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REPORTS OF ORIGINAL INVESTIGATIONS

Organ donation after cardiac death: donor and recipient outcomes after the first three years of the Ontario experience

Le don d'organes après un décès cardiaque: les devenirs des donneurs et des récipiendaires après les trois premières années de l'expérience ontarienne

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Abstract

Purpose *The aim of this study was to explore donor and recipient outcomes from organ donation after cardiac death (DCD) in Ontario and to examine the impact of DCD on deceased donation rates in Ontario since its implementation.*

Methods *Donor data were obtained from the Trillium Gift of Life Network (TGLN) TOTAL database from June 1, 2006 until May 31, 2009. All DCDs were tracked, including unsuccessful DCD attempts during that time. For the first 36 months after DCD implementation, all Ontario solid organ transplant programs that utilized organs from DCD provided clinical outcome data at one year. Total DCD activity until December 1, 2010 was also tracked. In*

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addition, we compared organ donation and DCD rates across all Canadian jurisdictions and the USA.

Results *For the first 36 months of DCD activity in Ontario, June 1, 2006 to May 31, 2009, there were 67 successful DCDs out of 87 attempted DCDs in 18 Ontario hospitals, resulting in 128 kidney, 41 liver, and 21 lung transplants. The one-year kidney patient and death-censored allograft survivals were 96 and 97%, respectively. Mean (SD) creatinine at 12 months was 150 (108) $\mu mol \cdot L^{-1}$. In 26 (20%) extended criteria donors (ECD-DCD), the one-year creatinine was 206 (158) $\mu mol \cdot L^{-1}$ vs 137 (80) $\mu mol \cdot L^{-1}$ in 102 standard criteria donors (SCD-DCD) ($P = 0.002$). The one-year liver and lung allograft survivals were 78% and 70%, respectively. Since its implementation four and a half years ago, DCD has accounted for 10.9% of deceased donor activity in Ontario. In 2009, Ontario had a record number of organ donors. Of the 221 deceased donors, 37 (17%) donors were DCD. By December 1, 2010 there were 121 DCD Ontario donors resulting in > 300 solid organ transplants and accounting for 90% of all DCD activity in the country.*

Conclusion *The rapid update of DCD in Ontario can be attributed to strong proponents in the critical care and transplantation communities with continued support from Trillium Gift of Life Network (TGLN). Ontario is the only province to demonstrate growth in deceased donor rates over the last decade (25% over the last four years), which can be attributed primarily to the success of its DCD activity.*

Résumé

Objectif *L'objectif de cette étude était d'explorer les devenirs des donneurs et des récipiendaires de dons d'organes après un décès cardiaque (DDC) en Ontario et d'étudier l'impact du DDC sur les taux de dons d'organes de personnes décédées en Ontario depuis sa mise en œuvre.*

Méthode *Les données des donneurs ont été récoltées dans la base de données du Réseau Trillium pour le don de vie (RTDV) TOTAL du 1er juin 2006 au 31 mai 2009. Tous les DDC ont été examinés, y compris les tentatives échouées de DDC au cours de cette période. Durant les 36 premiers mois de la mise en œuvre du DDC, tous les programmes de greffe d'organes solides utilisant des organes provenant de DDC comportaient des données de devenirs cliniques à un an. L'activité totale de DDC jusqu'au 1er décembre 2010 a également été examinée. De plus, nous avons comparé les taux de dons d'organes et de DDC de toutes les juridictions canadiennes et des États-Unis.*

Résultats *Au cours des 36 premiers mois d'activité de DDC en Ontario, soit du 1er juin 2006 au 31 mai 2009, 67 DDC ont réussi sur les 87 tentatives de DDC dans 18 hôpitaux ontariens, résultant en 128 greffes de reins, 41 greffes de foie et 21 greffes de poumons. Les taux de survie à un an des patients recevant des reins et des allogreffes sans décès étaient de 96 et 97 %, respectivement. La créatinine moyenne (ET) à 12 mois était de 150 (108) $\mu mol \cdot L^{-1}$. Chez 26 (20 %) de donneurs à critères étendus (DCE-DDC), la créatinine à un an était de 206 (158) $\mu mol \cdot L^{-1}$ par rapport à 137 (80) $\mu mol \cdot L^{-1}$ chez 102 donneurs à critères standards (DCS-DDC) ($P = 0{,}002$). Les taux de survie à un an des patients recevant des reins et des allogreffes de poumons étaient de 78 % et 70 %, respectivement. Depuis sa mise en œuvre il y a quatre ans et demi, le DDC a représenté 10,9 % de l'activité de dons d'organes de personnes décédées en Ontario. En 2009, l'Ontario a atteint un nombre record de donneurs d'organes. Sur les 221 donneurs décédés, 37 (17 %) donneurs étaient des DDC. Au 1er décembre 2010, on comptait 121 donneurs de DDC en Ontario, ce qui a résulté en > 300 greffes d'organes solides et a représenté 90 % de l'activité de DDC totale au pays.*

