Notifying patients exposed to blood products associated with Creutzfeldt–Jakob disease: integrating science, legal duties and ethical mandates

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Abstract

THE ISSUE OF NOTIFYING PEOPLE who have been exposed to blood products that have been associated with Creutzfeldt–Jakob disease (CJD) has arisen at a time when the Canadian blood system is under intense scrutiny. As a result, the Canadian Red Cross Society issued a recommendation to health care institutions that recipients of CJD-associated blood products be identified, notified and counselled. Although Canadian jurisprudence in the realm of informed consent may support a policy of individual notification, a review of the scientific evidence and the applicable ethical principles arguably favours a policy of a more general public notification. Indeed, situations such as this require a unique approach to the formation of legal and ethical duties, one that effectively integrates all relevant factors. As such, the authors argue that individual notification is currently not justified. Nevertheless, if a system of general notification is implemented (e.g., through a series of public health announcements), it should provide, for people who wish to know, the opportunity to find out whether they were given CJD-associated products.

Résumé

LA QUESTION DE SAVOIR S'IL FAUT PRÉVENIR LES GENS qui ont été exposés à des produits sanguins associés à la maladie de Creutzfeldt–Jakob se pose au moment où le système d'approvisionnement en sang du Canada est scruté à la loupe. C'est pourquoi la Société canadienne de la Croix-Rouge a recommandé aux établissements de santé d'identifier, de prévenir et de conseiller les personnes qui ont reçu des produits sanguins associés à la maladie de Creutzfeldt–Jakob. Même si la jurisprudence canadienne dans le domaine du consentement éclairé peut appuyer une politique d'avis individuels, on peut soutenir qu'un examen des données scientifiques et des principes d'éthique applicables appuie une politique d'avis publics plus généraux. De telles situations exigent en fait une démarche unique de constitution d'obligations légales et éthiques qui intègre efficacement tous les facteurs pertinents. C'est pourquoi les auteurs soutiennent que les avis individuels ne sont pas justifiés. Néanmoins, si l'on met en oeuvre un système d'avis généraux (p. ex., au moyen d'une série d'annonces sur la santé publique), il faudrait permettre aux personnes qui veulent le savoir de déterminer si elles ont reçu des produits associés à la maladie de Creutzfeldt–Jakob.

Over the past decade, institutions providing blood transfusion services have been under intense public scrutiny. Undertakings such as the Krever inquiry have sensitized the public to transfusion-related issues. In this climate of anxious uncertainty, the spectre of yet another serious illness transmissible through blood products arose in July 1995, when Health Canada and the Canadian Red Cross Society Blood Services initiated an urgent recall of blood frac-

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tionation products prepared from the plasma of a donor who subsequently died of Creutzfeldt–Jakob disease (CJD). The Canadian Red Cross Society issued a recommendation to health care institutions that recipients of recalled blood products be identified, notified and counselled. This recommendation created a serious dilemma for health care providers concerning the appropriate and responsible follow-up in relation to these patients.

In this paper we examine briefly the scientific, legal and ethical justifications for individually notifying patients who have been exposed to blood products that have been associated with CJD. Although the paper is not intended as a comprehensive analysis of the many conflicting factors that are relevant to this complex issue, we hope it will serve as an effective overview and thus promote a more interdisciplinary approach to the resolution of such dilemmas. Much of the commentary in this paper stems from deliberations of a task force established in Edmonton to examine the issue.

Scientific and medical background

From a scientific and medical perspective 2 questions are pertinent: Is the risk of acquiring CJD from blood products, at present called "theoretical" by Health Canada, likely to become real? And are there any diagnostic, therapeutic or lifestyle interventions that would permit recipients to clarify or modify this risk or prevent transmission of CJD to others? At this time the answer to both questions appears to be No. Canadian data on CJD are minimal but are consistent with those of other countries.[1,2] Direct epidemiologic data do not implicate transfusion as a risk for CJD transmission. Furthermore, the disease has never been linked convincingly to prior blood transfusion despite decades of worldwide use of fresh and stored whole blood, blood components and a wide variety of fractionated derivatives made from large plasma pools, some of which are virtually certain to have included plasma from donors who later manifested CJD.[3–6] Particularly reassuring is the fact that CJD has not developed in people with hemophilia exposed repeatedly over many decades to fractionated products.[3,5] Although surveillance is imperfect, the clinical presentation of CJD and its variants is so striking that it seems unlikely major epidemiologic shifts would have been missed. In fact, such shifts were noted in iatrogenic CJD and in a recent cluster of CJD cases in young people, likely related to bovine spongiform encephalopathy.[6]

