Canadian Council for Donation and Transplantation

Environmental Scan of Live Organ Donation Programs

Executive Summary

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Introduction

Organ transplants can have a remarkable impact on a person's quality of life, or even sustain life where death is otherwise certain. Yet Canada is reported to have one of the lowest rates of organ donation among developed nations. As the waiting list for people requiring organs in the nation grows, the total number of donated organs remains relatively low.

The Canadian Council for Donation and Transplantation (CCDT) was formed in 2001 with a mandate to develop advice for the Conference of Deputy Ministers of Health on issues and strategies related to organ and tissue donation and transplantation in Canada. To meet this mandate, the CCDT Organ Transplantation Committee (OTC) is developing a framework for action to facilitate a sustained, systematic approach to organ allocation at the local, provincial/territorial and national levels. This framework will be based on evidence provided through a review of existing practices, policies or guidelines (national/international), a review of science and literature, and expert consensus.

With the increasing gap between the demand for organ transplants and the supply of deceased donor organs, there has been substantial growth in living organ donation in many jurisdictions. Canada is no exception. Between 1994 and 2004, the number of living donor kidney transplants performed in Canada increased from 211 to 413, an increase of 195%. By 2004, living donor kidney transplants comprised 40.8% of all kidney transplants performed with the proportion being much higher for pediatric recipients at 61.0% (www.cihi.ca, accessed 16 January 2006).[1] London Health Sciences Centre performed the first living donor liver transplant in 1993. As of 31 December 2003, there were 5 living donor liver transplant programs in Canada; these centres performed 53 living donor liver transplants in 2004 representing 12.7% of all liver transplant activity. The first living donor lung transplant occurred in Winnipeg in 1999. As of 31 December 2004, 5 additional living donor lung transplants have been performed.

Recognizing an escalation in the number and rate of live organ donation, the Organ Transplantation Committee of the CCDT commissioned an environmental scan of national programs in Canada to determine current practices, issues and resources related to live organ donation. The results of the scan will inform further work in the area of live organ donation by the CCDT and this will subsequently inform the advice given to Canada's Deputy Ministers of Health on the topic of live donation public policy.

The objective of the scan was to obtain a comprehensive picture of current programs, policies, and practices related to live organ donation in Canada as well as perceptions and opinions regarding existing challenges and potential for improvement.

Methods

The survey contained 41 questions compiled by the CCDT project lead, the co-chair of the Enhancing Living Donation (ELD) Forum Steering Committee, and the consultant's project manager. It was then made available by email or fax along with a letter of introduction signed by the CCDT project Lead and the ELD Forum co-chair.

The program survey was distributed to a total of 35 programs in 10 provinces/territories and included live donor programs for kidney, liver, and lung. Program contacts were asked to consult other professionals connected with the program as needed in order to gain a comprehensive overview of the program. Respondents were informed that their participation was voluntary and anonymous. All completed questionnaires were reviewed and data was tabulated in spreadsheet format before preparation of tables and graphs. Data was spot-checked and reviewed twice during preparation of this report.

[1] Treatment of End-Stage Organ Failure in Canada, Canadian Organ Replacement Register, Canadian Institute for Health Information 2002/2003 CORR Annual Report.

Results

Survey responses were received from 18 live donor (LD) programs operating in 6 provinces across Canada. The majority (n=14) were kidney transplant programs, 2 liver transplant programs, and 2 lung transplant programs. Most (n=17) of the responding health care professionals were transplant program coordinators/nurse managers, nurse practitioners or nurse educators. One nephrologist responded and one social worker was part of a team that responded on behalf of the program. Program size varied substantially between responding living kidney donor programs, with a single program reporting > 40 LD transplants performed in 2004 and 3 to 4 programs each reporting 31-40, 21-30, 11-20 and 0-10 LD transplants respectively in 2004.

