

Living Organ Donation: Consent Challenges

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I. Introduction

The rates of related and unrelated living donation are increasing. Indeed, in some nations, almost half of all kidney donors are living (Truog, 2005). They are emerging as one of the most significant sources of organs for transplantation. For example, in 2003, there were 421 deceased organ donors and 434 living donors (mostly kidney) (CIHI, 2005). While this practice has increased the supply of available organs, it also introduced profound social dilemmas.

In this paper, I review some of the central legal and ethical challenges associated with live organ donation.¹ The emphasis is on Canadian consent law, a prime area of concern in this context. The paper starts with a consideration of each element of the consent process, including ensuring that consent is informed, voluntary and provided by an individual with capacity. This is followed by a consideration possible consent strategies that could be used to enhance the consent process in Canada. The paper concludes with a brief consideration of emerging consent issues.

II. Context

Given the frequency of living donations, it should come as no surprise that they are clearly legal in Canada. Provincial tissue legislation explicitly refers to the practice. Alberta's *Human Tissue Gift Act*, for example, states "a transplant from one living human body to another living human body may be done in accordance with this Act" (s. 2). Other provinces have similar provisions (see, for example, section 2 of Ontario's *Trillium Gift of Life Network Act*; section 2 of British Columbia's *Human Tissue Gift Act*; and section 9 of Manitoba's *Human Tissue Gift Act*). In addition, the policy issues associated with living donation have been the subject of several consensus statements by ethics groups and professional bodies, such as the American Society of Transplant Surgeons (2000), the Live Organ Donor Consensus Group (2000) and the Ethics Committee of the Transplantation Society (the Amsterdam Statement) (2004). And there is a growing body of ethics and legal literature on point.

Despite the legality, the growing frequency of the practice and the policy attention it has already received, there are a variety of legal and ethical issues that remain unresolved – particularly in the area of consent. And new living donation arrangements, such as "paired exchanges," are generating novel legal and ethical questions.

From the outset it is important to note that not all living donations are the same and each type of live donation raises different legal and ethical issues (Truog, 2005). There are, for example, directed donations by living donors to a relative or friend, anonymous donors who are unknown to the transplant recipient, and donations that may be the result of an advertising plea or internet solicitation by a desperate individual in need of an organ

¹The emphasis in this paper is on Canadian common law. Though most of the paper is relevant to all jurisdictions in Canada, Quebec civil law not covered. In addition, the paper should not be viewed as legal advice. The opinions are the author's and do not represent the views of the HLI.

(Delmonico, 2004). All of these donations scenarios raise unique legal issues, such as the possibility of subtle coercion and, as in the case of a parent donating to a child, the desire to donate regardless of individual risk to the donor. In this paper, I explore the consent issues associated with living donation generally. However, the CCDT may wish to consider a more in-depth consideration of the legal and social issues associated with each type of living donation.

III. Elements of Consent

In order for consent to be valid, it must be informed, voluntary and provided by an individual who has capacity. In the following section, I will analyze each one of these elements and relate it to issues relevant to live organ donation. The goal is not to provide a comprehensive analysis of all consent issues associated with live organ donation. Rather, I seek to provide background to inform a discussion on what I view to be the most pressing consent challenges.

a) Informed Consent

Probably the most analyzed element of the consent process is the obligation to ensure that consent is appropriately informed. Indeed, much of the Canadian case law and relevant literature has focussed on this one aspect of the consent process (Dickens, 2002). The doctrine of informed consent flows from the ethical principle of autonomy, a point explicitly noted by the Supreme Court of Canada: “This concept of individual autonomy is fundamental to the common law and is the basis for the requirement that disclosure be made to a patient” (*Ciarlariello v. Schacter*, 1993).

The doctrine imposes a legal duty on physicians to provide their patients with “material information” concerning the proposed treatment, so as to enable the patient to make an informed choice. “Material information” is defined in terms of what a reasonable person in the patient's position would want to know (*Reibl v Hughes*, 1980; Picard and Robertson, 1998). In other words, the scope of the disclosure obligation is determined through the lens of the patient, not the health care professional. In general, the courts have continued to expand what is defined as material information, thus making the disclosure obligation ever more expansive. As noted by Dickens: “The respect for personal autonomy shown by modern health law makes it likely that courts will continue to broaden the scope of required disclosure” (Dickens, 2002).

