consent.

We aimed to identify modifiable approach- and system-level factors that were associated with positive consent for organ donation in Ontario, Canada.

Methods

Study design, setting and context

We conducted a retrospective cohort study of all potential organ donors in Ontario, Canada, who were referred to Trillium Gift of Life Network, the sole organ donation organization in the province. All hospitals are required to notify Trillium Gift of Life Network when a patient has died or a physician is of the opinion that the death of a patient is imminent.[16] Calls are screened centrally and, if there is donation potential, a trained donation coordinator approaches the substitute decision-maker for donation consent. Since 2014, hospitals have also been assigned a hospital donation physician who acts as a clinical and operational resource. Ontario has a voluntary, online consent registry in which more than 30% of the population has recorded their consent to donate organs and tissue; even so, substitute decision-maker consent is sought at the time of donation for every patient. Existing best practices (e.g., uncoupling discussions of prognosis and consent, approach by a trained coordinator, approach in a quiet environment) are routinely performed by Trillium Gift of Life Network.[11,17]

Participants and data sources

We identified consecutive patients aged 18 years or older who were referred to Trillium Gift of Life Network between Apr. 1, 2013, and July 31, 2019, through a query of an electronic clinical database (Transplant Connect). This cohort includes virtually all mechanically ventilated deaths in intensive care units in Ontario because audited compliance with required patient referral is consistently 95% or greater. All donors in our study were receiving mechanical ventilation. Trained organ and tissue donation coordinators entered basic demographic and clinical information on each referral into the database. The database is routinely audited and maintained to ensure completion and quality of collected data for case management, public reporting and regulatory requirements.

Exposures and outcomes of interest

We linked each patient's residential postal code with Canadian Census data using the postal code conversion file package from Statistics Canada.[18] We obtained each patient's standardized household income quintile, local health administrative region, local immigration tercile (according to the proportion of immigrants and nonpermanent residents) and the rural or urban classification of their residential area. For patients whose substitute decision-maker was approached for consent, we obtained data on the approach and demographic information of the substitute decision-makers. We classified self-reported religion of the substitute decision-maker into broad groups derived from the 2011 Canadian National Household Survey.[19] We defined "premention" of donation as any record of discussion of organ donation that was initiated by the health care team before the approach for consent by the trained donation coordinator; we did not include introductions or liaison with the organ donation coordinator. We defined a "collaborative approach" as an approach for donation consent

in which the substitute decision-maker was approached by the physician and coordinator together and the physician was present for the discussion.

The primary study outcome was consent for organ donation. The secondary outcome was approach by a Trillium Gift of Life Network coordinator.

Statistical analysis

We generated descriptive statistics, including for subgroups of approached cases and consented cases, defined a priori. We also evaluated the cases in which consent was rescinded and those cases who were not approached for organ donation. We reported data as means, medians or proportions, and conducted comparisons with Student t, Fisher exact or χ^2 tests, as appropriate. We assessed linear trends using the Cochran–Armitage test.

We evaluated independent associations between case variables and consent using multivariable logistic regression. Potential covariates with plausible associations to consent were identified by experts in organ donation at Trillium Gift of Life Network. We substituted missing postal codes with the referring hospital to maintain linkage with a patient's referral centre and larger geographical area in Ontario's highly regionalized health care system. All other missing variables were handled by multiple imputation, with final parameter estimates pooled from 50 data sets with imputed missing data. We did not use any automated variable selection in the final model.

We performed all statistical analyses using the SAS 9.4 software package (SAS Institute).

Ethics approval

The study protocol was approved by the Heath Sciences Research Ethics Board at the University of Toronto (#00034755).

Results

We identified 34 837 adults who were referred to Trillium Gift of Life Network between Apr. 1, 2013, and July 31, 2019 (Figure 1). After case screening and review, the substitute decision-makers of 6548 patients (18.8% of all referrals) were approached for consent. Consent was obtained for 3927 (60.0% of cases approached) potential donors, and 1883 (48.0% of consented cases) donated at least 1 organ. Of these, 1311 (69.6% of all donors) were donors after neurologic determination of death and 572 (30.4% of all donors) donated after death by cardiocirculatory criteria (DCD). These successful DCD donations were from 849 consented potential donors who underwent withdrawal of life support (67.4% DCD organ donation rate). Demographics of patients whose substitute decision-makers were approached for consent for organ donation are shown in Table 1, stratified by consent status.

