Special Supplement

Supplément spécial

Legal and ethical considerations in blood transfusion

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Summary

The physician should obtain the patient's informed consent before administering blood products. This includes explaining to the patient the relative benefits and risks of receiving and not receiving the blood product, as well as any reasonably viable alternatives.

- It may be helpful to compare the risks of receiving the blood product with other risks surrounding the patient's medical treatment.
- Substitute consent must be obtained for incompetent patients according to provincial or territorial laws.
- Generally, in emergency situations where treatment is necessary to preserve the life or health of the patient and consent is not available (because the patient is unconscious or otherwise unable to consent) the physician may administer blood products (and any other treatment) necessary to preserve the life or health of the patient. Exact provisions will vary by province and territory. This does not apply if the patient has expressly refused the treatment before becoming incompetent.

A competent adult is entitled to refuse or cease any treatment for any reason.

Parents ordinarily have the responsibility to provide consent on behalf of their young children; however, it is highly unlikely that parents can refuse life-saving treatment for their children. Physicians may not simply override a parent's refusal; recourse must be through the relevant children's aid society.

Although it is legally clear that a mentally competent adult is entitled to refuse any medical treatment, including a blood transfusion, physicians have a responsibility to ensure that the refusal is truly informed and voluntary.

In the case of adults who were once competent, but have become temporarily or permanently incompetent, substitute consent laws, generally, provide that their prior wishes regarding treatment decisions should be respected to the extent that they are known or can be determined.

Many judgement calls arise in the day-to-day practice of all physicians. These judgements require awareness and respect for legal and ethical considerations, but above all, they require an empathetic understanding of the patient and his situation.

This report is a summary of the legal and ethical framework that was considered in the development of the clinical practice guidelines (CPGs) for the transfusion of red blood cells and plasma in adults and children. Generally, the legal and ethical principles that apply to transfusion medicine are no different from those applicable to any medical interaction or intervention. In this report, "transfusion" refers to any situation in which a patient receives any component of human blood from a single or multiple donors.

Legal issues surrounding blood transfusion

The law of informed consent

The four components of consent to medical treatment are

- consent must be given voluntarily
- a patient must have capacity

- consent must be specific to both the treatment and the person providing it
- consent must be informed, i.e., that the patient must understand the nature of the procedure, the attendant risks and benefits and any alternative treatments.

The landmark Canadian case on the issue of informed consent is the Supreme Court of Canada decision in *Reibl* v. *Hughes*.[1] Mr. Reibl underwent surgery to remove a blockage in his carotid artery. After the surgery, he suffered a massive stroke that left him paralyzed on his right side. Although he had consented to the surgery, his physician had not informed him of the risk of paralysis. The surgery was medically indicated for his condition and had been performed competently. Nonetheless, Mr. Reibl was successful in his suit based on the fact that had he been aware of the risk of paralysis he would have at the least postponed the surgery until his pension had vested. The case set a new standard for disclosure of information. The consideration of the perspective of a reasonable person in the patient's position is a change from the traditional standard of professional disclosure, which required the physician to disclose only what a reasonable physician would disclose and did not allow for any consideration of the particular patient's circumstances.

The difference between risks that should be disclosed and risks that some consider infinitesimal or theoretical is not always obvious. Serious risks have been held to be nonmaterial and, therefore, not worthy of disclosure: for example, a 0.3% chance of a serious hematoma[2] and a 0.25% chance of chronic pain. However, a 0.25% chance of birth defects was held to be material.[3] It is clear that the physician's knowledge of the particular circumstances of the patient is crucial.

A qualifier on disclosing the risks of a particular treatment, alluded to by Krever[4] in his interim report, is that the risks should not be presented to the patient in isolation. The patient should be given the information in a context that includes a comparison with other risks, such as those of other aspects of the treatment plan, those of alternative treatments that do not require transfusion and those of no treatment.