There seems little dispute that the disclosure obligation in the context of live donation is tremendously onerous. The literature in the area displays a clear desire to ensure that all donors are as informed as practicable. And most of the recent policy statements emphasize the need for a thorough discussion of all risks, procedures, alternatives and any other information that may be relevant to the particular donor. For example, the Amsterdam Statement provides that following disclosure guidelines recommendations (2004):

- The nature of the evaluation process;

- The results and consequences/morbidity of testing, including the possibility that conditions may be discovered that can impact future healthcare, insurability and social status of the potential donor;
- The risks of operative donor nephrectomy, as assessed after the complete evaluation. These should include, but not be limited to: the risk of death, surgical morbidities, changes in health and renal function, impact upon insurability/employability and unintended effects upon family and social life;
- The responsibility of the individual and health and social system in the management of discovered conditions (for example, if the donor is discovered to have tuberculosis, the donor should undergo treatment, the community has a responsibility to help the donor secure proper care with referral to an appropriate physician);
- The expected transplant outcomes (favorable and unfavorable) for the recipient and any specific recipient conditions which may impact upon the decision to donate the kidney;
- Disclosure of recipient specific information which must have the assent of the recipient.

Such lists are helpful as they serve as a reminder of the key elements of the informed consent process (see also U.S. Department of Health and Human Services Advisory Committee on Organ Transplantation, <http://www.organdonor.gov/acotreccs.html>, for an even more comprehensive list). But transplant teams should remember that, in Canada, the scope of the disclosure obligation must reflect the needs of the particular donor (or, more technically, “the reasonable person in the patient’s position”). Indeed, the information should be provided in a manner and a level that is appropriated for each donor. Professional and, even, widely accepted consensus statements, do not set the standard of disclosure. It is a patient centered standard.

This means that the disclosure process should include all information that may be relevant to a person in the patient’s position. For example, how will the procedure impact the donor’s employment and family life? Indeed, in *Reibl v. Hughes*, the famous Supreme Court of Canada decision on informed consent, one of the key issues was the impact that the operation in question might have on the plaintiff’s ability to work and obtain his pension (1980). As Taylor, et al. note: “Relevant information pertaining to psychological, financial, and insurance risks for the prospective donor need to be communicated. The prospective donor must realize some risks reach well beyond the single surgical event” (2004a).

Transplant teams should be aware of the special or unique risks associated with being a donor. For instance, the psychological impact of donation and other non-medical factors need to be considered as part of the consent process. It has been reported that “as many as 25% of live donors experience either depression or financial hardship after donating an organ.” (Tokarski, 2002). Likewise, the expectations, both realistic and unrealistic, of the donor should be explored (Taylor, 2004b). The consent process should, as much as possible, be informed by the emerging research on the needs and expectations of donors

and the psychological and social “risks” associated with the procedure (see Surman, et al., 2005).

Finally, cultural aspects should also be considered in the consent process. In one study, there was a clear difference in the willingness to donate an organ between individuals from the US, Japan and Germany (Dahlke, et al., 2005). The authors note that attitude toward donation was not determined by the national demand for organs or the profile of the living donation program (for example, Japan has one of the world’s largest living donor programs but the Japanese cohort “exhibited a lower inclination for organ donation in general”). The authors conclude that: “cultural background was a more relevant predictor of the attitude of the potential donor than was the actual need for organ grafts in the respective society” (at 62). Understanding these subtle cultural variations can help to inform the consent process and provide an understanding of the patient’s perspective.

Against the legal requirement of a thorough and comprehensive information disclosure process, the reality of the donor decision-making process should be considered. There is at least some evidence that the disclosure of information has little impact on the donor’s decision regarding donation. Surman, et al., notes that the available evidence suggests that donor decisions “were often immediate and formulated prior to objective inquiry” (2005, p 3). After the decision is made, donors tend to “interpret new information in a selective fashion in support of their initial decision” (2005, p 3). In a 2004 qualitative study of donor motivations the authors found similar results. Donors who were committed to the procedure (“openly motivated”) pushed for the operation and left little room for ambivalence (Walter, et al., 2004).

While such research should inform the transplant team’s interaction with the donor, it should not be used as an excuse for a less than robust consent process. There is no doubt that ethical and legal norms require a comprehensive disclosure process.

b) Fiduciary Law and Disclosure

The consent process must also be responsive to the fiduciary obligations that health care providers have toward their patients. In Canada, physicians are considered to be in a “fiduciary relationship” with their patients. Fiduciary obligations flow from the relationship of trust between physician and patient and the implicit or explicit understanding that physicians will focus, almost exclusively, on the best interests of the patient. As noted in the Supreme Court of Canada decision in *McInerney v. MacDonald*: “[c]ertain duties do arise from the special relationship of trust and confidence between doctor and patient, including an obligation to treat the patient with the utmost good faith and loyalty” (1982). In the case of *Norberg v. Wynrib*, Justice McLachlin stated that the “the most fundamental characteristic of the doctor-patient relationship is its fiduciary nature” (*Norberg v. Wynrib* 1992).