Conclusion *L'adoption rapide du DDC en Ontario peut être attribuée à de bons appuis dans les communautés des soins critiques et de la transplantation, outre le soutien continu du Réseau Trillium pour le don de vie (RTDV). L'Ontario est la seule province à avoir montré une augmentation des taux de dons après décès au cours de la dernière décennie (25 % au cours des quatre dernières années), ce qui peut être principalement attribué au succès de son activité de DDC.*

Canada has fallen short in terms of providing organ donations for patients awaiting solid organ transplantation (SOT). Canadian organ donation rates have averaged ~ 14 donors per million for the last ten years.[1] Traditionally, deceased donors have been exclusively "brain dead", i.e., they have no brainstem function and fulfill the criteria for neurological determination of death (NDD). In conjunction with some key Ontario donor hospitals, the Trillium Gift of Life Network (TGLN) began implementation of hospital protocols for donation after cardiac death (DCD) in 2005.

Donation after cardiac death has been commonplace in a number of jurisdictions for many years.[2] Formerly known as "non-heart-beating donors", these are patients whose organs are procured after cardiorespiratory arrest. Until recently, DCD was the only deceased organ donation practice in Japan.[3] European countries have been utilizing DCD organs for donation for more than 20 years,[4] and in the USA, DCD practices have been in place for at least the last decade, and even longer in a few regions.[5] In contrast, Canada abandoned DCD as soon as "brain death" was

defined in 1968 and has been late to reintroduce DCD practices. In February 2005, the Canadian Council for Organ Donation and Transplantation held a conference on DCD to establish the principles and practices of DCD for Canada. Recommendations from this conference were published in October 2006.[6] In September 2005, St. Michael's Hospital was the first hospital in Canada to have a formal DCD policy in place. The June 16, 2006 Ottawa Hospital DCD donation was requested by the donor family in the absence of a formal institutional DCD protocol. By December 2009, DCD donation had occurred in 30 Ontario hospitals, 14 of which had instituted formal DCD policies.

Our first objective was to examine both donor and SOT outcomes for the first 36 months of DCD activity in Ontario (June 1, 2006 to May 31, 2009), and our second objective was to examine the impact of DCD on organ donation rates in Ontario since its inception and to compare the Ontario DCD experience with that of the rest of Canada and the USA.

Methods

This was a retrospective cohort study examining both the DCD donor outcomes and SOT outcomes from all DCD donors for the first 36 months of DCD activity in Ontario (June 1, 2006 to May 31, 2009). All DCD donor and transplant activity from DCD donors until Dec 31, 2010 is reported. Research Ethics Board approval was obtained at the corresponding author's (J.Z.) institution.

Donors

The protocol for DCD has been previously described.[7] All DCD donations were Maastricht category 3[8] involving anticipated and planned withdrawal of ventilatory support in a controlled situation. In Ontario, the withdrawal of patients from ventilatory support occurred primarily in the intensive care unit. For the remaining cases, withdrawal occurred in anterooms adjacent to the operating theatre or, alternatively, in the operating room. The hands-off period after the first declaration of death was five minutes in all but three institutions where the local protocol mandated a ten-minute waiting period. Intravenous heparin was used in the majority of cases prior to declaration of death. In no instance was there placement of large calibre vascular catheters, nor was extracorporeal membrane oxygenation used in any case. When lungs were used, donors were reintubated to permit lung expansion of donor lungs prior to procurement.

