A Canadian hospital-based HIV/hepatitis C look-back notification program

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Abstract

Objective: To describe the process used to notify pediatric patients who received transfusions of blood or blood products at our institution before donor blood was routinely screened for antibodies to HIV (1985) and hepatitis C virus (1990), and to evaluate the effectiveness of the notification program.

Design: Patients who had received transfusions were identified through the hospital's medical records and the records from the Transfusion Medicine Laboratory. Patients were contacted by registered mail to provide notification of transfusion. A questionnaire was included with the notification to obtain information about the patient's awareness of the transfusion and whether he or she had undergone or planned to undergo testing for HIV and hepatitis C virus.

Setting: Tertiary care university-affiliated teaching hospital in Hamilton, Ont.

Patients: Patients 16 years of age or younger who had received blood products between February 1978 and November 1985. Patients who had received only albumin or immune serum globulin were not included as these products were not associated with viral transmission in Canada.

Results: Notification letters were sent to 1546 patients. Of these letters 522 (33.8%) were returned undelivered. Of the 1024 patients contacted 493 (48.1%) responded to the questionnaire, of whom 157 (31.8%) were not aware of their transfusion. A total of 130 (26.4%) of the respondents had already undergone testing for HIV, and 342 (69.4%) indicated that they would undergo such testing as a result of the notification. In contrast, only 30 (6.3%) of 474 respondents had undergone testing for hepatitis C virus, but 425 (89.7%) indicated that they would undergo such testing. Overall, the patients' response to the notification was neutral or positive; however, a number of patients expressed dissatisfaction and anxiety.

Conclusions: The high proportion of patients who were unaware that they had undergone transfusion and who decided to undergo testing for HIV and hepatitis C virus as a result of notification supports the use of notification programs such as this one.

Résumé

Objectif : Décrire le processus suivi pour prévenir les patients de moins de 17 ans qui ont reçu des transfusions de sang ou de produits sanguins à notre établissement avant qu'on analyse de routine le sang des donneurs pour y dépister les anticorps du VIH (1985) et le virus de l'hépatite C (1990) et évaluer l'efficacité du programme de notification.

Conception : On a identifié les patients qui avaient reçu des transfusions en consultant les dossiers médicaux de l'hôpital et ceux du Laboratoire de médecine transfusionnelle. On a communiqué avec les patients par courrier recommandé pour les prévenir de la transfusion. On a joint un questionnaire à l'avis afin de déterminer si les intéressés étaient au courant de la transfusion et s'ils s'étaient soumis à un test de dépistage du VIH et du virus de l'hépatite C, ou s'ils envisageaient de le faire.

Contexte : Hôpital d'enseignement de soins tertiaires affilié à une université à Hamilton (Ont.).

Patients : Patients âgés de 16 ans ou moins qui avaient reçu des produits sanguins

Evidence

Études

From the departments of *Pathology, †Medicine and ‡Family Medicine, McMaster University, Hamilton, Ont., and the departments of §Public Affairs, ‖Administration and ¶Laboratory Medicine, Chedoke–McMaster Hospitals, Hamilton, Ont.

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entre février 1978 et novembre 1985. Les patients qui avaient reçu de l'albumine ou de l'immunoglobuline sérique seulement ont été exclus, car on n'a établi aucun lien entre ces produits et la transmission du virus au Canada.

Résultats : Des lettres de notification ont été envoyées à 1546 patients et 522 (33,8 %) ont été renvoyées non livrées. Sur les 1024 patients avec lesquels on a communiqué, 493 (48,1 %) ont répondu au questionnaire et 157 (31,8 %) d'entre eux ne savaient pas qu'ils avaient reçu une transfusion. Au total, 130 (26,4 %) des répondants s'étaient déjà soumis à un test de dépistage du VIH et 342 (69,4 %) ont indiqué qu'ils se soumettraient à un tel test après avoir reçu l'avis. Par ailleurs, 30 (6,3 %) seulement des 474 répondants avaient subi un test de dépistage du virus de l'hépatite C, mais 425 (89,7 %) ont indiqué qu'ils se soumettraient à un tel test. Dans l'ensemble, la réponse des patients à l'avis a été neutre ou favorable, mais certains patients ont manifesté de l'insatisfaction ou de l'inquiétude.