In the context of live organ donations, this obligation can be strained because many different interests are engaged by a transplantation procedure, including that of the donor, the recipient and other individuals on the transplantation wait list. Fiduciary law demands that, at a minimum, such conflicts are disclosed to the patient and, where

possible, avoided or moderated (to be discussed further below). Indeed, even the mere appearance of a potential conflict should be addressed (*Cox v. College of Optometrists of Ontario*, 1988).

c) Voluntary: Coercion and Consent

Consent is only valid if it is truly voluntary. If consent is coerced or is the result of undue influence, it may not be legally valid (*Norberg v. Wynrib*, 1992). In the health care setting, inappropriate influence can come from a variety of sources, including family members, close friends and health care professionals. The British decision of *Re T* serves as a good example (1992; see also Nelson, 2002). The case involved a 21 year-old patient in need of a blood transfusion. Though she was not a Jehovah's Witness, her mother was a member of the faith. The patient refused a blood transfusion and the father took legal action to challenge the decision. The Court held that the consent was not valid because of the inappropriate influence of the mother in the decision making process.

One of the clear challenges associated with live organ donation is the potential for subtle coercion that might compromise the consent process. To cite just one example, when the recipient is a family member, a donor may feel morally obligated to donate, but, in reality, may not want to (Sanner, 2005). As a result of this potential, it is essential, from a legal perspective, to discuss the process away from family members or friends. There is, in fact, some evidence that such individuals are not the best support structure in the circumstance of an organ donation as they might be equally anxious about the operation (Sanner, 2005). Indeed, even when the family members or friends do not know the recipient, their presence may cause the donor to be less than frank about any apprehension toward the procedure. The donor may not want appear afraid or selfish.

Caplan has noted the "moral paradox of living donation" (Caplan, 2005). If an individual is a true stranger to the potential recipient, society wonders about the actual motivation and, even, the psychology behind such dramatic altruism ("Are they there because of impulse or are they there because of money? Are they there because of psychiatric issues?"). If the recipient is a close family member, then there are issues of emotional coercion.

Some authors have suggested that there may be signals or signs that an individual has been coerced (explicitly or implicitly). The Walter study of organ donors, noted above, found that there was group of donors who were "openly ambivalent" – expressing anxieties through arguments against donation (Walter, et al., 2004). The authors suggest that "statements of ambivalence towards donation or utterance of arguments against donation" should be viewed as hints that earlier coercion may have occurred. While such data is hardly definitive, it does suggest that health care providers should look for clues of coercion. More importantly, the consent process should be structured in a manner that allows careful reflection and ample opportunity to explore donor motivation and anxieties.

d) Capacity to Consent

In order for consent to be valid, the individual giving the consent must have the legal capacity to do so. In general terms, the patient must have the cognitive ability to understand the nature and consequences of the procedure. If an individual is legally competent, their consent is necessary and sufficient (*Ney v. Canada (Attorney General)*, 1993). Capacity issues can emerge in a variety of contexts. Here, I will briefly discuss capacity issues as they relate to minors and surrogate decision makers.

i) Minors

Can a minor consent to provide a live organ donation? This is, in fact, an issue that is specifically addressed in most provincial statutes. In Ontario and PEI, the relevant tissue donation legislation sets the age of competence at 16. For example, section 3 of the Ontario legislation states: “Any person who has attained the age of sixteen years, is mentally competent to consent, and is able to make a free and informed decision” may consent to a live organ donation. In other jurisdictions, such as British Columbia, Newfoundland and New Brunswick, the age is set at 19. The Manitoba legislation sets the default age of consent at 18. However, section 10 of the Manitoba Act also creates a framework that allows individuals as young as 16 to consent, so long as the donation is going to a member of the “immediate family” and there is an independent assessment of capacity (i.e., an assessment by physician with no relationship to the recipient). In Nova Scotia and Saskatchewan no specific age is mentioned. In section 4 of both the provinces’ legislation, it is stated that any person who has “attained the age of majority” can consent. In Alberta, “any adult person who is mentally competent” may consent (section 3). In general, this kind of wording will be interpreted to mean 18 (see, for example, Alberta’s *Age of Majority Act*)

Despite such legislation, we must consider the relevant case law in the area in order to determine if and when a child can consent to a procedure like a live organ donation. Indeed, it is possible that even though a specific age is mentioned (or implied) in the relevant legislation, a court may be able to apply the “mature minor” doctrine – thus allowing the consent of a minor under the statutory age to be deemed sufficient. The mature minor doctrine has been applied in circumstances where a minor has refused life saving treatment, such as a blood transfusion. In the New Brunswick case of *Walker v. Region 2 Hospital Corp.*, for example, a 15-year-old boy was deemed mature enough to make treatment decisions (1994), despite the fact the statutory age of consent is that province is 16.