The right to refuse

The corollary of the right to consent to medical treatment is the right to refuse to start or continue treatment. That right applies even when refusal of the treatment will result in harm to the patient or death. Several recent cases[5,6] have supported the right of the patient to refuse life-saving treatment; however, one important case that illustrates this right is *Nancy B.* v. *Hotel-Dieu de Quebec et al*.[7]

In the case of Nancy B., a young woman refused consent to continue using a ventilator that maintained her life. Nancy B. was a mentally competent young woman who had contracted a disease that left her completely paralyzed and in pain; it was clear that she would remain completely disabled. She decided that she would prefer to die and refused consent to continue using the ventilator. Although this case was tried in a lower court, and relied to some extent on Quebec laws, the result is nonetheless a persuasive statement as to physicians' obligations and liability under the *Criminal Code of Canada*.[8]

The court examined relevant Quebec statutes and the evolution of the law of informed consent and established that the statement in the Quebec civil code[9] prohibiting any treatment without consent is absolute. The court determined that the refusal of medical intervention could not be viewed as committing suicide and concluded that it was simply allowing the disease to take its natural course.[10] This distinction is important as the *Criminal Code of Canada* prohibits assisting a suicide.

Requirements and content of consent

Capacity to consent: To be able to give or refuse consent, the patient must be competent (adults are presumed to be competent unless proven to be otherwise). The cases of Malette[5] and Nancy B.[6] demonstrate that the test for competency is the ability to make a *reasoned* decision, as opposed to what others may view as a *reasonable* decision. There is no requirement in law that a person make an objectively "reasonable" decision. A patient is not judged capable or incapable across the board, but rather capacity is assessed in relation to each decision that must be made. One important factor in this assessment is ensuring that the patient understands the consequences of consent to, or refusal of, the treatment. If a physician is in doubt about a patient's capacity to make a particular decision, he or she should seek a second opinion. In the case of Nancy B., the court noted that she had been evaluated by a psychiatrist 4 times over several months. The psychiatrist testified that she was in good mental health, able to make decisions and understand the consequences. Her doctor had met with her and informed her of the consequences of her decision to withdraw from the ventilator.[11]

Obtaining informed consent: Although most hospitals use standard consent forms for major treatments and procedures, physicians should not rely on these forms to fully satisfy the requirements of informed consent. Consent forms are merely evidence of consent, they do not *constitute* "consent." A standard document does not take into account factors unique to individual patients; therefore, it cannot substitute for the participatory process of consent through which the physician informs the pa-

tient. If feasible, the discussions around consent should be documented in the patient's hospital chart. Ultimately, it is the physician who bears the legal responsibility for obtaining informed consent.[12]

Special situations

Emergencies: Provincial and territorial laws, which vary by jurisdiction, grant physicians the privilege to treat a patient without consent in emergency situations. These are usually described as situations in which the patient's life or health is at risk; the patient is incapable of giving or refusing consent; and there is no substitute decision-maker available. Physicians should make themselves familiar with the specific law of their province or territory.

Substitute consent and advance directives: Substitute consent is given by one person on behalf of another who is mentally or physically unable to do so. Most provinces and territories now have laws governing substitute consent. Such laws usually have provisions addressing who the substitute decision-maker will be (this may be presented as a hierarchical list); the standards to be used in decision-making (this may include a hierarchical list of criteria); and legal limitations on the decisions. Generally, these laws provide that in the case of adults who were once competent, but have become temporarily or permanently incompetent, their prior wishes regarding treatment decisions, to the extent that they are known or can be determined, should be respected. If specific or general advance directives exist, physicians should ensure that each directive has been properly executed before following it and that no directive has been executed, or decision-maker appointed, before referring to the statutory list of substitute decision-makers.

Consent to treatment by and on behalf of minors

Parents are charged with making medical decisions on behalf of their minor children, unless parental rights have been lost due to abuse or neglect. When parents refuse treatment for their children, it is most often on medical or religious grounds or where children have a disability.