Referral, approach and consent characteristics

The number of referrals received by Trillium Gift of Life Network increased from an average of 300 referrals per month in 2013 to 600 referrals per month in 2019 ($p < 0.01$ for linear trend). The proportion of referrals that were approached for consent
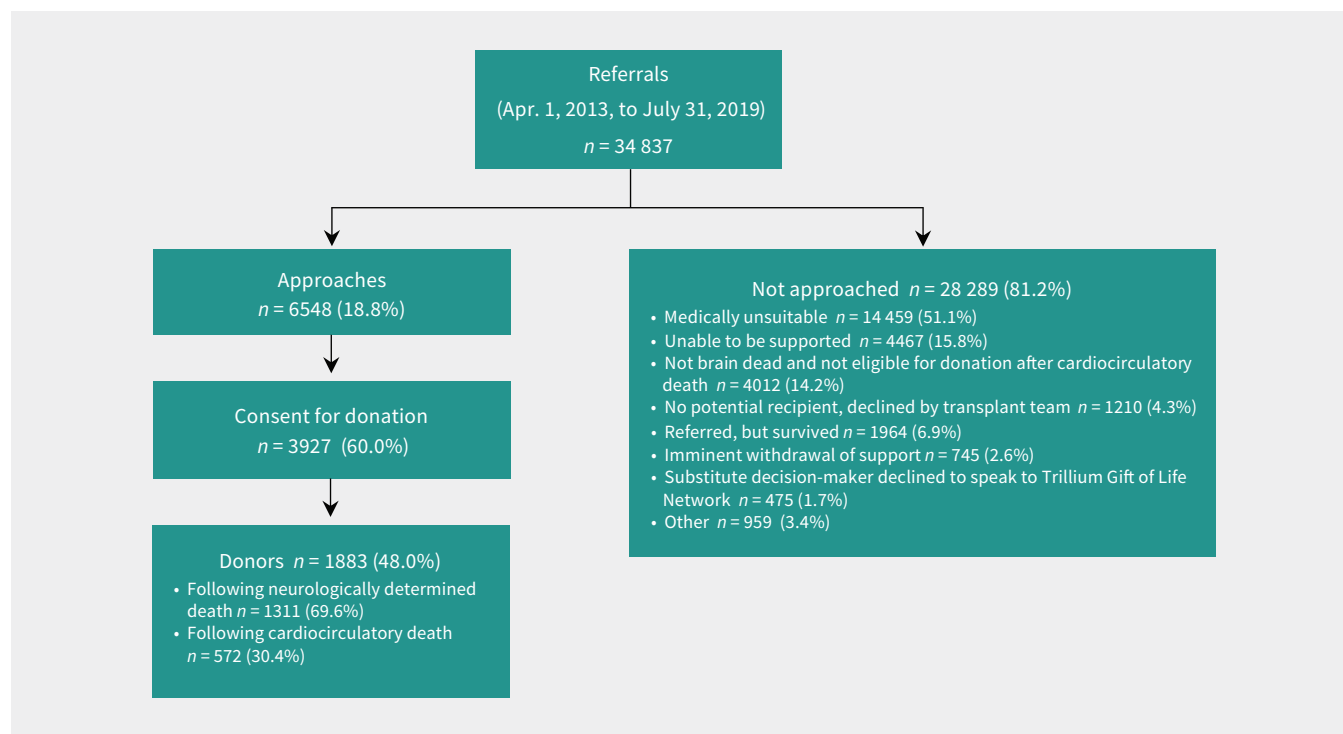
Figure 1: Cohort selection flowchart.