While there is no case law directly on point, the jurisprudence surrounding the mature minor rule would seem to be quite relevant in the context of live organ donation decisions. If minors can be held competent to refuse life saving treatment, it seems possible that they can be held competent to consent to organ donation (see also *B.H. v Alberta*, 2002; and *C. (J.S.) v. Wren*, 1987). The goal of consent law is to respect patient autonomy. And while the courts have given surprisingly little guidance regarding the assessment of capacity (Picard and Robertson, 1996), there is evidence that adolescents are capable of making life and death decisions. For example, Weir and Peters note as follows: “An expanding body of professional literature indicates that adolescents, with

some exceptions, are capable of making major health decisions and giving informed consent, whether in a clinical or research setting” (1997. p 31).

Likewise, health care professionals need to be careful not to be influenced by their perception of the soundness of the decision. In other words, just because a person, such as a competent adolescent, makes a decision that seems illogical to the health care provider this does not mean that the person lacks decisional capacity. As noted by Brazier: “[A]utonomy and the role of the right to self-determination includes the right to take decisions based on factors other than pure reason, and embraces the right to take a *wrong* decision.” (1987, 175. See also *Malette v. Shulman* (1990)).

The existing law may permit minors and young adults to donate organs, but there are unique ethical and policy issues that, as I understand it, have made such donations relatively rare. For example, the coercion issues, discussed above, might be particularly problematic when a minor is involved (e.g., family pressures). Likewise, some have questioned whether a young adult can appreciate the long-term ramifications of an organ donation. As such, some of the relevant policy statements have recommended against allowing minors to donate. For example, the Consensus Statement of the Amsterdam Forum declares: “Minors less than 18 years of age should not be used as living kidney donors” (2004, at 492).

In total, if an individual is competent and meets the age specified in the relevant legislation, they can clearly consent to a live organ donation. It is arguable, however, that the mature minor rule applies. If so, “mature minors” would be capable of providing consent regardless of the age mentioned in the legislation.

ii) Surrogate Decision Making

Another controversial area is the possibility that a third party, such as a legal guardian, could consent to the donation of an organ for transplantation. The donation of an organ in this manner would, obviously, be relatively unusual. However, there have been circumstances when it seemed a viable option. For example, in the US there is a report of a 20-year-old male who was in a coma and his family wished to donate the patient’s kidney to a relative. Because the patient did not meet the relevant brain death criteria, the donation would be considered a living donation. After a long and involved ethical consultation, the kidney transplantation was permitted and successfully completed (UCLA Medical Center Ethics Committee, 2004).

In Canada, under specific circumstances and in at least one jurisdiction, this type of donation is, technically, legally possible. Section 3(3) of the Alberta legislation states that “an agent may, on behalf of the maker, consent to the removal of tissue from the maker’s body ... if the personal directive under which the agent is authorized to act states that the consent may be given.” So, in Alberta, if an individual has executed a valid personal directive and specifically mentioned the possibility of donating an organ, the surrogate decision maker may consent to the removal of an organ. In all other common law provinces, however, no such provision exists. Moreover, many of the statutes note that the consent is only valid if the procedure is done in accordance with the consent

provisions in the relevant Act (for example, “consent” will be defined as “consent under this act” – see, for example, the definitions section of the Alberta, BC, Nova Scotia and Newfoundland Act).

It is arguable, therefore, that third party consent is not allowed in most jurisdictions because it is not a form of consent contemplated in the relevant legislation. At a minimum, it would make the validity of a third party consent questionable, particularly if no advanced directive exists.

That said, the courts have not addressed the issue and it is possible that a court would, despite the wording of relevant provincial legislation, respect the existence of an advanced directive or the directions of a legally appointed guardian – especially if there were strong evidence that the donation would correspond to the wishes of the patient. Canadian courts place tremendous emphasis on autonomy and, as we have seen in other cases, will often err on the side of protecting even previously made wishes (e.g., *Malette v. Shulman* (1990)).

e) Withdrawal

One of the fundamental tenets of Canadian consent law is that individuals always retain the right to withdraw their consent. In fact, the only exception to the right to withdraw consent is if the timing of the withdrawal means that the cessation of treatment would significantly impact the patient’s health. As noted in the Supreme Court of Canada case of *Ciarlariello v. Schacter*:

An individual's right to determine what medical procedure will be accepted must include the right to stop a procedure.... Thus, if it is found that the consent is effectively withdrawn during the course of the proceeding then it must be terminated. This must be the result except in those circumstances where the medical evidence suggested that to terminate the process would be either life threatening or pose immediate and serious problems to the health of the patient (1993, 136).