Conclusions : La proportion élevée de patients qui ne savaient pas qu'ils avaient reçu une transfusion et qui ont décidé de se soumettre à un test de dépistage du VIH et du virus de l'hépatite C après avoir reçu l'avis appuie le recours aux programmes de notification comme celui-ci.

Since November 1985 Canada's donor blood supply has been screened for antibodies to HIV, and since 1990 routine screening for antibodies to hepatitis C virus has been performed. Although the transmission of HIV by blood transfusion in Canada was uncommon before 1985, it did occur in some patients, particularly those who received large amounts of pooled blood products. The risk of transmission of hepatitis C virus through transfusion during this time was even higher, with one Canadian study suggesting that 9.1% of surgical patients who had received a transfusion could have been infected.[1] Because of these risks it has been suggested in Canada and the United States that patients who received transfusions before viral screening of donor blood was routine should be notified and that testing for viral infection should be recommended.[2,3]

There have been a number of information campaigns through the media and advertising in Canadian hospitals suggesting that patients who were admitted to hospital and received a blood transfusion between 1978 and 1985 should be tested for HIV and that patients who received transfusions between 1978 and 1990 should be tested for hepatitis C virus.

The advantages and disadvantages of formal notification have been described.[4–7] Most reports have involved children, since many of these patients would now be sexually active, and could transmit HIV if they are unaware that they were infected.[4,6,7] In contrast, many adults who received transfusions during the period in question would now be dead, since transfusion in adults is often associated with conditions having a high risk of death.

A survey of 117 hospitals by the Ontario Hospital Association showed that 41% of Ontario hospitals had attempted some type of "look-back" notification program;[8] however, only 1 Ontario hospital has published information about the procedure used and the results of the project.[4] In general, follow-up information on the usefulness of general notification is lacking.

In 1995 Chedoke–McMaster Hospitals (CMH) carried out a look-back notification program for pediatric patients. The objectives of the program were to identify and notify pediatric patients who had received transfusions at CMH between February 1978 and November 1985 and recommend testing for HIV and for exposure to the hepatitis C virus; to describe the notification procedure used and the difficulties encountered; to determine what proportion of transfusion recipients were aware of their transfusion; and to determine whether transfusion recipients had been or intended to be tested for HIV and hepatitis C virus.

Methods

A database was created with the use of D-Base III Plus software (Ashton–Tate Corp, Torrance, Calif.) to facilitate data management, word processing, letter preparation and mailing.

Steering committee

A steering committee formed to implement the program had representation from medical staff (chief of medicine and chief of family medicine), the Transfusion Medicine Laboratory, the Neonatal Intensive Care Unit (NICU), the Infectious Disease Service, Patient Information Services, senior hospital administration and the Public Affairs Department. The program was reviewed and approved by the hospital's Clinical Ethics Committee.

Identification of transfusion recipients

We tried to identify all CMH patients 16 years of age or younger who had received blood products between Febru-

ary 1978 and November 1985, through the hospital's medical records and the records from the Transfusion Medicine Laboratory. Patients who had received only albumin or immune serum globulin were not included as there were no data to suggest that these products were associated with viral transmission in Canada. Recipients of coagulation concentrates who had previously been notified were also excluded.

The availability and completeness of records from the Transfusion Medicine Laboratory involved 3 categories. Between 1978 and 1982 complete records were available from the blood product sign-out log, identifying the patient's given name, surname, hospital identification number, date of transfusion and type of blood product given (group 1). Records were not available for a 19-month period between 1982 and 1984 (group 2). For the balance of 1984 and 1985, records were available and contained all the information listed for group 1 except the patient's hospital identification number (group 3).

The following information was retrieved for each transfusion recipient: surname, given name(s), address, hospital identification number, age, birth date, family Ontario Health Insurance Plan (OHIP) number, family physician's name and address, date of transfusion, product type and number of transfusions. Different search strategies were used for the 3 groups. For patients in group 1 the computerized Central Patient Index (CPI) was searched to identify the attending physician and the patient's OHIP number. The CPI also provided documentation of death if it occurred in the hospital. Attempts were made to identify all deceased patients to avoid sending a notification letter to family members.