All of the over 80 cases of iatrogenic human-to-human transmission of CJD have involved material derived from the central nervous system applied directly to the central nervous system of the recipient (incubation period 1 year to several years) or inoculated peripherally (incubation period 10 years to more than 20 years). Nonprimate animal studies are also consistent with the lack of spread of naturally occurring forms of spongiform encephalopathy by blood. In sum, available data suggest that the risk of acquiring CJD via transfusion is likely to remain theoretical to minuscule.[3,7–13] The issue of new variants and their significance has recently been reviewed.[14,15]

Furthermore, no diagnostic, therapeutic or lifestyle interventions now exist that would permit recipients of CJD-associated products to clarify or modify their risk or to prevent potential transmission to others. Although familial forms of CJD exist, there are no reports of CJD transmission by sexual or casual contact, and spouses of patients with CJD do not appear to be at increased risk. No treatment exists for CJD, definitive diagnosis is by brain biopsy, and once the disease is clinically evident, death usually follows within a year. A spinal fluid test has recently been reported for diagnostic use in patients with dementia.[16,17] In addition, protein analysis of brain extracts from healthy people and those with CJD has provided a biochemical tool that appears useful in the differentiation of various strains of CJD and other forms of spongiform encephalopathy.[18,19] However, the spinal fluid test is not suitable for screening people without dementia, and the protein test can currently be applied only to brain tissue.

Legal background

In many respects the "duty to warn" former patients of the potential risks related to a past medical procedure (such as receiving a blood product) is part of a health care provider's continuing duty to disclose risks.[20] Indeed, in the recent Supreme Court of Canada decision in *Hollis* v. *Dow Corning Corp.*[21] Justice La Forest drew a comparison between the duty of informed consent and the ongoing duty to warn patients of the risks associated with a medical product.[20,22]

The duty of informed consent requires, among other things, that all material risks be disclosed to a patient. A material risk is something a "reasonable person" in the patient's position would want to know in order to make an informed decision about treatment.[23] Given the strong evidence that the risk of contracting CJD through "tainted blood" is — at least at present — purely theoretical, a persuasive argument could be mounted that this is not a risk worthy of disclosure. Although Canadian courts have been quite lenient in their determination of what risks should be considered "material,"[20,21] risks that are so remote as to be almost negligible have been held not to be material.[24]

However, even though a risk may be negligible (or even only theoretical), Canadian law regarding informed consent may still require the information to be disclosed if it can be conceived of as something a "reasonable person" would want to know. In this regard, a community's perception of a given risk, which may not be an accurate reflection of the actual risks,[25] is likely relevant to both the legal

and ethical disclosure obligations. What a "reasonable person" would want to know will not necessarily be connected to the scientific and medical facts concerning the risks.[26] (For an analysis of the disclosure obligations associated with HIV-infected physicians see references 27 to 31.)

So, if it can be shown that most people would want to have information about their exposure to CJD, this is arguably material information that should be provided as part of a health care provider's continuing duty of disclosure.[32,33] However, adequately informing both the person and the community involves providing information not only about risks but also about alternatives.[34–36] When such alternatives are provided, the "reasonable person" may choose to forgo receiving specific information in favour of broader social goals.

In sum, by applying the standard of disclosure relating to informed consent to the physician's continuing duty to warn, we can see that there is a modest legal foundation for the premise that health care providers have an obligation to notify former patients about the theoretical risks associated with exposure to blood products contaminated by CJD. However, this conclusion is based on the belief that this is information a "reasonable person" would want to know, which may not always by the case. In addition, it does not incorporate other policy considerations, such as costs and broader ethical concerns.