In the context of live organ donation, the issue of withdrawal is tremendously relevant. Indeed, many of the above noted consent concerns, particularly coercion, might manifest themselves in the context of a reluctance to withdraw consent. Because so many interests are involved in a transplantation procedure – such as the recipient, the recipient’s family, the transplant team, and other individuals on the waiting list for a transplant – an individual may be reluctant to withdraw their consent. One research study has found that “Most donors, especially those who felt an obligation to donate, thought that the possibility to withdraw – stressed by doctors – was just a myth. The repeated information that they could withdraw was sometimes annoying and regarded as a doubt about the decision” (Sanner, 2005 p 710).

Transplant teams should do their best to dispel such beliefs and to ensure donors that the right to withdraw is real and can be exercised for any reason (and that the reasons for withdrawal will be kept confidential). Given the medical and life altering ramifications of a withdrawal, it might be tempting to craft consent information in a manner to discourage donors from withdrawing consent after the process has commenced. However, transplant

teams should avoid this practice as it could be viewed as a subtle form of coercion. It should be made clear that an individual could withdraw for absolutely any reason. Indeed, no reason needs to be provided (and, as such, donors do not need to fabricate an “out”). This is a point highlighted in the Amsterdam Statement where it is suggested that donors be explicitly told about the “the freedom to withdraw from the donation process at any time” and provided with an “assurance that medical and individual reasons for not proceeding with donation will remain confidential” (2004).

IV. Dealing with the Legal Challenges: Consent Strategies

Given the myriad consent issues associated with live organ donation, how should consent be obtained? Below, I will briefly highlight a few of the recommendation that have emerged in the literature.

a) Independent assessment and “donor advocates”

One of the most common suggestions is to develop a process whereby the donor can be assessed by a team that is as independent from the transplantation process as possible. In addition, it is suggested that this team, or a member of the team, could act as a “donor advocate.” The goal is to avoid any possible coercion or conflicts of interest. For example, the Amsterdam Statement suggests as follows:

“In order to minimize the appearance of a ‘conflicts of interest,’ transplant centers should make efforts to assure that the medical and psychosocial assessments and the decision to donate incorporates health care professional(s) not involved in the care of the recipient. The concept of this recommendation is to provide a health care professional advocating the welfare of the potential donor.” (2004, 492)

The U.S. Department of Health and Human Services Advisory Committee on Organ Transplantation comes to a similar conclusion. Recommendation 2 of their recent report states: “That each institution that performs living donor transplantation provide an independent donor advocate to ensure that the informed consent standards and ethical principles described above are applied to the practice of all live organ donor transplantation” (HHS 2005 – this recommendation was formulated in 2002).

Some of the policy statements in the area call for the use of a fairly comprehensive independent team and advocacy system. In 2002, New York’s Mount Sinai Hospital struck a committee to formalize the rules surrounding live donations. One of the requirements that emerged from the policy debate was that there must be a “‘donor advocate team’ consisting of an independent medical specialist, a social worker who works with donors but not with intended recipients, and a transplantation psychiatrists” (Surman, et al., 2005, 4).

While the utilization of a donor advocate and independent medical assessors seems a logical policy option, in some areas of Canada it may be difficult to implement. Indeed, in many regions, there are a limited number of health care professionals with an expertise in the area. As such, it will be difficult to find a medical expert who is not involved, in some way, with each transplant procedure. In addition to this practical dilemma, there is

an interesting legal problem. Responsibility for the ensuring that a patient understands the consent rests with the treating physician. As noted by the Supreme Court of Canada: “it is appropriate that the burden should be placed on the doctor to show that the patient comprehended the explanation and instructions given” (*Ciarlariello v. Schacter* 1993, 140). As such, an odd conflict emerges. An independent team may be obtaining the consent but the legal responsibility for the consent remains with the treating physician.

Despite these challenges, some form of independent assessment seems essential. So many of the consent issues associated with living organ donation could be tempered, at least partially, through the use of a donor advocate. As such, the CCDT should strive to make a recommendation about the use of donor advocates and independent assessments that reflect the reality of transplantation practices and resources in Canada.

b) “Cooling off” period

A number of policy entities have recommended the use of a “cooling off” period. For example, the Amsterdam Statement notes as follows: “Procedural safeguards should be utilized and explored to minimize coercion and enhance autonomous decision making, for example, by a ‘cooling off period.’” In practical terms, this would mean providing a potential donor with all necessary information for the consent process. They would then be asked to reflect on their decision (perhaps for a number of weeks). The recommendation for a ‘cooling off period’ needs to be balanced by the urgency with which a transplant may be required, for example in the case of fulminant hepatic failure. Such an urgent situation creates some unique concerns regarding coercion that need to be appreciated and carefully monitored.