Table 1 (part 1 of 2): Characteristics of patients whose decision-makers were approached for consent, by consent status			
	No. (%) of patients approached for organ donation*		
Variable	**Consented** $n = 3927$	**Declined consent** $n = 2621$	**p value**
Age, yr, mean ± SD	54.3 ± 15.3	58.5 ± 14.0	< 0.001
Sex, female	1553 (39.6)	1094 (41.8)	0.07
Primary diagnosis or cause of death			< 0.001
Stroke or other neurologic	1352 (38.7)	519 (22.5)	
Postcardiac arrest or anoxic brain injury	1249 (32.3)	391 (15.3)	
Trauma or traumatic brain injury	450 (13.7)	94 (7.8)	
Other medical	361 (9.1)	214 (15.9)	
Missing	254 (10.7)	831 (50.6)	
Telephone approach	126 (3.2)	221 (8.4)	< 0.001
Time between admission and referral, d, median (IQR)	1 (0–4)	1 (0–5)	0.1
Local health region†			< 0.001
Central	192 (5.8)	211 (9.4)	
Central East	227 (6.9)	177 (7.9)	
Central West	218 (6.6)	1465 (6.4)	
Champlain	379 (11.4)	195 (8.6)	
Erie St. Clair	216 (6.5)	135 (6.0)	
Hamilton Niagara Haldimand Brant	351 (10.6)	170 (7.5)	
Mississauga Halton	194 (5.9)	165 (7.3)	
North East	179 (5.4)	153 (6.8)	
North Simcoe Muskoka	63 (1.9)	55 (2.4)	
North West	90 (2.7)	89 (4.0)	
South East	187 (5.7)	136 (6.0)	
South West	269 (8.1)	191 (8.5)	
Toronto Central	592 (17.9)	349 (15.5)	
Waterloo Wellington	155 (4.7)	85 (3.8)	

Table 1 (part 2 of 2): Characteristics of patients whose decision-makers were approached for consent, by consent status

Variable	No. (%) of patients approached for organ donation*		p value
	Consented n = 3927	Declined consent n = 2621	
Population size			< 0.001
Large urban centre (≥ 100 000 people)	2872 (74.2)	1920 (75.1)	
Medium centre (30 000 to 99 999 people)	347 (9.0)	215 (8.4)	
Small centre (1000 to 29 999 people)	222 (5.7)	79 (3.1)	
Rural area	432 (11.2)	343 (13.4)	
Neighbourhood household income quintile			0.6
Highest income quintile	937 (24.9)	657 (26.4)	
Medium-high income quintile	865 (23.0)	555 (22.3)	
Middle income quintile	798 (21.2)	499 (20.1)	
Medium-low income quintile	408 (10.8)	278 (11.2)	
Lowest income quintile	759 (20.2)	496 (20.0)	
Immigration tercile			< 0.001
Lowest tercile of foreign-born population	2165 (58.6)	1347 (56.1)	
Middle tercile of foreign-born population	1087 (29.4)	679 (28.3)	
Highest tercile of foreign-born population	443 (12.0)	374 (15.6)	
Religion of substitute decision-maker			< 0.001
Catholic or other Christian	1453 (57.6)	613 (42.8)	
Other or did not specify	500 (15.9)	291 (20.3)	
Agnostic, atheist or no religion	412 (16.3)	106 (7.4)	
Muslim	26 (1.0)	77 (5.4)	
Buddhist	35 (1.4)	47 (3.3)	
Hindu	44 (1.7)	35 (2.4)	
Aboriginal spirituality	34 (1.4)	54 (3.8)	
Christian Orthodox	17 (0.7)	27 (1.9)	
Jewish	15 (0.6)	18 (1.3)	
Substitute decision-maker, non-English primary language	1873 (47.7)	1182 (45.1)	0.04
Hospital donation physician at referring hospital	3141 (80.0)	2062 (78.7)	0.2
Premention by health care team	2033 (51.8)	998 (38.1)	< 0.001

Note: IQR = interquartile range, SD = standard deviation.
*Unless indicated otherwise.
†Ontario Local Health Integration Network (LHIN).

decreased slightly over the study period, from an average of 21.4% in 2013 to 17.5% in 2019 ($p < 0.001$ for trend). Of the 34 837 referrals during the study period, 28 289 (81.2%) were not approached for donation. The most common reasons for a case to be ruled out before approach was a lack of donation potential either because of medical ineligibility ($n = 14 459$, 51.1%) or an inability to maintain physiologic parameters for donation ($n = 4467$, 15.8%) (Figure 1). In patients with donation potential ($n = 1750$), the most common reason for not being approached was a late referral by the health care team; 812 (46.4%) of such cases had referrals made either contemporaneously or after withdrawal of life support. Less frequently, the substitute decision-maker declined to speak to Trillium Gift of Life Network ($n = 475$, 1.7%), or no substitute decision-maker was available ($n = 127$, 0.5%). This may be considered a refusal of consent, in which case the overall consent rate would be 55.9% (3927 donation consents in 7023 cases). The donation coordinators did not collect complete demographic data in these cases, and thus we did not include these cases as consent refusals in our adjusted analysis, given the high proportion of missing data.