For patients in group 3 the CPI was searched with the use of the patient's surname and given name to identify the appropriate hospital identification number. If more than 1 name match was identified, the medical records of all of the patients in question were reviewed to confirm the correct match. With the use of the patient's hospital identification number, the attending physician's name and the patient's OHIP number were obtained. Infants who received transfusions in the NICU were identified only as "infant" or "baby" plus a surname, which made it difficult to determine the correct identification number from the CPI. In these cases the NICU log book documenting all hospital admissions was used to determine the appropriate hospital identification number.

To identify patients in group 2, Patient Information Services generated monthly lists of all pediatric patients discharged from CMH. The list included the hospital identification number, the primary diagnosis, the length of stay, the name of the service and the attending physician. The lists were reviewed by a resident in hematology, and the patients were categorized as having a high probability of transfusion, possible transfusion or unlikely to have received a transfusion. The medical records of all patients in the first 2 categories were reviewed for documentation of blood transfusion. To validate the accuracy of this process a 2-month period was selected during which the medical records for all patients categorized as unlikely to have received a transfusion were reviewed to verify that they had not received a transfusion; none of the patients had documentation of transfusion in the chart.

Letters and questionnaire

The Public Affairs Department drafted the letters to patients and physicians, which were circulated to the steering committee for comments and editing. Letters used by other hospitals that had completed look-back notification (the Hospital for Sick Children, Toronto, the Mississauga Hospital, Mississauga, Ont., and the Children's Hospital of Eastern Ontario, Ottawa) were also reviewed.

Physician letters

An information letter about the notification project was sent to the physician identified as the family or primary care physician for each patient. Each physician was also provided with a specific report that included the names of his or her patients who would receive a letter. Two information brochures from the Canadian Liver Foundation were also included.[9,10]

A more general letter was distributed to all active medical staff at CMH approximately 1 week before the notification to inform them of the program and of the fact that former patients might be contacting them about this issue.

Patient letters

Two types of patient letter were prepared. One letter, addressed directly to the patient, was for patients 17 years of age or older at the time of the mailing; the second letter, addressed to the patient's parents, was for patients 16 years or younger. The following information was included in the patient letters: reason for the notification; how to be tested for HIV and hepatitis C virus, including anonymous testing and testing through the family physician; a disclaimer about the Freedom of Information and Protection of Privacy Act (required by the Ontario Ministry of Health); and details about the CMH telephone information line. All letters were signed by the chief of staff.

A confidential questionnaire was included with the patients' letters. Patients were asked whether they were aware that they had received a blood transfusion between 1978 and 1985; whether they had undergone testing for HIV and hepatitis C virus, and, if not, whether they would undergo testing as a result of the notification (the

reason for choosing not to undergo testing was requested); and whether they would see their family physician as a result of the notification.

Mailing process

The Ontario Ministry of Health assisted the hospital in identifying the patients' most current address. Copies of the patient letters and a summary of the proposed mailing procedure were reviewed by the ministry's legal counsel, after which a memorandum of understanding was signed between the ministry and CMH. To ensure an accurate address match, the ministry required a unique match on several key identifiers, including the patient's surname, given name, age and sex. The ministry can provide this information under the jurisdiction of the Freedom of Information and Protection of Privacy Act. When the address provided by the ministry was different from the information retrieved from the hospital's records, the address provided by the ministry was used.

The physicians' letters were mailed several days before the patients' letters. Window envelopes were used to avoid separate labelling of the envelopes, with the possibility of errors. All patient letters were sent by registered mail. If the registered letter was returned, it was assumed that the patient's address was not current, and no further attempts were made to contact the patient at that address.

Public affairs

A news release was distributed to local media just before patient notification, and a question-and-answer sheet of frequently asked questions was prepared. A hospital spokesperson was selected to answer any questions from the media, and a telephone information line was set up to assist with calls from patients or their families. Hospital staff members were informed about the project through the staff newsletter.

Statistical analysis

Proportions were compared with the χ^2 test.

Results

Between 1978 and 1985, 2400 patients 16 years of age or younger received transfusions of blood products at CMH. Of the 2400, 854 were excluded because they had died or because they had had transfusion with albumin or immune serum globulin. Of the 1546 remaining patients 1239 (80.1%) were 16 years or younger at the time of mailing and 307 (19.9%) were 17 years or older.