Programs were asked to estimate the number of work-ups initiated (defined as a minimum of a blood group) in 2004. As expected, there is a substantial gap between the volume of initiated donor work-ups versus the actual number of LD transplants performed. For most programs transplant activity represented 5-20% of the volume of initiated evaluations. The most common reasons for non-acceptance of ABO-compatible, cross-match negative living kidney donors were reported to be the presence of donor hypertension, renal insufficiency, proteinuria or the identification of other co-morbidities such as donor diabetes. Technical barriers (size mismatch or vascular anatomy) were identified more commonly by liver and lung living donor programs. Half of the programs recalled referring a small number of potential LD (≤ 5 from any one program over the previous 5 years) to another centre for a second opinion. Acceptance by another program of a previously declined donor was relatively uncommon in kidney LD programs and was not seen in liver or lung LD programs.

Access to resources for living donor programs

Given the fact that living donor kidney transplantation is both the optimal form of renal replacement therapy and offers superior cost-effectiveness, the survey sought to identify any potential barriers present in the health care system to the timely and efficient evaluation of potential LD. Of the 18 programs responding, 5 (27.8%) do not have staff dedicated specifically to the LD program. Of the remaining 13 programs, 100% have coordinators, 10 of 13 (76.9%) have clerical support, and 9 of 13 (69.2%) have some social worker support (Table 1).

Table 1: Staff support to living donor programs

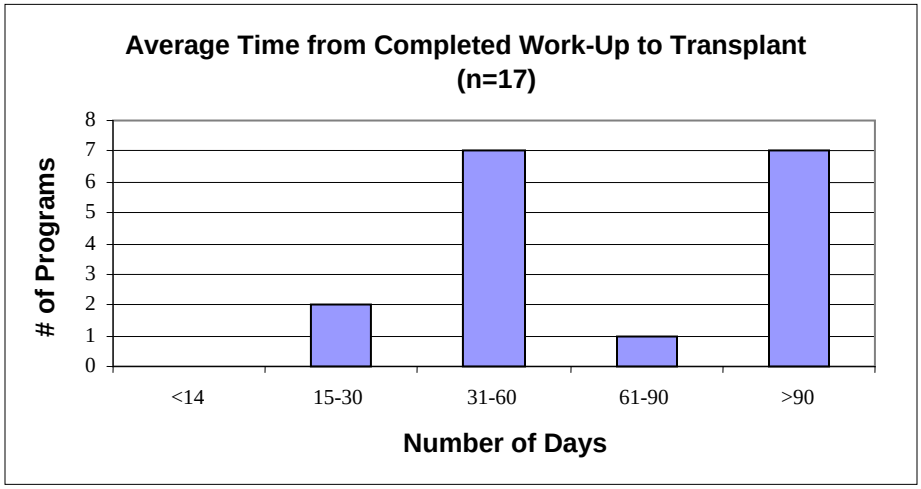
Discipline	Number of Programs	Total FTEs	Average FTE per Program
Coordinator	13	11.48	0.88 FTE
Clerical staff	10	6.7	0.67 FTE
Social worker	9	3.4	0.37 FTE
Psychologist/psychiatrist	2	0.43	0.22 FTE

Programs were asked about other possible health system barriers to LD assessments. Access to radiology services seems to be the most common problem with 10 centres indicating it is sometimes a problem and 3 centres that it is usually a problem. Access to medical consultation was difficult some of the time for 7 centres, although 8 others reported this was rarely a problem. Similar opinions were expressed regarding access to surgical consultation (6 sometimes a problem, 10 rarely a problem). Individual programs also identified delays in obtaining tissue-typing results, collecting results of the assessment including a medical history and examination by family physicians, and access to a social worker, as occurring frequently within their programs.

Poor access to operative services resulted in significant delays between the completion of the work-ups and the scheduled surgery in some LD programs. This occurred sometimes for 6 programs and always for 1 program. Ten of 17 (58.8%) programs indicated that they had regularly scheduled OR time set aside with an average of 4 OR slots per month. As shown in Figure 1, 10 programs were generally able to perform the LD transplant within 90 days of completion of the work-up, with the majority (n=7) specifying a usual wait-time of 31-60 days. Seven LD (41.2%) programs reported that they do not have dedicated OR time; delays of > 90 days between completion of the work-up to the actual LD transplant were common. The majority of programs (73.3%) indicated that the OR time identified for LD transplants was never

cancelled. In the remaining programs, this was an extremely rare event, usually occurring when OR time was required for another more urgent non-transplant case or there was insufficient access to anesthesia or in-patient beds.

