



Hospital Law

The Krever Commission Recommendations: What They May Mean for Hospitals

By Pamela Spencer



In September 28, 1998, Canadian Blood Services (CBS) assumed responsibility for the operation of Canada's blood supply system. (Quebec has established its own blood supply system, called Héma-Québec). CBS was set up in response to the recommendations of the Krever Inquiry into Canada's blood supply system.

Like its predecessor the Canadian Red Cross Society, CBS is responsible for donor recruitment and management, whole-blood and plasma collection, processing, testing and laboratory work, storage and distribution, and inventory management. CBS has advised that current reporting mechanisms and current shipping and delivery schedules will continue. In addition, at least for the near future, CBS has committed itself to the continued delivery of all existing core and non-core programs and services. While the operation of the blood supply system in Canada under CBS is thus to remain at the status quo in the near term, it is important to recognize that we are in a period of transition and that there will likely be some changes in the relationship between CBS and hospitals in the future, in part growing out of the implementation of the Krever recommendations.

The final Krever report, released in November 1997, contains 50 recommendations which are directed at all parties involved in the blood supply system in Canada, including hospitals and physicians. This article will focus on the Krever recommendations directed at hospitals and discuss their potential legal and practical implications. Some or all of the discussion which follows may prove to be academic, however, as it is uncertain, at this date, which of the Krever recommendations directed at hospitals will be implemented.

INFORMED CONSENT/ DISCLOSURE OF RISKS PRIOR TO TRANSFUSION

One of the central recommendations in the Krever report is that the blood supply system be operated in an open and accessible

manner. These principles of openness and accessibility serve as the framework for the construction of an effective information transfer system among the various players in the blood supply system. This information relates both to disclosure of the potential risks of transfusion and disclosure to recipients of the potential contamination of transfused blood or blood products.

The need for an effective information transfer system is the basis for several of the recommendations directed at hospitals. For example, the Krever report recommends that a national integrated database be created to store and manage information about donors, donations and recipients. The operation of this database will clearly depend upon an effective exchange of information between CBS and hospitals that supply blood and blood products. The report also recommends that CBS make it a condition of supplying blood and blood products to hospitals that they maintain adequate records and that the blood service's standards for storing blood and blood products be observed. The issue of record maintenance will be dealt with later in this article under "Post-Market Surveillance." With respect to storage, it should be noted that none of the legal cases to date which have considered a hospital's potential liability for the transfusion of contaminated blood products took issue with the hospital's storage of blood products, nor has there been any suggestion of a hospital's independent duty to test blood products supplied by the national blood service.

The Krever report takes the position that one aspect of an open and accessible blood supply system is that the risks inherent in blood products should be fully disclosed, "even when the gravity or likelihood of a risk is still uncertain." The rationale for this position is that transfusion recipients must be able to make informed choices, in consultation with their physicians, about the relative benefits and risks of receiving blood or blood products.

With respect to the disclosure of risks relating to a blood transfusion, the law is reasonably clear that the obligation to obtain a patient's informed consent to a medical procedure

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rests with the attending physician. Thus, when the physician is not an employee of the hospital, there should be no vicarious liability or other liability imposed upon the hospital if the physician fails to properly advise the patient of the risks of the blood transfusion. One possible exception to this might be where CBS has provided information to the hospital blood bank, which has not, in turn, passed it on to physicians working in the hospital. It is thus very important that hospital blood banks have a system in place to ensure that any alerts received by it from CBS are immediately communicated to its physicians. Written records of these communications should be maintained.