Donor data included demographics, warm ischemic time - defined as time from withdrawal of ventilatory support until perfusion of organs, and cold ischemic time - defined as time from perfusion of organs until reanastamosis. In addition, organ donor yield data (i.e., number of organs transplanted per donor) were extracted from the TGLN database. All DCD donors were evaluated using the University of Wisconsin tool as a predictor of cardiorespiratory death within two hours of withdrawal of ventilator support. The proponents of this tool suggest a direct correlation of a cumulative clinical score with increased likelihood of death.[9] All donor data were obtained from the TGLN database.

Transplant recipients

There is no centralized database for transplant outcomes in Ontario, therefore all recipient outcomes were provided by the individual Ontario transplant programs using a standardized spreadsheet. The participating transplant centres were: London Health Science Centre (kidney, liver),[10] St. Joseph's Healthcare (kidney), St. Michael's Hospital (kidney), Hospital for Sick Children (kidney), University Health Network (kidney, liver, lung), and Ottawa Hospital (kidney). For all SOTs, the following variables were obtained: patient age and sex and one-year patient and allograft survival. In addition, further information was specified for renal transplant recipients, including rate of delayed graft function (DGF), defined as the need for dialysis within the first week; use of antibody depleting induction agents; renal function using serum creatinine at seven days and one, three, six, and 12 months post-transplant; and use of pulsatile perfusion pumps. Specific causes of allograft loss were identified. Lastly, we compared the renal transplant outcomes between standard criteria DCD donors (SCD-DCD) and extended criteria DCD donors (ECD-DCD). The definition used by the United Network of Organ Sharing is: any donor age $\geq$ 60 or donors ages 50 to 59 with two of the following: a history of hypertension, terminal serum creatinine > 132 $\mu mol \cdot L^{-1}$, or spontaneous intracerebral hemorrhage.

As a comparator, we obtained total and DCD deceased donor activity for all Canadian provinces and the United State for 2009, and using the Canadian Organ Replacement Register database, we examined deceased donor activity in Canadian regions for the last decade.

Statistical analysis was primarily descriptive, with means (SD) reported for all continuous data. The Student's *t* test was used for comparison of ECD-DCD *vs* SC-DCD donor creatinine values, and University of Wisconsin DCD scores were used for comparison of successful and unsuccessful cases. Correlations with DGF and use of perfusion pumps and antibody depleting agents are reported.

Results

Donors

From June 1, 2006 to May 31, 2009, there were 67 successful DCD cases out of 87 attempts (77%) in 18 Ontario hospitals, resulting in 128 kidney, 41 liver, and 20 lung transplants. In addition, there was a single kidney-pancreas transplant. The mean age of the successful DCD donors was 43 yr (range 15 to 64). Thirteen donors (19%) were also classified as ECD. All other donors not meeting those criteria were classified as SCD. There were 24 males and 43 females. The mean (SD) warm ischemia time was 42 (13) min. Twenty attempted DCDs were not successful; 18 patients did not die within the protocol defined maximum time limit of two hours, and two attempts failed due to poor perfusion of organs at time of procurement. The mean Wisconsin score for the unsuccessful cases was 14.9 (2.3), which did not differ statistically from the successful cases where the score was 15.3 (3.1).[9]

Kidney

The 128 kidney recipients had a mean age of 53 (12.7) yr and 78 (61%) were male. This is reflective of the renal transplant population. In order to minimize cold ischemia time, only low immunologic-risk recipients were allocated DCD kidneys in most cases. The mean panel reactive antibody (PRA) reflecting degree of allosensitization was 10% (range: 0 to 44%). The one-year patient and death-censored allograft survivals were 96% and 97%, respectively (Fig. 1). The five recipient deaths were due to cerebral vascular accident, motor vehicle accident, lymphoma, mesothelioma, and amyotrophic lateral sclerosis. There were three graft failures, two from venous thrombosis and one from recurrent glomerulonephritis. The delayed graft function rate (DGF) was 67%. Although not compared in this study, the DGF rate for NDD donors at one centre in Ontario (St. Michael's Hospital) was 30%. Perfusion pumps were used in 34% of cases, and induction with an antibody-depleting agent was used in 90% of cases. Neither of these interventions had any statistically significant bearing on renal function or rate of DGF. Mean (SD) serum creatinine values at seven days and one, three, six, and 12 months post-transplant were 534 (264), 199 (128), 149 (74), 144 (76), and 150 (108) $\mu mol \cdot L^{-1}$, respectively. In 26 (20%) ECD-DCD transplants, the one-year serum creatinine was 170 (87) $\mu mol \cdot L^{-1}$ *vs* 137 (80) $\mu mol \cdot L^{-1}$ in 102 SCD-DCD transplants ($P = 0.06$).