Such an approach seems reasonable, particularly if is coupled with a mechanism that would allow the donor to ask questions from an independent source (such as a donor advocate available through a 1-800 number). Such a procedure may allow individuals who are ambivalent or genuinely concerned to gracefully back out of the procedure. Given the data on the degree to which most donors are committed to the procedure prior to becoming formally involved with the consent and assessment procedure, it seems likely that the cooling off period will only be relevant to a minority of donors.

c) Consent forms and lists

The CCDT may also want to consider the development of a consent template or a checklist of the items to be covered during the consent process. Some entities, such as the U.S. Department of Health and Human Services Advisory Committee on Organ Transplantation (2005), have developed template consent forms (see <http://www.organdonor.gov/acotapp1.html>).

Such forms can be useful as reminders of the scope of the disclosure process and what basic information should be provided. However, they should not replace a more nuanced and responsive consent procedure, one that respects individual differences. Consent is not a one time event or a signature at the bottom of a page, it is an ongoing process – a reality noted by the US Advisory Committee on Organ Transplantation: “Moreover, ACOT does not believe that these or any forms are a substitute for in-person

communication between physicians and other involved professionals and the potential donor. These forms should be viewed instead as only the written evidence of discussions leading to informed consent based upon full disclosure.”

(<http://www.organdonor.gov/acotrecs.html>).

d) Risk communication

As much as possible, the consent process should be informed by the literature about how best to provide risk information to patients (Lipkus and Hollands 1999; Edwards and Elwyn, 1999; and Edwards, 2001). Indeed, it has been noted, “Effective risk communication is the basis for informed patient consent for medical treatment, yet until recently doctors have lagged behind other professionals in learning this skill.” (Paling, 2003). The CCDT should consider reviewing available data and literature to help provide recommendation about risk communication to patients - examples strategies include the use of visual aids, standardized vocabulary, an understanding of cultural differences and the use of a consistent denominator (e.g., 40 out of 1000 and 5 out of 1000 instead of 1 in 25 and 1 in 200) (Paling, 2003; Alaszewski and Horlick-Jones, 2003).

It is unclear whether better risk communication would alter the decisions of live donors. Nevertheless, it might help create a better understanding of the experience and what to expect. While available studies have shown that most donor were satisfied with the experience and felt that their decision to donate was well grounded (Sanner, 2005), a better understanding of the risks involved can only enhance the decision process.

V. Emerging Consent Issues

In this section, I briefly highlight a few of the emerging consent issues. Each topic is complex and, as such, a thorough analysis is beyond the scope of this paper. However, the CCDT may wish to consider each of the following as a topic for a more comprehensive examination.

a) Paired Exchange

The use of donor exchange programs creates interesting opportunities for increasing organ supplies (Delmonico, 2004; Delmonico, et al., 2004). However, they also intensify existing consent challenges (in addition to resource allocation concerns, Ross and Zenios, 2004). For example, because paired exchanges involve an “agreement” with another recipient and transplant team, a donor may feel much more hesitant to withdraw consent.

b) Directed Donations

Different kinds of directed donation raise different kinds of ethical challenges. For example, all forms of directed donation can raise issues of justice (is the organ going to the individual in the most need?) (Caplan, 2005). They can also implicate broader social concerns. For example, one of the most ethically problematic forms of directed donation is when the recipient is chosen on the basis of race, religion, or ethnic group (Truag, 2005). If allowed in an unrestricted manner, directed donation may also result in subtle (and not so subtle) forms of payments (Truag, 2005).

From a consent perspective, directed donations require a careful consideration of coercion issues and donor expectations (e.g., what are they expecting out of the process?). One author has noted, “expectations of secondary rewards, such as financial compensation, an emotional bond with a recipient, or the desire to benefit a specific population are unacceptable” (Talyor, et al., 2004b).

c) Internet solicitation

Though there have only been a handful of news reports in Canada (CanWest News Service 2005; News, 2004), the use of websites to solicit organs seems likely to become a more common phenomenon. “The solicitation of organs over the Internet is probably here to stay, but it will require higher standards of responsibility and accountability than are currently in place” (Truag, 2005). The CCDT should consider addressing this issue, including the impact it may have on the consent process.

d) Compensation

Though the debate seems to be opening again (Kishore 2005; Pattinson, 2003), existing ethical and legal norms prohibit the buying and selling of human organs (Stempsey, 2000). All of the relevant provincial legislation prohibits commercial dealings with human tissue. For example, section 10 of Alberta’s legislation states “No person shall buy, sell or otherwise deal in, directly or indirectly, for valuable consideration, any tissue for a transplant ...”