Figure 1. Average time from completed work-up to LD transplant.



In identifying the barriers to success of their living donor program, staffing issues was one of the most frequent concerns. The need for more medical staff was part of a larger picture which included not only dedicated program personnel such as coordinators, nurses, and clerical resources, but also better access to other medical services such as tissue typing lab, operating theatres, radiological testing, assessment consults, psychiatry, and social work.

Donor evaluation

Kidney living donor programs uniformly requested 24 hour urine collections to measure creatinine clearance; radioisotope GFR studies were performed routinely by 50% of programs. The majority (12 of 14) measured protein excretion in a timed urine collection while 64.3% of programs measured urine albumin:creatinine ratio. Despite controversy surrounding donor hypertension as an exclusion criteria and the impact of kidney donation on blood pressure, it is interesting to note that 3 programs required only a single in-centre blood pressure measurement by a health professional as part of their donor evaluation; 9 centres required at least 3 measurements and 1 centre routinely performed 24 hour ambulatory blood pressure monitoring. More than 85% of programs obtain a fasting glucose and lipid panel as part of their evaluation; only 3 programs require an oral glucose tolerance test. Twelve centres perform renal ultrasound as part of the donor work-up; vascular anatomy is assessed by spiral CT in 11 programs, renal angiography in 3 programs, and MRA in 2 centres.

There were significant similarities observed in the components of the LD assessments as reported by each of the 2 liver and 2 lung LD programs responding. In both settings, emphasis is placed on the anatomic aspects of the assessments.

Many health care professionals are involved in the assessment of potential LD. Of the 18 programs responding, 94% indicated that a medical subspecialist (nephrologist/hepatologist/respirologist) is involved. The great majority (16 of 18) also routinely included assessment by the surgeon, live donor coordinator, and social worker. Nine programs (50%) routinely involved the family physician.

To evaluate the degree to which the donor and recipient assessments are conducted independently, programs were asked how frequently the medical specialist (nephrologist/hepatologist/respirologist) involved in the donor assessment is also involved in the recipient assessment. In 61% of programs, the same medical specialist (nephrologists/hepatologist/respirologist) rarely (n=1) or never reviews both the donor and recipient. Four programs (2 kidney, 1 liver, 1 lung) responded that this occurred usually (n=1) or always (n=3). In one liver living donor program, it was reported that either the hepatologist or surgeon

evaluating the donor was likely to also have been involved in the care of the recipient; this program employed an assessment by an internist as an independent donor advocate. A single lung living donor program reported that both the donor and recipient were usually seen by the same respirologist; in this program the donor was also referred to an external respirologist as part of the donor evaluation.

Transplant surgeons were more likely to be involved with both donor and recipient with only 4 programs reporting that this never or rarely happens. In 5 programs, this routinely occurs, perhaps because a single surgeon may perform both donor and recipient operations.

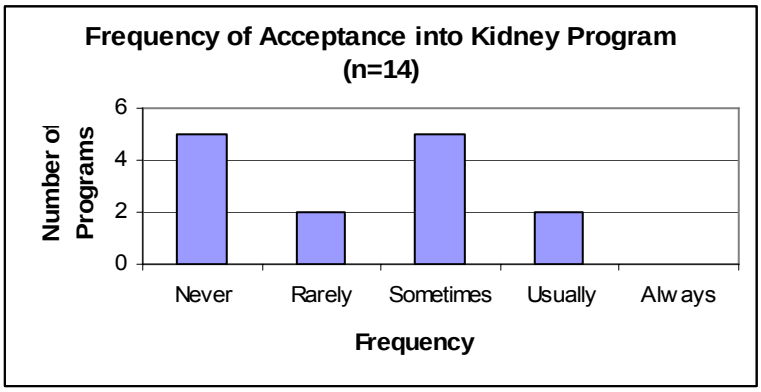
When the assessments are concluded the final decision as to donor suitability is most often (n=14) a team decision. In the other programs, the final decision is made by the donor's primary specialist (n=4).