Ethics background

Although the law may call for individual notification, there are ethical principles that, in certain circumstances, favour nondisclosure. The main ethical values relevant to this dilemma are the following:[37]

- The individual's right to know (rooted in the principle of individual autonomy).
- Acknowledgement to the public of a state of ignorance over how to assess the theoretical risk associated with exposure to blood products contaminated by CJD (rooted in the principle of truth-telling and avoiding deception).
- Protection of individuals from possible immediate harm through undue anxiety, balanced by the need to protect against possible future harm (grounded in the principles of beneficence and nonmaleficence).
- Maintenance of public trust in health care professionals (grounded in the principles of social solidarity and mutual respect).
- Just allocation of resources during a time of fiscal constraint (argued from the principle of distributive justice).

At this time, there are grounds for believing that the public's right to know, individually and retroactively — a dominant component of ethics — is outweighed by other relevant ethical values (e.g., beneficence, nonmaleficence and distributive justice). This is particularly so considering the potential this information has for causing individual harm, the purely theoretical basis of the information and the potential for alternative modes of disclosure (e.g., public education). Considerable anxiety may be generated by the knowledge that one may have been exposed to an agent associated with CJD, especially when there is ignorance about routes of further transmission. In fact, there are many who may not wish to know.[38,39] Disclosing this information to people who choose to remain uninformed does not coincide with the notion of autonomy, a principle that gives individuals the right to control information about themselves, including the right not to know.[40]

The public has the absolute ethical right to be fully informed about the knowledge, or lack of knowledge, about this theoretical risk. However, the mechanism for such disclosure need not be individual notification.[41] Rather, a general public notification (through the use of a pamphlet, with subsequent updates, and an opportunity for concerned individuals to "trace back") would provide the relevant information without offending the principles of beneficence and nonmaleficence. Likewise, the notion of autonomy would be respected by establishing an information centre where people could learn about their individual exposure to this theoretical risk. A system of general public notification would also respect the interests of those who wish to exercise their right not to know.

If, in the future, evidence were to show that trust in public authorities was being undermined as a result of a decision not to notify individuals, an argument could be made — based on the principle of social solidarity — that the policy decision be reconsidered. Similarly, there may be other reasons why the policy might change from one of general notification to one of individual notification (e.g., a single, well-documented case in the literature establishing that there is a real risk).

Currently, however, the most ethical course seems to be that of general notification. This action must, however, be predicated on 3 principles: honesty (admitting to the public that, although at present it remains a theoretical risk, the experts truly do not know whether there is a risk of CJD transmission from having been exposed to blood or blood products); integrity (being prepared to acknowledge the public's right to know and to be involved, through sustained commitment by public authorities to keep the public informed of new knowledge in this area); and mutuality (inviting the public's involvement in ongoing assessment of the reasonableness of this course of action instead of individual notification).

Conclusion

A strict reading of the law may lead to the conclusion

that individual notification remains the best course. However, a more comprehensive consideration, including an analysis of the scientific evidence and the relevant ethical values, suggests that general notification may be the better approach. Issues such as the CJD dilemma will inevitably require a balancing of numerous factors and concerns. No single response will be entirely satisfactory. Nevertheless, a system of general notification, although imperfect (e.g., completeness may be an issue), responds more effectively to the various conflicting ethical and legal principles than does the currently favoured method of individual notification.

As public health concerns become more common, the connection between individual information needs (as manifested in such legal concepts as the "reasonable person"), the "community's" opinion (as illustrated by survey results, for example) and sound public policy will become increasingly strained. In part, this is because jurisprudence concerning informed consent and ethical disclosure obligations are founded predominantly on notions of autonomy, a principle centred on the individual. Such an approach does not easily accommodate disclosure issues in which the broader community may have a vested interest. This is particularly so when there is little scientific evidence concerning the existence of a real risk.

We postulate that situations such as this require a unique approach to the formation of legal and ethical duties, an approach that more effectively balances individual information needs with the scientific evidence, conflicting ethical principles, and the individual and social costs of providing such information. Currently, however, there remains a legal argument — albeit a relatively weak one — that health care providers have a duty to warn past recipients about the theoretical risks associated with blood products contaminated with CJD. Nevertheless, policymakers should not be swayed by one-dimensional legal arguments. On balance, we feel that individual notification is not justified at this time. However, general notification should provide, for those members of the public who wish to know, an opportunity to determine whether they were given CJD-associated products.

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