Nevertheless, it may be permissible to provide an organ donor with financial reimbursement for expenses incurred. It is unclear, however, what kind of reimbursement would be considered ethically appropriate and just. One of the policy justifications for the ban was to avoid the creation of a financial incentive that might lead to a market and, thus, the exploitation of vulnerable populations. From a consent perspective, the nature of the reimbursement needs to be carefully communicated. Likewise, the potential for coercion should not be underestimated.

VI. Conclusion

As live organ donation becomes more common, dealing with the challenging consent issues seems increasingly essential. In addition, a comprehensive and ethically sound consent policy can help to maintain public trust in the Canadian donation and transplantation system. As such, the CCDT should consider the following consent initiatives.

- The development of a comprehensive disclosure policy that aims to provide donors with all information relevant to the donation process. This policy should be developed in a manner that is sensitive to the needs and differences of individual patients and the regional variation in transplantation resources and practices. Issues that need to be considered include: the timing of consent; the individual (or team) who will be obtain the consent; the availability of someone to answer questions; and the “form” of consent (i.e., how best to combine the use consent forms with the provision of information by a physician or nurse).

- The development of a list of key elements that need to be disclosed to the donor (this may also include the development of a consent form template). This list could build on the work that has already been done by other entities, such as the U.S. Department of Health and Human Services Advisory Committee on Organ Transplantation. However, this list should be treated as merely a guide to ensure that all relevant information is provided. Individual needs and interests must be considered during the consent process. A process to determine donor comprehension of the relevant information and risks may also be worthwhile.
- The development of a resource document that provides transplant teams with information about recent research and literature relevant to the consent process. This document should be updated periodically. For example, this document could provide a summary of key legal issues (e.g., when can a minor consent?), new research on donor perceptions and expectations, and information on how best to communicate risk information. The document should be short, practical and user friendly.
- The development of a policy aimed at moderating the concerns associated with coercion, including a consideration of a donor advocate, a “cooling off” period, and independent assessment. Indeed, given that so many of the consent issues are associated with the threat of coercion, this seems a particularly important policy area.

References:

Alaszewski, A., and Horlick-Jones, T. (2003) How can doctors communicate information about risk more effectively? *BMJ*, 327, 728-31.

American Society of Transplant Surgeons' Position Paper on Adult-to-Adult Living Donor Liver Transplantation (2000) (<http://www.ast.org/positionpaper1.cfm>)

Brazier, M. (1987) Patient Autonomy and Consent to Treatment: The Role of the Law. *Legal Studies*, 7, 169-175.

Canadian Institutes of Health Information (CIHI), "CORR Frequently Asked Questions" (http://secure.cihi.ca/cihiweb/dispPage.jsp?cw_page=services_corrfaq_e) (accessed Dec 1, 2005).

CanWest News Service. (22 March 2005). Kidney transplant recipient backs against paying for replacement organs. *Edmonton Journal* A11.

Caplan, A. (25 July 2005) The ethics of living organ donation. *Science and Technology News*, (www.stcnews.org/rlr-1279.htm).

Dahlke, M. et al. (2005). Differences in Attitudes Toward Living and Postmortal Liver Donation in the United States, Germany and Japan. *Psychosomatics*, 46, 58-64.

Delmonico, F. (2004a). Exchanging Kidneys – Advances in Living-Donor Transplantation. *New Eng J Med* 350, 1812.

Delmonico, F. et al. (2004b). Donor Kidney Exchanges. *American Journal of Transplantation* 4,1628-34.

Dickens, B. (2002). Informed Consent. In Jocelyn Downie, Timothy Caulfield, and Colleen Flood, eds., *Canadian Health Law and Policy*, 2nd ed. (Toronto: Butterworths Canada Ltd., 2002)

Edwards, A. and Elwyn, G. (1999). How should effectiveness of risk communication to aid patients' decisions be judged? A review of the literature. *Med Decis Making*, 19, 504-5.

Edwards, A. (2001). Understanding risk and lessons for clinical risk communication about treatment preferences. *Quality in Health Care*, 10, i9-i13.