Acceptance of donors with incremental risk

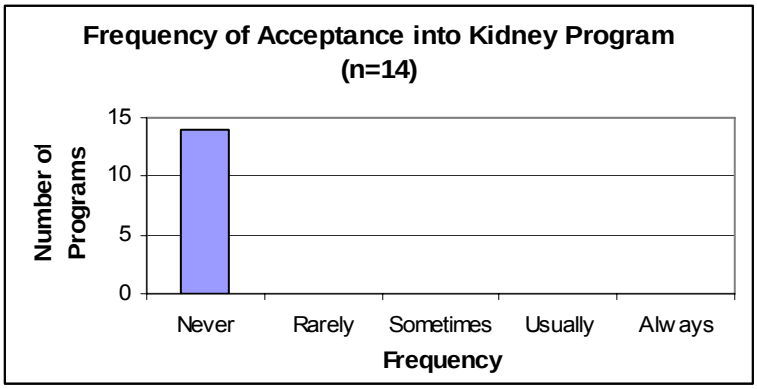
To assess the degree to which individuals with incremental medical risk may be accepted as possible kidney donors, 3 scenarios were presented to the kidney donor programs.

Figures 2a-c. Frequency that kidney living donor programs would accept the following:

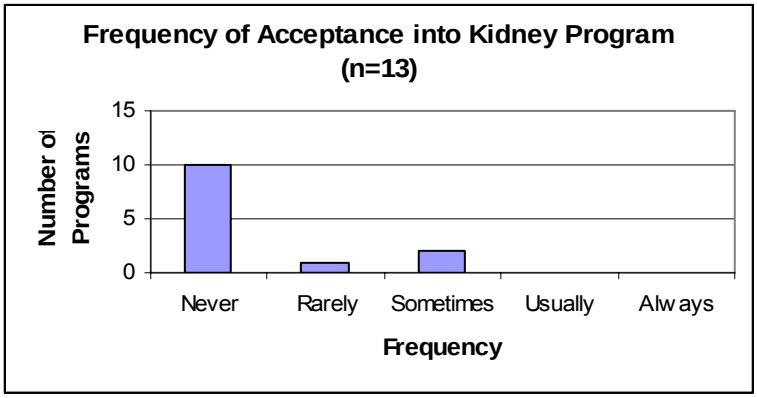
a. 50-year-old man with a 4 year history of hypertension treated with a thiazide diuretic alone. Repeated blood pressures average 130/80 mmHg.



b. 40 year old male with a 3 year history of diabetes mellitus controlled with metformin. He has no history of hypertension, his creatinine clearance is 120 ml/min, and his urine is negative for microalbuminuria.



c. **45-year-old healthy, average-sized male is found to have an elevated serum creatinine of 125 umol/L during the donor assessment. His inulin GFR was 75 ml/min, urinalysis and renal ultrasound were normal.**



*Note: One program indicated they do not know; they would refer to the transplant team.

As illustrated in Figure 2, there is considerably variability in practice particularly when in comes to accepting a potential living donor with hypertension or mildly abnormal renal function. No program accepted individuals with frank diabetes mellitus as a potential living donor.

The liver living donor programs were asked if they would accept a 30 year old female with a BMI of 32 and evidence of fatty liver: both programs responded “sometimes”. The lung living donor programs were split on whether a 45 year old male who is a current smoker with a 25 pack-year smoking history; one program stated “never” while the other responded “sometimes”.