While a discussion of the parameters of the informed consent that an attending physician is required to obtain before a transfusion is beyond the scope of this article, it should be noted that the Expert Working Group (EWG) established by the Canadian Medical Association, in partnership with the Red Cross, the Canadian Blood Agency and Health Canada, to develop practice guidelines on red-blood-cell and plasma transfusions, was unable to reach a consensus on this issue. The EWG agreed that healthcare workers should inform patients about the likely necessity for blood transfusion, and solicit any questions that the patient might have. Beyond that point, the EWG had difficulty providing guidelines for informed consent that “reconcile requirements for full disclosure irrespective of the clinical scenario with a more pragmatic approach that considers disclosing transfusion-related information in light of the patient’s clinical situation.” Thus, while it remains good practice for a hospital to require its physicians to obtain written consent to transfusion from patients where possible, given the disagreement among medical professionals as to the scope of informed consent relating to transfusions, the written consent form will never be a substitute for face-to-face physician-patient communication.

POST-MARKET SURVEILLANCE

The Krever report recommends that there be an active program of post-market surveillance for blood and blood products, the central feature of which is the reporting of adverse reactions from the infusion of blood products. A related recommendation is that licensing bodies make it a standard of practice that physicians report adverse transfusion reactions to CBS, and adverse reactions from the infusion of blood products to CBS and the blood-products manufacturers. To effect this recommendation, hospitals should develop a system to ensure that

physicians submit post-transfusion reports to their blood banks, which in turn will be required to report to their blood transfusion committees (where they exist) and to CBS.

Active post-market surveillance will also be a factor in the ability of CBS to manage its inventory effectively and to plan for the future supply of blood components and blood products. Since much of the blood inventory in the system is, in fact, held not by CBS but by hospitals, it will be incumbent upon hospitals to ensure that systems are in place to transfer current inventory information to CBS. The Krever report recommends that the most efficient way to communicate this information is by daily electronic transfer.

The monitoring of inventory levels and, more specifically, the usage patterns of individual physicians relates to a different potential area of exposure for hospitals in the matter of transfusions. While no Canadian case has yet explored this issue, a possible negligence claim could be made against a physician for transfusion involving contaminated blood products on the basis that the transfusion was not medically warranted. This claim could also be directed at a hospital in the case where it is alleged that the hospital blood bank or hospital transfusion committee failed to monitor and react appropriately to an abnormal usage pattern related to the physician in question. While the possibility of a hospital being held liable on this basis is, at this date, entirely speculative, hospitals should develop and implement protocols with respect to monitoring usage patterns for blood and blood products.

As a general point, it seems clear that the implementation of the comprehensive post-market surveillance recommended by the Krever report will not only require a substantial financial commitment by hospitals but will also result in increased responsibilities for hospital blood banks and hospital transfusion committees. Any hospitals which does not currently have a blood transfusion committees in place should, during this transitional period, consider establishing one. For its part, CBS has indicated that it intends to support the formation and continuance of hospital transfusion committees.

POST-TRANSFUSION DISCLOSURE

The Krever report recommends that, on learning of potential risks to the safety of blood components or blood products, CBS should “cause the recipients to be informed.” Since, however, only hospitals will know who the recipients of the possibly contaminated blood products are, the report leaves it open as to whether, in practice, CBS or the hospitals will

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assume the responsibility (and the costs) for notification. It should also be noted that this recommendation is premised on the position that the recipients of blood products are entitled to be informed of potential risks to transfused components or blood products, “even in circumstances where the risk is theoretical and no treatment is currently available,” thereby establishing a non-negotiable safety threshold.

How, in practice, post-transfusion disclosure of risks should be carried out between the hospitals and CBS, how the costs of notification should be apportioned between the parties, and what the safety threshold for disclosure should be are controversial policy questions beyond the scope of this article. That being said, and bearing in mind that several contaminated-blood liability cases are still before the courts (though many may settle as the plaintiffs opt for government-funded compensation schemes), the existing case law does give some limited guidance as to when a hospital may be found liable in cases where there has been a contaminated blood transfusion. Specifically, a hospital may be found liable in negligence for its failure to implement and operate an adequate “lookback” program. Essentially, a lookback program is a process by which CBS, with the aid of hospitals and doctors, upon the discovery of the possibility of contaminated blood, traces back to the original infected donor all recipients of that donor’s blood.