The Ministry of Health was able to provide a current address for 1128 patients (73.0%). The letters for the remaining 418 patients were sent to the original address retrieved from the hospital's records. Within 8 weeks of the mailing 522 letters (33.8%) were returned undelivered; hence, it was assumed that 1024 letters were delivered successfully (Table 1). The return rate for the group for which the ministry was able to provide a current address was 22.9% (258/1128), compared with 63.2% (264/418) for the group for which a current address had not been provided ($p < 0.001$). Because the ministry was unable to provide a current address without a given name and surname, the proportion of letters returned was much higher for the neonatal group. Also, there was a high return rate for out-of-province patients (9/10) because the patient's current address could not be confirmed by the ministry.

Of the 924 letters mailed to physicians, 145 (15.7%) were returned undelivered.

Table 1: Letter return rate in a look-back notification program directed to pediatric patients who received blood products at Chedoke–McMaster Hospitals between 1978 and 1985, by patient's age at the time of mailing

Patient category	No. of letters mailed	No. (and %) of unique matches from Ontario Ministry of Health*	No. (and %) of letters returned
≤ 16 yr			
Surname and given name available	1080	892 (82.6)	311 (28.8)
Surname only	159	9 (5.7)	108 (67.9)
Total	1239	901 (72.7)	419 (33.8)
≥ 17 yr			
Surname and given name available	289	226 (78.2)	87 (30.1)
Surname only	18	1 (5.6)	16 (88.9)
Total	307	227 (73.9)	103 (33.6)
Overall total	1546	1128 (73.0)	522 (33.8)

*The Ontario Ministry of Health was able to provide the most current address for the patient based on key demographic data that ensured accurate patient identification.

Information line

A total of 104 calls were received. The largest group of calls involved parents requesting confirmation of the transfusion data. There were 8 calls from physicians to inform the hospital that patients were no longer in their practice or to clarify whether they should contact patients or wait for the patients to initiate contact. The other reasons for the calls are summarized in Table 2.

Questionnaire

Of the 1024 patients contacted, 493 (48.1%) returned questionnaires. Of the 493 patients 157 (31.8%) were unaware that they had received a blood transfusion during their hospital stay. A total of 342 patients (69.4%) indicated that they would undergo testing for HIV as a result of the notification, 130 (26.4%) had already undergone testing, and 21 (4.3%) indicated that they would not undergo testing; 13 of those who did not intend to undergo testing did not give a reason. Of the 474 patients who responded to the question about hepatitis C testing, 425 (89.7%) indicated that they would undergo testing, 30 (6.3%) had already undergone testing, and 19 (4.0%) indicated that they would not undergo testing; 8 of those who did not intend to undergo testing did not give a reason. Hence, 472 (95.7%) of patients contacted had been tested or planned to be tested for HIV, and 455 (96.0%) had been tested or planned to be tested for hepatitis C virus. A total of 80.1% of the patients (350/437) indicated that they would see their family physician as a result of the notification.

A number of patients or parents wrote specific comments on the returned questionnaires. These comments included information about test results, notification that the patient had died, criticism of the hospital for waiting so long to notify patients, expression of concern that transfusion had occurred without the parents' consent, and criticism for causing anxiety to families by notifying them directly. Several patients or parents praised the hospital for the notification and the continuing excellent care to patients and their families. All comments expressing concern were answered in writing by the Public Affairs Department.

Table 2: Nature of calls received on the hospital information telephone line

Nature of call	No. of calls
Request to recheck mailing address	11
Request to confirm transfusion data and provide information about transfusion data*	30
Request for confirmation that a letter was being sent from patients who had heard about the program	12
Physician call†	8
Notification of deceased patient	2
Request for other information‡	41
Total	104

*Most of these calls were from parents who did not know their child had received a transfusion.
†Included notification that the patient had died or was no longer in the physician's practice.
‡Included information from birth mothers that their children had been placed for adoption and requests for clarification as to why the hospital had waited so long to notify patients.

Blood product use

Most of the patients (1118/1546, 72.3%) received 5 or fewer blood products. Erythrocytes were the product most often used, having been given to 1295 patients (83.8%) (Table 3). Plasma was the next most frequently used product, having been given to 680 patients (44.0%).