Telephone approaches were carried out in 347 cases (5.3% of approaches). Phone approaches were not associated with day of the week, but were associated with geography ($p < 0.01$). Phone consent was more common in the Ontario North East health administration region (9.9% of all approaches), which is primarily rural, and was also more common in smaller urban centres (e.g., 7.7% for Hamilton Niagara Haldimand Brant and 7.1% for Waterloo Wellington), and the suburban areas surrounding the largest urban centre (6.6%).

The number of referrals for whom consent was obtained for organ donation increased steadily during the study period, from 36 consents per month in 2013 to 64 consents per month in 2019 ($p < 0.01$ for trend). However, the proportion of consented cases relative to approaches did not change over time (data not shown).

Role of the health care team in premention and approach

Most approaches for consent from substitute decision-makers were conducted by the donation coordinator alone. When the patient's physician was present with the coordinator for approach discussions (n = 441, 6.7%) the consent rate was significantly higher (n = 310, 70.3%) than with the coordinator alone (n = 3617, 59.2%; p < 0.01). Premention of organ donation by a health care provider before approach by a trained coordinator occurred in 2252 (34.4%) cases; 1651 (73.3%) were subsequently approached by a trained coordinator and, of these, 891 (54.0%) consented to donation. In cases where the initial response of the substitute decision-maker after premention was to decline donation (n = 876, 38.9%), 457 (52.2%) were reapproached by a trained coordinator, resulting in 42 consents (9.2% of reapproaches). When the initial response of the substitute decision-maker after premention was either positive or undecided (n = 954, 42.4%), 842 (88.2%) were reapproached by a trained coordinator for consent and 661 (78.5% of reapproaches) consented. Because every eligible case with a non-negative response to physician premention was subsequently approached by a donation coordinator, we were also not able to determine the independent impact of physician premention or conduct exploratory multivariable analysis.

Factors independently associated with consent

Before multiple imputation, 5020 cases (76.7% of all records) had complete data. No variable had more than 5% missing data except for substitute decision-maker religion, which had greater than 10% missing data. After multiple imputation, our multivariable analysis identified several patient-level, approach-level and demographic factors that were independently associated with consent for organ donation (Table 2).

Increasing patient age (odds ratio [OR] 0.99, 95% confidence interval [CI] 0.98–0.99 per decade of increased age) and telephone approach for consent (OR 0.46, 95% CI 0.35–0.58) were negatively associated with consent. Substitute decision-makers who identified with Aboriginal spirituality or Buddhist, Christian Orthodox, Hindu, Jewish or Muslim faith had significantly lower odds of consent than those who identified as Christian, and those who identified as atheist, agnostic or as having no religion had significantly higher odds of consent (Table 2). There was significant geographic variability in consent, with 4 health regions showing statistically different adjusted odds of consent compared with the baseline region, Toronto Central (Table 2). A collaborative approach was independently associated with consent (OR 1.26, 95% CI 1.01–1.59).

Other patient demographics were associated with consent. Patients from small centres had higher odds of consent than those from large urban centres (OR 1.73, 95% CI 1.29–2.33). Household income had an inconsistent effect across income quintiles. Patients with a home address in the highest income quintile had significantly lower odds of consent (OR 0.81, 95% CI 0.67–0.97) than those in the middle income quintile. Patients whose home address was in a region with the highest tercile of foreign-born population had lower odds of consent (OR 0.80, 95% CI 0.64–0.99).

Interpretation

Despite increasing numbers of organ donors every year, patients die while on transplant waiting lists because organs are unavailable. Optimization of the approach of potential organ donors to support consent decisions is critical to ensure patient wishes are respected and to remove any barriers to organ donation. We identified 3 potentially modifiable factors that were independently associated with approaches to substitute decision-makers and consent, specifically timely referrals to the organ donation organization, telephone consents and physician participation in the approach for consent.