It is sometimes difficult to identify the point at which treatment should be discontinued on medical grounds. Perhaps the most difficult cases are those where the child will likely die if untreated, but where the treatment options are grueling and only offer limited chances of success or involve significant side effects. Such cases can be decided by parents, physicians, other members of the health care team and, perhaps, the child looking at the situation together. In rare cases where the physician feels the parent's decision is unjustified, the advice of colleagues and the hospital ethics board or similar resource should be sought.

A frequent issue in medical care disputes is parental refusal of blood transfusions or other medical treatment for their children based on their religious beliefs. Recently in Canada parents have attempted to raise arguments based on the *Canadian Charter of Rights and Freedoms*. An Ontario Court of Appeal[13] found that parents have the right to choose medical care for their child in accordance with their religious beliefs, only as long as it does not impede the vital and overriding state concern with the life and health of the child. This finding was later upheld by the Supreme Court of Canada.[14] A balancing of rights will always be required; however it seems likely that when the risks to the child are serious, the court's *parens patriae* jurisdiction will be paramount to the parents rights.

In a number of cases, parents have attempted to withhold consent to treatment on behalf of disabled children, largely because they have felt it would be better for the child to die.[15,16] As society's view of disabled citizens has evolved, the courts have increasingly upheld the child's right to life and the appropriate treatment. In such situations, the physician has an obligation to alert the provincial or territorial child welfare society. Physicians should also be aware of their provincial or territorial laws, medical association's recommendations and their own hospital's policy for proceeding in such cases.

Case law indicates that minors may consent to their own medical treatment if they are competent and capable of appreciating the full nature and consequences of the treatment.[17] Some provincial statutes set out specific age limits at which children may consent to all or particular procedures. However, the determination of capacity of the minor to give consent appears to be the responsibility of the medical practitioner. Once an adolescent develops the capacity to consent, he or she is entitled to the full panoply of rights accorded to adults in relation to that treatment or procedure, including confidentiality. As several studies have shown that adolescents consistently demonstrate less understanding than is initially apparent,[18] physicians must be careful to assess their capacity.

Physician liability

A physician can be liable for breaches of the principle of informed consent in 3 ways: by failing to seek consent, by failing to disclose properly the information required for the consent to be considered "informed" and by providing treatment in the face of an express refusal.

A frequent concern of physicians in relation to any type of CPG is whether they can be held liable for malpractice if the recommended guidelines are not followed. In the case of *ter Nuezen* v. *Korn* (SCC),[19] the Supreme Court of Canada decision noted that when es-

tablishing the legal standard of care in a situation involving a professional, it is the professional expert who establishes the standard, not an adjudicator. The criterion by which a physician is judged negligent is whether the care he or she provided varied significantly from what a reasonable physician would have provided in similar circumstances. This is judged by legal standards of care set by the legal system, the courts and legislatures, although the content of such standards may be influenced by the medical community through, for example, the development of CPGs.[20]

Ethical issues surrounding blood transfusions

The role of ethics in the development of CPGs and recommendations to health care providers is to ensure that values, which may not be adequately incorporated into the law, are given reasonable consideration.[21] The framers and users of the guidelines must be aware of the potential ethical conflicts inherent in many medical decisions, and the guidelines must reflect a thoughtful consideration and balancing of the issues.

Like the legal issues, the ethical issues related to blood transfusions are fundamentally no different than those relating to most forms of medical treatment. One feature that may be somewhat different is that in response to the fear of HIV, consent to blood transfusions has taken on an increased significance, such that the amount of information and level of consent required are closer to that usually required for more complex and risky procedures.

In this section, several ethical issues related to blood transfusion are discussed in practical terms. This is not an exhaustive discussion; it is intended to provide the reader with a general understanding of the issues.

