

Results of a General Hepatitis C Lookback Program for Persons Who Received Blood Transfusions in a Neonatal Intensive Care Unit Between January 1975 and July 1992

Henry H Cagle, BS; Jack Jacob, MD; Chriss E. Homan, BS; James L. Williams, BSN, ANP; Carol J. Christensen, BSN, RN; Brian J. McMahon, MD

Objective: To notify persons who received a blood transfusion in a neonatal intensive care unit between January 1975 and July 1992 of their risk for hepatitis C infection and to encourage them to seek hepatitis C antibody testing.

Design: Neonatal intensive care unit, blood bank, and public access records were queried to identify current mailing addresses and persons deceased. All persons were notified by letter.

Setting: Anchorage, Alaska.

Participants: Persons who received health care in an integrated health care system, the Alaska Native Medical Center, or in the private sector.

Main Exposure: Transfusion in the neonatal period.

Main Outcome Measures: Prevalence of test results positive for the hepatitis C virus antibody and RNA and awareness of having received a blood transfusion in a neonatal intensive care unit.

Results: Alaska Native Medical Center (n=401) and private sector (n=1396) persons were targeted for notification. Letters were mailed to 277 Alaska Native Medical Center (69%) and 374 private sector (27%) persons, with 151 (55%) and 65 (17%) screened for hepatitis C, respectively. Among those screened (n=216), 7 (3%) were hepatitis C antibody positive, with 6 (<3%) also hepatitis C virus-RNA positive. Among 147 persons who responded, 75 (51%) were unaware they had received a transfusion.

Conclusions: Compared with the private sector, a higher proportion of persons were identified and tested from the integrated health care system and more than half of respondents were unaware of their transfusion history. It would be prudent to screen neonatal intensive care unit patients who received transfusions before July 1992 for hepatitis C virus infection.

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THERE ARE AN ESTIMATED 3.9 million persons in the United States infected with hepatitis C virus (HCV), with 7% (approximately 300 000) possibly infected by transfusion.¹ Fortunately, the risk for HCV infection from a transfusion has diminished over time because blood banks implemented screening of donor blood beginning in 1986-1987 with a surrogate test (serum alanine aminotransferase and antibody to hepatitis B core antigen) for non-A, non-B hepatitis,² followed by a first- and second-generation HCV antibody (anti-HCV) enzyme immunoassay in May 1990 and July 1992.³ Persons who received transfusions as neonates before July 1992 represent an unknown, but potentially significant, proportion of those estimated to be HCV infected. Neonates were particularly susceptible to infection be-

cause of the receipt of multiple transfusions and the potential for multiple donor exposure.⁴⁻⁶

*For editorial comments
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Few studies involving neonates have previously been conducted, none of which were conducted in the United States, to our knowledge. In an HCV follow-up study of children who received a mean of 2 (range, 1-13) transfusions as a neonate between 1968 and 1974, 26 (46%) of 57 tested were HCV-RNA positive, with a majority of those positive having received blood from a common HCV-RNA-positive donor.⁷ A lookback study involving neonates who received transfusions between 1980 and 1991 with blood from potentially infected do-

Author Affiliations: Liver Disease and Hepatitis Program, Division of Community Health, Alaska Native Tribal Health Consortium (Messrs Cagle, Homan, and Williams, Ms Christensen, and Dr McMahon), and Alaska Neonatology Associates, The Children's Hospital at Providence, Providence Alaska Medical Center (Dr Jacob), Anchorage.

nors found that 12 of the 20 tested were anti-HCV positive, 7 of whom were HCV-RNA positive.⁸ A second lookback study of neonates who received transfusions between 1978 and 1990 found that 12 (1.4%) of 881 tested were HCV infected.⁹ Beeby et al¹⁰ screened 45 neonates who received transfusions between 1985 and 1990 and found none with HCV infection, which, as the authors state, impacts the ability to estimate the true risk of infection in this population. Importantly, 3 of these 4 neonatal transfusion studies involved very small sample sizes.