Organ donation organizations require time to operationalize an in-person consent approach, particularly in rural areas or geographically large jurisdictions. Accordingly, untimely or late referral to organ donation organizations will negatively impact the approach of potential organ donors. One study found that untimely referral was the greatest cause of missed DCD donation potential in medically suitable patients undergoing withdrawal of life support.[20] Quality improvement interventions that include a focus on timely referral have improved donation rates in the United States,[21,22] and implementation of electronic clinical decision tools improved time to referral with increased organ donation in a pediatric hospital.[23]

Consent rates are affected by the approach process and by who approaches substitute decision-makers. Although uncommon, we found that approaches for organ donation by telephone were associated with decreased consent compared with in-person approaches, even after adjustment for other covariates. Telephone discussions regarding organ donation may limit a donation coordinator's ability to provide emotional support or respond to nonverbal cues from the substitute decision-maker; indeed, other studies have found that the duration and extent of coordinator interaction influences consent rates.[24,25] Organ donation organizations could develop capacity or strategies to reduce telephone approaches.

Specially trained donation coordinators have been associated with increased donation consent,[17,26] and we observed a considerable consent rate (9.2% of reapproaches, leading to 42 additional donors) when a substitute decision-maker who initially declined donation after mention by the health care team was approached by a trained coordinator. We also observed that consent approaches that included both physicians and coordinators were independently associated with higher consent. Although we adjusted for prementions of organ donation by the health care team, we cannot exclude that this association was confounded by other unmeasured factors related to the physician, substitute decision-maker or clinical situation. Although widely advocated, support for a collaborative approach is mixed.[27,28] The only randomized trial evaluating collaborative approaches did not report increased consent rates,[28] although this study has been criticized for its design and imbalances between the study groups, which limit confidence in its findings.[9] This study also compared physician-only approaches against collaborative approaches. A previous study in Quebec found most approaches were made by physicians, and fewer than half involved the organ donation coordinator.[29] Our study is unique because most cases

Table 2: Multivariable adjusted analysis for positive consent for organ donation

Variable	OR (95% CI) for positive consent	
	Crude	Adjusted
Age, yr (per decade of age)	0.83 (0.80–0.86)	0.99 (0.98–0.99)
Gender, male (v. female)	1.10 (0.99–1.12)	1.06 (0.95–1.18)
Telephone approach	0.36 (0.29–0.45)	0.46 (0.35–0.58)
Hospital donation physician at referring hospital	1.08 (0.96–1.22)	1.01 (0.76–1.34)
Time between admission and referral (per 7-d increment)	0.97 (0.95–0.99)	1.00 (0.99–1.00)
Premention of donation by health care team	0.72 (0.64–0.80)	1.03 (0.90–1.17)
Collaborative consent approach with physician	1.37 (1.10–1.69)	1.26 (1.01–1.59)
Population size, (reference: large urban centre, population ≥ 100 000)		
Medium centre (30 000 to 99 999)	1.09 (0.92–1.31)	1.12 (0.91–1.39)
Small centre (1000 to 29 999)	1.87 (1.44–2.42)	1.73 (1.29–2.33)
Rural area	0.86 (0.74–1.00)	0.80 (0.66–0.96)
Neighbourhood household income (reference: middle income quintile)		
Highest income quintile	0.91 (0.79–1.10)	0.81 (0.67–0.97)
Medium-high income quintile	0.97 (0.84–1.13)	0.88 (0.73–1.05)
Medium-low income quintile	0.92 (0.77–1.11)	0.89 (0.72–1.10)
Lowest income quintile	0.97 (0.83–1.13)	0.87 (0.72–1.06)
Primary language of substitute decision-maker not English	1.11 (1.01–1.23)	1.18(1.02–1.37)
Religion of substitute decision-maker (reference: Catholic or other Christian)		
Aboriginal spirituality	0.27 (0.17–0.41)	0.28 (0.18–0.46)
Agnostic, atheist, or no religion	1.64 (1.30–2.07)	1.51 (1.18–1.93)
Buddhist	0.31 (0.20–0.49)	0.35 (0.22–0.56)
Christian Orthodox	0.27 (0.14–0.49)	0.32 (0.17–0.62)
Hindu	0.53 (0.34–0.84)	0.52 (0.32–0.85)
Jewish	0.35 (0.18–0.70)	0.28 (0.18–0.81)
Muslim	0.14 (0.90–0.22)	0.13 (0.09–0.23)
Other	0.58 (0.49–0.69)	0.48 (0.42–0.54)
Referral year (reference: 2013)		
2014	1.07 (0.86–1.33)	0.71 (0.56–0.92)
2015	0.91 (0.73–1.12)	0.66 (0.46–0.94)
2016	1.16 (0.94–1.43)	0.86 (0.60–1.23)
2017	1.23 (0.99–1.51)	0.94 (0.65–1.35)
2018	1.21 (0.98–1.48)	0.95 (0.65–1.39)
2019	1.16 (0.93–1.45)	0.92 (0.62–1.36)
Local health region (reference: Toronto Central)*		
Central	0.53 (0.42–0.66)	0.62 (0.48–0.80)
Central East	0.78(0.63–0.96)	0.89 (0.70–1.13)
Central West	0.86(0.68–1.10)	1.06 (0.80–1.41)
Champlain	1.12 (0.91–1.38)	1.12 (0.89–1.42)
Erie St. Clair	0.93 (0.73–1.18)	0.89 (0.68–1.18)
Hamilton Niagara Haldimand Brant	1.13 (0.94–1.37)	1.14 (0.91–1.42)
Mississauga Halton	0.67 (0.53–0.84)	0.81 (0.62–1.05)
North East	0.67 (0.53–0.84)	0.63 (0.47–0.84)
North Simcoe Muskoka	0.80 (0.58–1.09)	0.71 (0.50–1.01)
North West	0.58 (0.42–0.80)	0.71 (0.50–1.01)
South East	0.79 (0.61–1.01)	0.74 (0.55–0.99)
South West	0.81 (0.67–0.99)	0.78 (0.62–0.98)
Waterloo Wellington	1.02 (0.78–1.34)	0.87 (0.64–1.19)
Immigration tercile (reference: lowest tercile)		
Middle tercile of foreign-born population	1.00 (0.89–1.12)	0.93 (0.80–1.09)
Highest tercile of foreign-born population	0.74 (0.63–0.86)	0.80 (0.64–0.99)