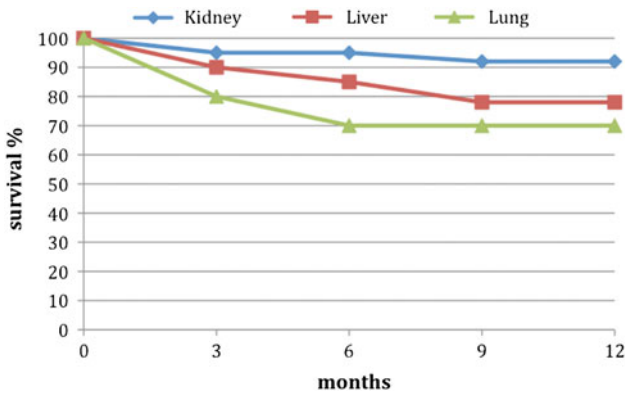

Fig. 1 One-year allograft survival for kidneys, livers, and lungs for the first three years of donation after cardiac death activity (June 2006 to May 2009) in Ontario

Liver

The first Canadian liver transplant from a DCD donor occurred at London Health Science Centre. There were 41 DCD liver transplant recipients from the two adult liver transplant programs in Ontario. The mean recipient age was 55 and 32 (78%) were male. Antibody depleting induction agents were not used in liver transplant recipients. The one-year patient and allograft survivals were 88% and 78%, respectively (Fig. 1). Four of the five deaths were attributed to recurrent hepatitis C, and one death was due to primary non-function. Three death-censored graft losses were secondary to ischemia of the biliary tract, and one loss resulted from primary non-function in a recipient who subsequently received a retransplant. Like the kidney programs, the liver programs maintained an initial maximum wait time of two hours from withdrawal of ventilatory support until death. However, it was recognized that prolonged ischemia increased the rate of complications, and the programs subsequently chose to reduce the warm ischemic time for liver donation to no more than one hour.

Lung

In the first three years, there were 20 lung transplants from DCD donors (four single, 16 double). The mean recipient age was 52 and ten (50%) were male. The one-year allograft and patient survival was 70% (Fig. 1). Four recipients died as a result of sepsis, one due to hemorrhage, one from pulmonary embolus, and one secondary to acute respiratory distress syndrome. Of note, 14 of the 20 DCD lungs were treated using *ex vivo* lung perfusion prior to implantation.[11] The initial lung transplant outcomes using DCD donors at the University Health Network has been previously published.[12]

In addition to the aforementioned transplants, there was a single successful kidney-pancreas transplant from a DCD donor during the first three-year experience.

Comparisons

In 2009 and 2010, DCD in Ontario accounted for 17% and 18% of deceased donor activity, respectively. By December 31, 2010, there were 124 successful DCDs out of 158 attempted (78%), resulting in 300 SOTs in Ontario, including 221 kidney, 54 liver, 21 lung, two pancreas, and one islet cell transplant. In the USA, where DCD has been in place much longer, the benchmark rate is 10% for DCDs in organ procurement organization (OPO) regions. In 2009, the DCD rate across the USA was 11.1% compared with 17% in Ontario. Three donor regions in the USA had higher DCD rates than Ontario (Gift of Life Michigan [20%], New England Organ Bank [27%], and University of Wisconsin [27.4%]).[13] In some jurisdictions, such as The Netherlands, DCD accounts for 50% of the deceased donor activity.[4]

With the establishment of TGLN in 2002, the average number of deceased organ donors per year in Ontario during the first four years (2002 to 2005) was 145. Coincident with the establishment of the DCD program in 2006, the average annual number of donors was 191, representing a 24% increase in deceased donation activity from 2006 to 2009. In 2009, Ontario had 218 deceased organ donors. The organ donation rates and DCD activity for 2009 for Canadian provinces and the USA are shown in the Table 1. Along with Quebec, Ontario has achieved the highest organ donation rates in the country. As illustrated in Fig. 2, because of DCD, Ontario has been the only province to achieve a sustained growth in deceased donation numbers over the last decade.