Psychosocial evaluation of living donors

The great majority (16 of 18 living donor programs) indicated that psychosocial assessment of the potential living donor is mandatory. Of these 16 programs, a social worker is consulted by 15; in the remaining program a psychiatrist is routinely consulted. In addition to the social worker, some programs also consulted either psychiatry (n=5) or psychology (n=5). The format of these assessments varied somewhat from program to program but most used a structured interview (n=6) or a combination of interview and discussion (n=10). In some programs (n=2) an additional tool in the form of a psychological assessment tool was utilized. Assessments generally took a total of 45 – 90 minutes for all responding programs.

Informed consent

Preliminary information concerning risks was conveyed by telephone and/or in person by the donor coordinator in 16 of the 18 programs. The remaining 2 programs relied on written resources first. Twelve programs included written materials and/or references to websites. In all programs, the donor coordinator and the medical specialist were involved in most aspects of the communication of risk and benefit, with the coordinator most often being the one to discuss the benefits of live donation (n=13), and the specialist (n=12) most often discussing long-term medical risks. The surgeon (n=14) covered surgical risks, while financial and psychosocial risks were most often communicated by the social worker.

For kidney programs, the primary long-term medical risks discussed were hypertension (n=14), proteinuria (n=12), kidney failure (n=11), chronic kidney disease (n=10), and chronic pain (n=7). Potential liver donors in both programs (n=2) were told about risks for bile duct problems, possible liver failure, need for re-operation, and chronic pain. Lung transplant programs (n=2) were unanimous in discussing the risks for increased shortness of breath, decreasing lung function with age, and chronic pain.

All transplant programs (n=18) indicated they informed donors about balancing risks and benefits, effect of recipient outcomes, and risk of coercion. Freedom of choice and the impact of being declined for donation were important topics for 94% (n=17) of programs while protection of donor privacy and protection of donor interests are discussed by 15 and 16 programs respectively.

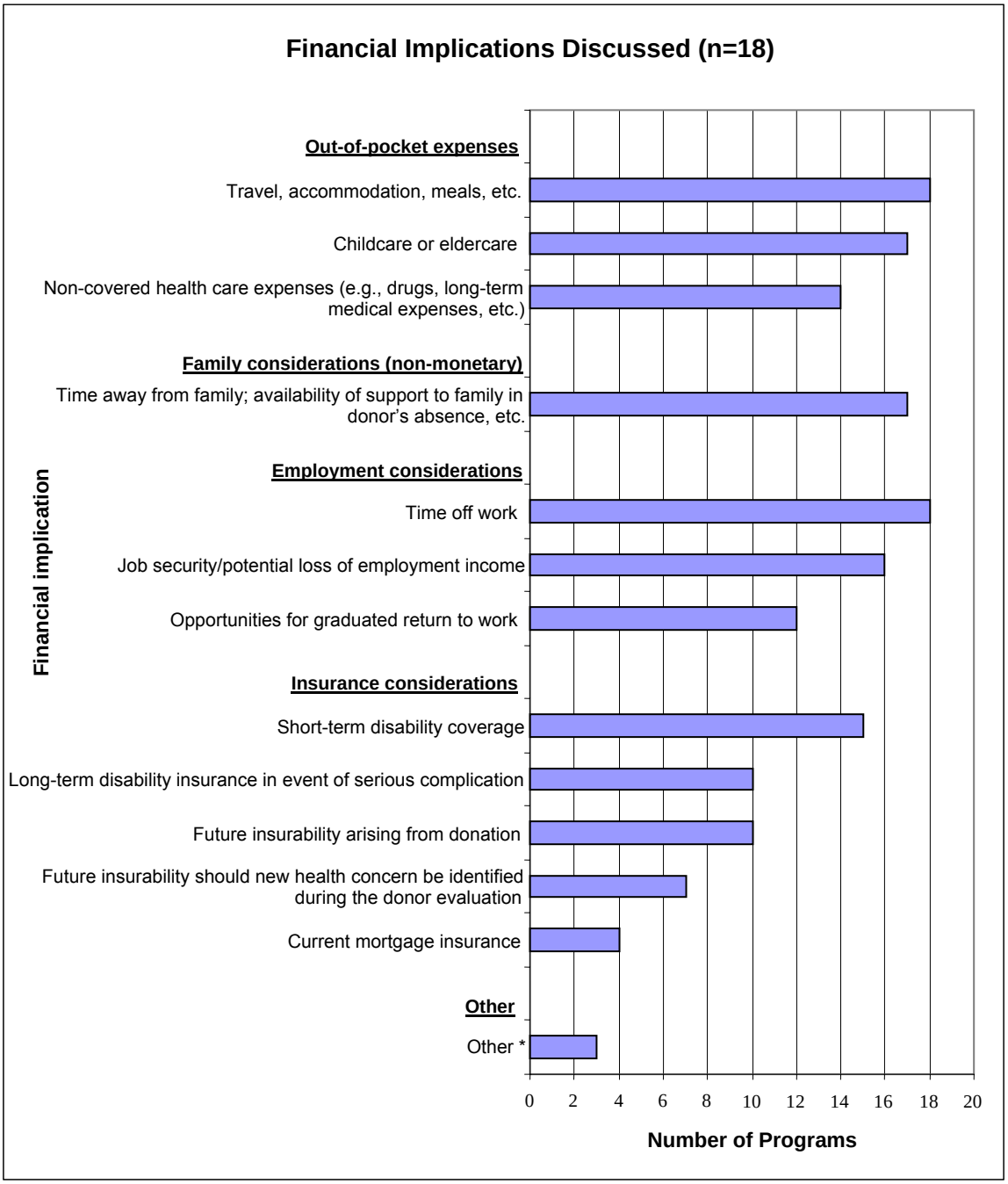
There are a variety of peer supports to which donors may be referred. Of 18 programs, 50% (n=9) referred donors to identified previous donors for support; no program had a formal peer support group organized by the living donor program. Two programs referred donors to outside programs organized by others. Five programs stated they did not routinely refer donors to either peers or a support group.