Note: CI = confidence interval, OR = odds ratio.
*Ontario Local Health Integration Network (LHIN).

were approached by a donation coordinator without a physician. A collaborative approach occurred in fewer than 10% of cases in our study, making it a potential target for improvement.[28] Finally, we did not observe an impact of local hospital donation physicians on consent. It is possible that hospital donation physicians improve referral rates without affecting consent rates; we observed steadily increasing referral rates during the implementation of these physicians and over the study period.

We observed variability in consent geographically, even after adjusting for patient demographics, approach details and regional income and ethnicity. Regional variability in consent rates has been previously documented across administrative jurisdictions.[25,30] One strength of our study is the consistency of process as a result of a single overarching organ donation organization. It may be that the observed variability in consent rates is because of the local population or cultural attitudes toward donation not captured in our study, or because of subtle regional variability in approach process.

Limitations

Despite the diversity of our population, our findings may not be generalizable to other jurisdictions, given that attitudes toward donation are sensitive to social, demographic and cultural factors. Race has been found to have an impact on donation rates,[13,15,31,32] and patient- or substitute decision-maker-level data on race and ethnicity were not available in our data set. We did adjust for the foreign-born population tercile, but this crude surrogate of ethnicity may not have allowed accurate adjustment for racial and cultural influences on consent.

We were not able to investigate the impact of registered wishes on consent because of privacy limitations. Registries may increase consent rates by providing substitute decision-makers with the patient's expressed wishes. One study found that more than half of all substitute decision-makers did not know the donation preference of the patient.[24,33] The creation of donation consent registries has been associated with an 8% increase in donation rates,[34] and the creation and public promotion of donation registries has been found to be a good investment, even though most registrants will never become organ donors.[35] Given the impact of registration data on consent rates and the positive return on investment, governments and organ donation organizations could focus on public engagement campaigns to increase registration.

We used multiple imputation to replace missing data with plausible values and calculated aggregate estimates. The religion of the substitute decision-maker was imputed in 20% of records, thus this association with consent should be interpreted with caution. The distribution of religious and spiritual beliefs among our complete-case cohort was comparable to Census data, supporting the assumption that these data were missing at random.[19] Missing residential addresses were also replaced with those of the referring institution, which may have misclassified patients from rural locations to the urban address of their large receiving hospitals and undermined statistical power when comparing urban and rural groups. Despite this potential bias, however, we observed a significant difference between patients from urban and rural areas.

Conclusion

Consent for organ donation was associated with modifiable factors in a large, multicultural jurisdiction with a single high-performing organ donation system. Specific interventions to ensure timely referrals to organ donation organizations, to increase in-person approaches to substitute decision-makers for consent and to encourage physician participation in the approach process may increase rates of organ donation consent.

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