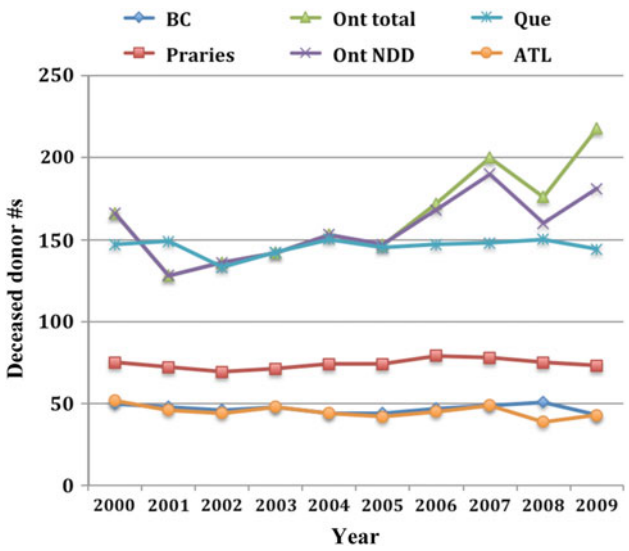

Fig. 2 Ten-year deceased donor numbers across Canadian provinces/regions. Prairies include Alberta, Saskatchewan, and Manitoba. Atlantic includes Prince Edward Island, Nova Scotia, New Brunswick, and Newfoundland. Ontario data are shown as both total and only counting neurological determination of death. Donation after cardiac death began in Ontario in 2006. (Courtesy Canadian Blood Services)

Discussion

The transplant outcomes from DCD donors in Ontario are consistent with what has been described elsewhere[5,14-16] (Fig. 1). Kidney outcomes were excellent and equal to those with NDD donors, however DGF rates were high, as described by most centres, and the use of ECD-DCD donors resulted in somewhat decreased renal function. The one-year liver allograft survival at 78% is slightly less than the 82% reported for NDD donation.[1] The lung transplantation outcomes, although good at 70%, were inferior to those with NDD donors at 82%.[1] In Ontario, this has led to a more conservative approach to the selection of liver and lung DCD donors and less tolerance for long warm ischemia times.

Although DCD is not novel, the Canadian experience with this practice is in its infancy. In most Canadian

Table 1 2009 comparison data for deceased donation rates across Canada and USA

2009	NDD *n*	DCD *n*	TOTAL *n*	%DCD	2008 Census (1,000 s)	Donors/ Million
British Columbia	32	0	32	0	4,114	7.8
Alberta	37	1	38	2.6	3,290	11.5
Saskatchewan	14	0	14	0	970	14.4
Manitoba	14	0	14	0	1,114	12.6
Ontario	181	37	218	17	12,160	17.9
Quebec	133	5	138	3.6	7,546	18.3
Atlantic*	33	0	33	0	2,283	14.5
CANADA	444	43	487	8.9	32,000	15.2
USA**	7,101	920	8,021	11.1	303,500	26.4

NDD = neurological determination of death; DCD = donation after cardiac death. *Atlantic includes Prince-Edward Island, Nova Scotia, New Brunswick, Newfoundland. ** In the USA, donors are counted even if organs are recovered but not transplanted. In Canada, a donor is counted only if an organ is transplanted (data from Trillium Gift of Life Network, Statistics Canada, and reference #17)

provinces, organ donation from deceased organ donors has remained unchanged over the last decade. Within four years, the Ontario experience with DCD has surpassed expectations. In 2009 and 2010, DCD accounted for 17% and 18%, respectively, of deceased donor activity in the province. As illustrated in Fig. 2, the sustained growth in deceased organ donation in Ontario is directly attributable to DCD activity.

Buoyed by the success of DCD in other jurisdictions, champions within the Ontario critical care community, along with transplant physicians and surgeons, worked with TGLN to develop DCD protocols. It was important to get agreement and understanding from senior hospital administrators, surgical personnel, and neurosurgical and critical care staff. Recognizing that this was a new endeavour, early success was critical, and therefore some degree of caution was warranted.

Ontario critical care physicians recognized the importance of providing the best practices in end-of-life care, with the potential for organ donation being one such consideration. Many of these physicians have struggled with families who previously would have wanted to proceed with organ donation for their loved ones but could not have because DCD policies were not yet in place.