The Ethics Committee of the Transplantation Society (Amsterdam Statement) The Consensus Statement of the Amsterdam Forum on the Care of the Live Kidney Donor (<http://www.transplantation-soc.org/downloads/ConsensusStatementfinal.pdf>) *Transplantation* · Volume 78, Number 4, August 27, 2004

Kishore, R. (2005). Human Organs, Scarcities, and Sale: Morality Revisited. *Journal of Medical Ethics*, 31, 362.

Knoll, G., Cockfield, S., Blydt-Hansen, T. et al. (2005). Canadian Society of Transplantation Consensus Guidelines on Eligibility for Kidney Transplantation. *CMAJ* 173, 1181.

Live Organ Donor Consensus Group. (2002). Consensus Statement on the Live Organ Donor. *JAMA*, 284, 2919-2926.

Lipkus, IM, Hollands JG. (1999). The visual communication of risk. *J Natl Cancer Inst Monograph*, 25, 149-63

Nelson, E. (2002). The Fundamentals of Consent. In J. Downie, T. Caulfield, C. Flood, eds. *Canadian Health Law and Policy* (Butterworths, 2002).

News, (23 October 2004). Kidney transplant recipient met the organ's donor through a commercial Web site. *National Post* A10.

Paling, J. (2003). Strategies to help patients understand risks. *BMJ* 327, 745-46.

Pattinson, S. (2003). Paying Living Organ Providers. *Web Journal of Current Legal Issues* 3.

Picard, E. and Robertson, G. (1996) *Legal Liability of Doctors and Hospitals in Canada*, 3rd ed. Toronto: Carswell, chapter 3

Ross, L., and Zenios, S. (2004). Practical and Ethical Challenges to Paired Exchange Programs. *American Journal of Transplantation*, 4,1553-54.

Sanner, M. (2005). The donation process of living kidney donors. *Nephrol Dial Transplant*, 20, 1701-13.

Stempsey, W. (2000). Organ Markets and Human Dignity: On Selling Your Body and Soul. *Christian Bioethics* 6, 195.

Surman, O., Fukunishi, I. (2005). Live Organ Donation: Social Context, Clinical Encounter, and the Psychology of Communication. *Psychosomatics*, 46, 1-6.

Taylor, G., et al. (2004a). Informed Consent for Living Anonymous Adult Donors: Truth or Dare. In T. Gutmann, A.S. Daar and R.A. Sells, *Ethical, Legal and Social Issues in Organ Transplantation*, Pabst, 201-03.

Taylor, G. et al., (2004b). Living Anonymous Adult Donor Motives. In T. Gutmann, A.S. Daar and R.A. Sells, *Ethical, Legal and Social Issues in Organ Transplantation*. Pabst, 206-07.

Tokarski, C. (2002) *Conference Report Live Organ Donation: One Step Forward, Two Steps Back Highlights From National Committee for Quality Health Care's Conference On Organ Donation & Transplantation: A Commitment to Quality*; November 21, 2002; Washington, DC Medscape Transplantation 3(2), 2002

Truog, R. (2005). The Ethics of Organ Donation by Living Donors. *The New Eng J Med*, 353, 444-446.

UCLA Medical Center Ethics Committee. (2004). Surrogate Consent for Living Related Organ Donation. *JAMA*, 291, 728-731.

U.S. Department of Health and Human Services Advisory Committee on Organ Transplantation (these recommendations were developed between November 2002 and May 2005). <http://www.organdonor.gov/acot.html>

Walter, M. et al. (2004). Willingness to donate: an interview study before liver transplantation. *J. Med Ethics*, 30, 544-550.

Weir R. and Peters, C. (November-December, 1997). Affirming the Decisions Adolescents Make about Life and Death. *Hastings Centre Report* 29.

Case Law:

B.H. v. Alberta (2002) ABCA 109 (CanLII)

C. (J.S.) v. Wren, [1987] 2 W.W.R. 669 at 671 (C.A.).

Ciarlariello v. Schacter [1993] 2 S.C.R. 119 at 135.

Cox v. College of Optometrists of Ontario (1988) 65 O.R. 461 (Ont. High Ct.).

McInerney v. MacDonald (1992) 93 D.L.R. (4th) 415 (S.C.C.).

Malette v. Shulman (1990), 67 D.L.R. (4th) 321 (Ont. C.A.)

Ney v. Canada (Attorney General), [1993] 6 W.W.R. 135 (B.C.C.A.).

Norberg v. Wynrib (1992) 92 D.L.R. 449 (S.C.C.).

Reibl v. Hughes (1980) 114 D.L.R. (3rd) 1 (S.C.C.).

Re T [1992] 4 All E.R. 649 (C.A.).

Re Walker v. Region 2 Hospital Corp (1994), 116 DLR 477 (N.B.C.A.).