Budget

The total cost to the hospital for the notification program was at least $42 665. This included $26 376 for personnel costs, $6954 for mailing costs, $6900 for leasing microfilm retrievers and $2058 for miscellaneous costs (paper, photocopies and printing). The program was not supported by external or grant funding.

Discussion

CMH has now joined several other hospitals in completing a notification program to ensure awareness of transfusion of blood or blood products. The steering committee chose to notify initially pediatric patients who received transfusions from 1978 to 1985 about the risk of transmission of both HIV and hepatitis C virus. Depending on the results of the program, the committee planned to decide whether to notify pediatric patients who received

Table 3: Blood product use during the study period

Blood product	Total no. of units transfused	Median	Mode	Range	No. of patients
Erythrocytes	4863	2	1	1–148	1295
Platelets*	724	2	1	1–56	184
Plasma	1748	2	1	1–57	680
Cryoprecipitate	2629	12	4	1–646	39

*Single-donor apheresis platelets or a pool of random-donor platelets.

a transfusion between December 1985 and June 1990 about the potential risk of hepatitis C virus transmission.

For many hospitals the availability of records has been a limiting factor in the decision to notify transfusion recipients, because the legal requirement for record retention in the early 1980s was only 3 years. Transfusion records at CMH were available during this entire time except for a 19-month period. Hospital discharge lists were used to identify transfusion recipients during this 19-month period; however, this procedure was extremely time-consuming and may not be cost-effective.

In retrospect, several inefficiencies in the mailing procedure were identified. The letters to physicians should have been mailed several weeks, not days, before distribution of the patients' letters, so that physicians could notify the hospital of deceased patients. This would have prevented contact with the family about a dead family member in some cases.

Availability of a current mailing address was an important concern. The assistance from the Ministry of Health was helpful, but the ministry's records could not provide a current address for 27% of the patients. The letter return rate for this group was 63.2%, compared with 22.9% for the group for which the ministry was able to provide a current address. Even with the ministry's assistance 33.8% of the target group could not be contacted.

Approximately one-third of the patients were unaware that they had received a transfusion. We suspect that most of these patients had received transfusions as neonates; however, because the questionnaire was confidential, we were unable to confirm this assumption. This observation suggests that information about transfusion was not provided effectively before 1985.

The responses to the questionnaire also suggest that almost all patients would choose to undergo testing for HIV and hepatitis C if they knew they had received a blood transfusion.

During the planning stages of the project the feasibility of obtaining the results of testing for HIV and hepatitis C virus was discussed. Although this information would have been useful, the steering committee was concerned about issues of confidentiality. Also, it was assumed that the hospital would eventually be notified of any HIV-positive patients, either through patient referral to the HIV Consultation Clinic or through the hospital's Risk Management Department. We are not aware of any HIV-positive patients identified through this effort. It is likely that some patients with a hepatitis C virus infection were identified through the notification process, as a higher percentage of donor blood was contaminated with this virus than with HIV during the study period.

It is difficult to compare the results of our study with those obtained at the Hospital for Sick Children.[4] That hospital's study was designed to obtain results of testing for HIV and hepatitis C virus for all transfusion recipients, whereas we focused on patient awareness of the transfusion and intention to undergo testing. In addition, blood product use was significantly higher at the Hospital for Sick Children, which makes it difficult to generalize their results to our patients.

Our results highlight both practical and ethical issues surrounding look-back notification. From a practical perspective, the value of the process could be questioned. A third of our patients could not be located, the resources required to perform the notification were significant, and we do not know whether patient care was improved by the process, especially in our area, where the prevalence of HIV infection is low. However, many patients were unaware that they had received transfusions, and almost all patients indicated that they would now undergo testing for HIV and hepatitis C virus. Based on this information, we feel that the notification was useful, and CMH has proceeded with notifying former patients who received transfusions between November 1985 and June 1990 regarding possible exposure to hepatitis C virus.

We thank the Hospital for Sick Children, the Children's Hospital of Eastern Ontario and the Mississauga Hospital for providing us with copies of their notification letters, and the Canadian Liver Foundation for supplying hepatitis C information brochures. Special thanks to the Ontario Ministry of Health for providing current address information, Dorothy Adams for collating the responses to the questionnaires, Bonnie Hagen for running the telephone information line and responding to the calls, and Janice Butera and Barbara Lahie for providing clerical assistance.

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