The Trillium Gift of Life Network worked diligently with all stakeholders to establish DCD policies within institutions and to facilitate DCD in hospitals without formal policies. Precise coordination and liaison with the critical care and transplant personnel enabled the early successes, and each new experience provided a learning opportunity. In addition, TGLN helped to facilitate the first DCD donor in Halifax and provided mentorship for BC Transplant to help that province establish DCDs.

Most important were the donor families who greatly advocated for DCD. As stated earlier, the donor family initiated the first DCD case in Ottawa in the absence of a formal DCD policy. Very early on, it became apparent that families did not care about the distinctions between NDD and DCD. For these families, organ donation and not wanting to miss important end-of-life care opportunities was of paramount importance. One important offshoot of the DCD program was that a number of hospitals that had not participated in organ donation were able to play an active role for the first time. DCD has become the primary driver of growth in deceased donor activity in Ontario. To determine if there was a true net growth in activity or merely a shift from NDD to DCD donors, we compared the mean time in the ICU until either declaration of NDD or decision to withdraw life-sustaining therapy in eventual DCD donors. The mean ICU stay was 65 $\pm$ 70 hr for NDD donors *vs* 110 $\pm$ 83 hr for DCD donors ($P < 0.01$). Thus, critical care physicians in Ontario waited nearly twice as long to consider withdrawing care in those who did not meet brain death criteria, suggesting that they did not "rush" to withdraw care in those who might have gone on to brain death. Second, and most important, donation activity grew by 24% over the last four calendar years, with no decrease in NDD activity. With all these considerations, there were 953 SOTs performed in Ontario in 2009 compared with 641 in 2001, a 49% growth in transplantation over the decade.

For the rest of Canada, with the exception of Quebec (where a DCD pilot program was undertaken in 2007, resulting in 17 DCD donations at the time of this submission), there has been very little uptake in DCD activity. As noted above, initiation of DCD requires a number of stakeholders working together. Ethical concerns,[17] inertia, or resource limitations may be responsible for the relatively meagre DCD activity in other regions. It must be recognized, however, that the use of organs from DCD donors has limits. First, this is a resource-intensive activity. The "failure of DCD" to proceed because the donor did not expire within the two-hour time limit occurred in about 20% of the Ontario cases. This puts constraints on resources involving critical care physicians and nurses, operating room personnel, and transplant surgeons, in addition to disappointment for the potential organ donor families. The criteria for acceptance of both liver and lung donors are more conservative than for kidney donor acceptance. To date, no cardiac transplants have been performed in Canada using DCD donors, although DCD pediatric cardiac transplants have taken place, raising a number of ethical concerns.[18] As a result, the 2009 organ yield in Ontario (organs transplanted per donor) was 4.48 for NDD donors and 2.62 for DCD donors. However, Ontario has transplanted more recipients per DCD donor than the USA, where the yield was 1.98[19] Some of this difference may reflect a high degree of initial enthusiasm for DCD on the part of Ontario transplant physicians and surgeons, in addition to a very innovative lung transplant program.[12]

Our study has some limitations. Although all DCD donor and recipient activity was obtained for the first 36 months of DCD activity, our data were limited in terms of capturing differences between institutions with regard to specific organ donor management. It is recognized that critical care physicians may have different approaches in terms of withdrawal of life-sustaining therapy. As an example, we were not able to ascertain differences in sedation or patient positioning during or following extubation. In addition, we were unable to quantitate the change in surgeons' transplantation practices after some initial experiences. For example, over the course of the DCD experience, Ontario surgeons who performed liver transplants became more conservative in terms of both acceptable donor age and warm ischemic time for DCD

donors. Last, direct outcomes of SOT from NDD donors during the study period were not available.

Even with the establishment of best practices, a substantial growth in organ donation by NDD alone is unlikely. Over the last decade, the USA has seen improvements in organ donation rates, some of which were due to implementation of best practices. However, most of this growth has been attributed to DCD. Most recently, organ donation rates in the USA have reached a plateau.[19] Canada has the potential to improve its deceased donor rate significantly. As has been demonstrated in Ontario, champions within the Canadian critical care community who are proponents of DCD and supported by their regional OPOs are essential in achieving this goal.

Competing interests None declared.

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