Risk

A major ethical concern surrounding the use of blood products is that the public perception of the risk is, in most cases, far greater than the objectively measurable risk.[21,22] This raises questions related to the true need for increased access to alternatives to anonymous donor blood products and the requirement for fully informed consent. However, the perception of risk must be recognized. The physician should understand the patient's point of view and the patient's fears and suffering.

Access to the anonymous donor-based blood system and alternatives

In Canada, blood is currently available, free of charge, to all Canadians requiring it or its components. The system is a voluntary one, in which anonymous donors are not paid for their donations. One of the questions being asked is whether alternatives to the anonymous donor system should be made available to all or some recipients of blood. Alternatives, such as directed donations and the use of autologous blood, may reduce the already low risk of contamination while introducing substantially higher costs into the system.

Currently, there is a significant additional cost involved in the collection, storage and delivery of non-anonymous blood. Therefore, in the short term it is economically more efficient to rely on the traditional system.[23] However, over the long term, the financial premium may not be as great as it appears. Like any preventive program, there is a cost saving associated with the harm prevented. Although it may not be possible to determine this yet, it must be considered in a cost–benefit analysis. The larger issue is whether the financial cost of alternatives to anonymous blood transfusions are justified.

In addition to financial costs, ethics requires consideration of the costs and benefits at other levels: societal and psychological. In the end, a multifactorial consideration may favour the allocation of resources to research on new medical interventions that obviate the need for transfusion or on improving current alternatives.

Decisions about access to alternatives may require a discussion about the broader societal good versus the individual good. The greater good of society may dictate the minimal use of directed and autologous donations as they may be an unnecessary drain on the health care budget. However, the individual good may require allowing such procedures as they provide psychologic benefits to the patient, for example, parents donating blood for their child. The psychologic benefit to the donor may outweigh the cost to society. Furthermore, in the exceptional cases where patients receive a large number of transfusions as a regular part of their care plan, alternatives to anonymous donor transfusions should certainly be available. CPGs should recognize that the physician's primary responsibility is to his or her own patient and balance this responsibility against the needs of other people and society in general.[21]

Depression and voluntariness

It is legally clear that a mentally competent adult is entitled to refuse any medical treatment, including a blood transfusion. However, if screening indicates that a patient may be incapable, further expert opinion is generally recommended to ensure that the refusal is truly informed and voluntary, particularly in cases where the

patient's life is at risk. One particular area of concern is patients with underlying depression that may influence the decision of a seemingly competent person.

Symptoms of depression may be masked by the patient or complicated by medication or other interventions. A depressed patient may refuse life-saving treatment that he or she might accept if the depression were identified and treated. If depression is suspected in situations where transfusions that may preserve the patient's life or health are refused, an expert assessment should be conducted by individual practitioners (e.g., psychiatrists and psychologists) or hospital ethics committees.[24]

Cultural issues

Canadian physicians come from a variety of cultural backgrounds and treat patients from a variety of cultural backgrounds. It is difficult to apply cultural and legal standards expected by the Canadian legal system and medical profession to people who may not share the same belief structure. For example, in some cultures medical decision-making is the responsibility of men; in other cultures the physician is regarded as an authority figure who is not to be questioned. Ethically, it is necessary for the physician to respect the cultural practices of the patient while meeting legal and professional obligations. To accomplish this, the physician may explain to the patient and the patient's family members, either directly or via a trusted member of the patient's cultural community, the need to provide information and obtain consent.

Conclusion

It is difficult to reduce the legal and ethical obligations of physicians to a set of guidelines. Although the legal principle of informed consent can be stated in a few words, it does not convey the scope of responsibility and how it may vary depending on the circumstances, the patient and the procedure. It certainly fails to convey the ethical complexity involved in a physician–patient interaction and the potential clash of values and beliefs that can occur in our multicultural society. The various issues discussed in this paper demonstrate that many judgement calls arise in the day-to-day practice of all physicians. These judgements require awareness and respect for legal and ethical considerations, but above all, they require an empathetic understanding of the patient and his or her situation.

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