In the recent Ontario case of *Pittman v. Bain*, the court found that where a blood bank, after a transfusion, learns that its products may have been contaminated, it is under an obligation to advise the patient of this fact and to do so in an timely manner. Although there is no obligation to warn the patient directly – the hospital may choose to do so through the patient’s family physician – it must be done expeditiously and the family physician must be provided with the necessary information to adequately warn his or her patient. A hospital should never assume that notification has taken place and should follow up with the notifying physician to ensure that the patient has been notified. As the specifics of an adequate lookback program are beyond the scope of this article, hospitals should undertake their review of their lookback programs in consultation with their legal advisers.

PUBLIC HEALTH: REPORTING INFECTIOUS DISEASES TO PUBLIC HEALTH AUTHORITIES

The Krever report takes the position that one of the most important roles that the public health system plays in contributing to the safety of the blood supply is the surveil-

lance of infectious diseases transmitted by blood components and blood products, a function which is dependent upon physicians reporting incidences of reportable infectious diseases to public health authorities. The report thus recommends that licensing bodies enforce the standard of practice that requires physicians to report infectious diseases. It further recommends that any reports of cases of diseases that can be transmitted by blood specify the means of transmission.


It should be noted here that underlying the physicians’ standard of practice is a legal duty imposed by provincial statute upon physicians and others (including hospital administrators) to report infectious diseases. For example, the *Ontario Health Protection and Promotion Act* sets out reporting obligations on both physicians and hospital administrators. Any person who fails to make a report as required by the legislation is guilty of an offence. While all provinces have legislation similar to the Ontario act mandating the reporting of infectious diseases, the provinces differ in their reporting procedures and in their classifications of reportable diseases. Health administrators must therefore ensure that the applicable statutory notification procedures are followed in their hospitals.

CONCLUSION

The final Krever report is a comprehensive, voluminous document containing over 50 recommended changes to the Canadian blood supply system, many of which have implications for hospitals. In addition to the recommendations discussed in this article, the report contains several other recommendations which, if implemented, would have significant implications for hospitals, the most dramatic of which is that CBS be funded by direct payments from hospitals for the blood components and blood products supplied to them by CBS.

As stated earlier, we are in a period of transition in regard to the Canadian blood delivery system. Hospital administrators should take this time to review the Krever recommendations as well as their hospital’s internal blood supply systems. In particular, hospital administrators should consider the following:

1. Any hospital that does not currently have a blood transfusion committee should consider establishing one. As CBS will likely be more proactive than its predecessor, transfusion committees will play an increasingly important role in setting hospital policy in regard to responding to CBS alerts and setting disclosure-of-risk thresholds. At a minimum, a hospital should review the resources and personnel currently available to its blood bank.

2. Hospital blood banks should have a system in place to ensure that any alerts received from CBS are immediately communicated to the physicians working in the hospital. All communications should be in writing and any queries from physicians should be handled promptly.
3. Hospital blood banks should review their standards for storing blood and blood products and ensure that they are consistent with the standards set by CBS.
4. Hospital blood banks or transfusion committees should ensure that the physicians working in the hospital are familiar with the practice guidelines on red-blood-cell and plasma transfusions established by the Canadian Medical Association. After consultation with its physicians and its transfusion committee, a hospital may wish to review its transfusion consent form with input from legal counsel.
5. Hospital policy should mandate that physicians working in the hospital submit post-transfusion reports to the hospital's blood bank. In turn, the blood bank will be mandated to transmit these reports to the hospital's transfusion committee, where it exists, and to CBS.
6. Hospitals must ensure that systems are in place to accurately monitor blood inventory levels and to transfer current inventory information to CBS.
7. Hospital blood banks should monitor the blood usage patterns of individual physicians and, in consultation with the hospital's transfusion committee, develop and implement protocols with respect to acceptable usage patterns.
8. Hospitals should review their existing lookback programs and ensure that they are able to meet the legal minimum standards set by the case law.
9. Hospital administrators should familiarize themselves with their provincial statutes mandating the reporting of infectious diseases and ensure that the applicable statutory notification procedures are followed in their hospitals. 

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