In 1998, the US Food and Drug Administration issued guidelines for conducting targeted lookback programs to identify blood donors found to be HCV infected and then to notify persons who had received units from these infected donors of their HCV risk.¹¹ As a result, support of such programs and an expanded effort to identify at-risk persons who received transfusions as neonates was strongly advocated by Aach et al.¹² Implementation of general, rather than targeted, lookback programs better serves to accomplish the objective of Aach et al in that the goal of these programs is to identify and attempt to notify any persons who received transfusions before July 1992.

Beginning in 2001, the Liver Disease and Hepatitis Program, which provides specialty clinical services at the Alaska Native Medical Center (ANMC), initiated an HCV general lookback program aimed at identifying individuals who received transfusions while in the Newborn (formerly Neonatal) Intensive Care Unit (NICU), Providence Alaska Medical Center before July 1992. At that time, Providence Alaska Medical Center operated the only NICU in Alaska and at-risk newborns from ANMC and around the state were referred there. The NICU lookback program described herein followed the initiation of a general lookback program conducted previously by the Liver Disease and Hepatitis Program among children and adults who received transfusions at ANMC.¹³ Under this program, 63% of persons notified were screened and the prevalence of HCV infection was 2%. One objective of this current program was to determine the outcome of conducting a lookback program among former NICU patients who received care at ANMC, which is part of an integrated health care system, vs those who received care in the private sector. Additional objectives were to (1) identify persons still living who received a transfusion in the NICU before July 1992, (2) attempt to locate recipients, notify them of their HCV risk, and provide them with information and/or counseling about testing, (3) determine the prevalence of anti-HCV and HCV RNA, (4) determine if there are differences between anti-HCV test result and the date of first transfusion as well as the number of transfusions received, and (5) determine if transfusion recipients or their parents were aware of their NICU transfusion history.

METHODS

SETTING AND PATIENTS

The ANMC is a 150-bed tertiary hospital located in Anchorage that provides services to 32 000 Alaska Natives locally with referral care to 120 000 patients statewide. This hospital, formerly run by the US Indian Health Service, is part of an inte-

grated health care system comprising Alaska Native-owned and -operated regional hospitals and community health clinics. Delivery of health services under this system is similar to that of US managed health care systems. The NICU, Providence Alaska Medical Center, also in Anchorage, is a 38-bed level II and III unit that is the regional referral center for the state of Alaska. The Alaska Area Institutional Review Board chairman at ANMC provided an exemption for the need of informed consent for this program based on the following reasons: (1) it consisted of a review of previous transfusion records, (2) it was consistent with the Centers for Disease Control and Prevention recommendation to counsel and test persons who received transfusions before July 1992,¹⁴ and (3) identifying information would be removed from all reports. Persons sought under this program (hereafter referred to as *transfusion recipients* or *patients*) were NICU patients who received blood products between January 1975, the date from which NICU logbooks were available, and July 1992, the date at which second-generation anti-HCV testing was available.

DATA MANAGEMENT

Preliminary data, such as patient's medical record number, ethnicity, name, and date of birth and parent's name and address, were retrieved from hard-copy NICU logbooks and keyed into a database application (Access; Microsoft, Redmond, Wash) for all infants who were in the NICU 2 or more days and discharged alive. A number of newborns admitted to the NICU were admitted for brief periods (<2 days) because of transient difficulties postbirth, and these infants were deemed to be unlikely to have received transfusions based on the experience of 1 of us (J.J.). The occurrence of a blood transfusion was not a part of NICU logbook records. Blood bank records were available in an index card and microfiche format (1975-1990) and in an electronic file (1991-1992), which only included the occurrence of a transfusion, indicated by a yes or no. Using the NICU logbook data, an application was created for entering blood bank record data, such as number of transfusions, tallied by aliquot number and date of transfusion. Persons who had no evidence of a transfusion were purged from the database, which was then queried with an ANMC database to produce separate databases for ANMC and private sector patients. These databases were queried with a state of Alaska vital statistics database to identify patients who died post-NICU discharge. Current mailing addresses were sought through a search of ANMC and public access records, with additional searches of Providence Alaska Medical Center records, using the patient's medical record number for those with incomplete names (eg, Jones, baby girl) or addresses or who had no listing in public access records. Public access records available for use included hunting and fishing licenses, motor vehicle registration, voter registration, and the Alaska Permanent Fund, a fund that provides an annual payment to eligible Alaskan residents.