Potential donors are provided with information about costs associated with transplant that may not be covered by public or private heath care insurance (Figure 3). Out-of-pocket expenses most often discussed were travel and accommodation costs (n=18), and childcare or eldercare (n=17). Cost of time away from family, (n=17), and time off work (n=18) were also discussed. Insurance considerations were important topics with short-term coverage (n=15), long-term disability (n=10), and future insurability (n=10) topping the list. Only 7 programs discuss the possibility that future insurability could be affected by a new health concern identified during the donor assessment.

When asked about provisions for reimbursement of out-of-pocket expenses, all 18 centers stated there is no financial support for these costs. One program did comment there may be limited funding available to qualified donors through the Kidney Foundation of Canada. Several programs indicated that they felt that reimbursement of donor expenses and loss of income would result in increased living donor activity.

In terms of an actual written consent form for live donation, only 4 programs indicated use of a consent form specific to living organ donation. The donor coordinators of two additional programs obtain consent for diagnosis, treatment and care related to the donor evaluation.

Figure 3. Financial implications discussed with potential live donors.



* Other:

- Employment insurance.
- Financial hardship as a result of donation; wage replacement benefits such as EI; financial preparation and planning.
- Representation agreements and enduring power of attorney and will.

Out-of-country living donors

Sixteen programs have been involved with evaluating living donors residing outside of Canada. When asked if knowledge of health care access in the donor country was a factor in accepting the donor, half of the respondents indicated yes and half said it is not a factor.

Programs assist with letters of support (n=13), and/or help with visa applications (n=8). Programs were asked to list any barriers they encountered. Nine programs provided comments on barriers, all of which had to do with visas or immigration. Six programs or 67% agreed that approval of a temporary visa was the biggest barrier. Problems included the length of time required or unreliable donor information. Often the visa was denied depending on the donor's country. The remaining comments simply indicated that immigration was a barrier.

Follow-up of potential living donors

Considerable variation exists as to the type and frequency of follow-up of living organ donors. The majority of programs provide post-operative follow-up within the first 3 months after donation, usually by the surgeons and donor coordinators. All 18 programs indicated that follow-up at one year post-donation was scheduled. However, in only 6 of 18 programs was this provided by either the medical specialist (n=4) or surgeon (n=2) involved in the donor assessment. In 5 programs, the donor coordinator provided the 1 year follow-up. Thirteen programs request that all donors be followed by their family physician while 12% (n=2) only require this for non-local donors and 12% (n=2) do not rely on family physicians at all. In many programs, follow-up was arranged by the donor coordinator by contacting the donor (n=10) and/or their family physician (n=7) with a written reminder to perform certain investigations annually. Several programs commented that it was up to the donor to initiate follow-up and that the program does not keep track as to whether this actually occurred. Approximately half of the donor programs that rely on family physicians for follow-up never (n=5) or rarely (n=1) receive the follow-up information. In response to a question concerning opportunities to improve practice, several centres felt that better and more complete donor follow-up data would be important.

Psychosocial follow-up was recommended in only 4 of the 18 programs. Two programs have the social worker contact the patients between 2-5 months post-donation. In one, the donor coordinator screens for psychosocial concerns at 6-8 weeks and 1 year post-donation. In another program, the psychiatrist/psychologist reviews lung donors at 6-8 weeks after donation.

When asked about the duration of follow-up provided to living donors, the most frequent responses were either that there was no follow-up (n=5) by the program, or that the follow-up could continue for more then five years (n=5).

Donor registry

When asked if they would support the development of a Canadian live donor registry that would include long-term follow-up data, all but one (94%) of 17 responses were positive. In order to participate, programs identified the need for clerical support (n=7), database infrastructure (n=2), nursing/coordinator support (n=1), and funding (n=1).

Conclusions

This environmental scan of Canadian living donor programs identifies a number of opportunities to enhance the activity and quality of care provided to living organ donors. Some programs struggle with inadequate health care resources, most notably the lack of dedicated living donor coordinators and clerical support. Access to certain diagnostic tests (especially radiology) and operative services remains a challenge in some centres. Those programs with dedicated operating room time experience the smallest delays in scheduling a living donor transplant once the evaluations are complete. Given the cost-effectiveness of living donor transplantation (at least for kidney transplants), solutions to the lack of local resources directly supporting living donor programs should be aggressively pursued.

Many living donor programs employ similar protocols to evaluate potential kidney donors from both a medical and psychosocial perspective. However there are some inconsistencies in the type of information provided about the risk of living organ donation, particularly when addressing the medical and financial risks. The development of standardized information to be provided to each potential organ donor would ensure that every individual, no matter what program is delivering the care, would have access to consistent and accurate data concerning the risks and benefits of living donation. It is also clear from the survey, that a number of isolated medical abnormalities (i.e., donor hypertension) pose a contraindication in some programs but not in others. This variability in practice has arisen in the vacuum created by the absence of solid outcome data concerning the risks of donation should such individuals proceed with organ donation. Thus it is particularly important to develop a framework that guides the assessment of the potential for incremental risk, optimal strategies for the communication of that risk, and the process of informed consent.

Despite recommendations that living donors be offered life-long follow-up, it appears that only a minority of Canadian donor programs assume responsibility for this beyond the first few months following surgery. However a number of living donor programs did identify that more complete follow-up information was required to better understand the long-term risks of living donation. The great majority supported the development of a living organ donor registry provided additional resources were identified to support this initiative.

Donor programs also identified the financial disincentives to living organ donation as a significant barrier for potential donors. There was uniform support for the principle that living donors should be reimbursed for out-of-pocket expenses and loss of income. This survey, and others, indicates that individual living donor programs in Canada are currently unable to reimburse donors for part or all of the costs. Whether reimbursement of expenses would result in greater activity of living donor programs is uncertain. However a reimbursement strategy would, at a minimum, ensure that the living donor is not further disadvantaged by their altruistic act of organ donation.

Note: Complete results of the environmental scan will be available on the Canadian Council of Donation and Transplantation website.