PATIENT NOTIFICATION

Beginning April 2001, ANMC patients or their parents, if the patient was younger than 18 years, were mailed a letter informing them of their transfusion history and risk for HCV infection and encouraging them to get tested at ANMC or their community health clinic. This letter also listed a toll-free telephone number that patients could call to speak with a program nurse. A second letter was mailed to patients who, several months after the first letter, had not yet had an HCV test or whose first letter was returned undeliverable and an alternate address was found. Next, a letter was mailed to all physicians and midlevel health care professionals (approximately 1200 total) inform-

ing them of the existence and intended goals of the lookback program and that their patients may contact them with concerns about HCV infection or requests for HCV testing. Private sector patients or their parents were mailed a letter similar to the one sent to ANMC patients, but they were encouraged to contact their primary care physician for HCV testing. Given that counseling and testing would occur in the private sector, an anonymous questionnaire for patients to complete and return (prepaid envelope provided) was included with the letter. The questionnaire elicited information about their awareness of having received a transfusion, whether they had already been tested or were undecided about or refusing testing, and their results if tested. A second letter was mailed only to private sector patients whose letter was returned undeliverable and an alternate address was found, since we were unable to determine which of those letters not returned had been received by persons who had already returned the questionnaire.

HCV COUNSELING

This program used an HCV counseling manual that focused on blood transfusions received before July 1992 as a risk factor for HCV infection¹⁵ and made the manual available to ANMC-affiliated clinics and private sector physicians. At ANMC, pre-test counseling was delivered by telephone or in person at the time of blood draw. Posttest counseling was completed by appointment, telephone call, or letter as per the patient's request. For private sector patients who called the program, counseling was provided by telephone on request and they were encouraged to contact their primary care physician for additional information and HCV testing.

DONOR BLOOD AND SEROLOGIC SCREENING

Blood products used in the NICU were obtained from the Blood Bank of Alaska (Anchorage), an accredited source that initiated surrogate anti-HCV screening of donor blood in September 1986 and first- and second-generation anti-HCV testing in May 1990 and July 1992, respectively. The Blood Bank of Alaska reported an anti-HCV prevalence of 0.2%.¹⁶

For specimens collected at ANMC, the presence of anti-HCV was determined by enzyme immunoassay using commercial reagents (Abbott Laboratories, Abbott Park, Ill). Hepatitis C virus infection was confirmed commercially by recombinant immunoblot assay (Quest Diagnostics, Seattle, Wash) or real-time quantitative polymerase chain reaction (ANMC Laboratory, Anchorage).¹⁷ All work was performed in a Clinical Laboratory Improvements Amendments-accredited facility.

STATISTICS

Program data collected between April 2001 and February 2003 were included in the analysis. Analyses were performed with SAS version 9.1 (SAS Institute, Cary, NC). The χ^2 test, Fisher exact test, and Cochran-Armitage trend test were used for 2-way classification tables, and 95% confidence intervals (CIs) were calculated for the binomial proportion of 1-way tables. Statistics are descriptive and *P* values $\leq .05$ (2-sided) were considered statistically significant.

RESULTS

Nearly two thirds (3182 [64%]) of the 4979 patients identified from the NICU logbooks had no evidence of transfusion in the blood bank records (**Figure**). Of 1797 patients targeted for notification, 401 (22%) were from

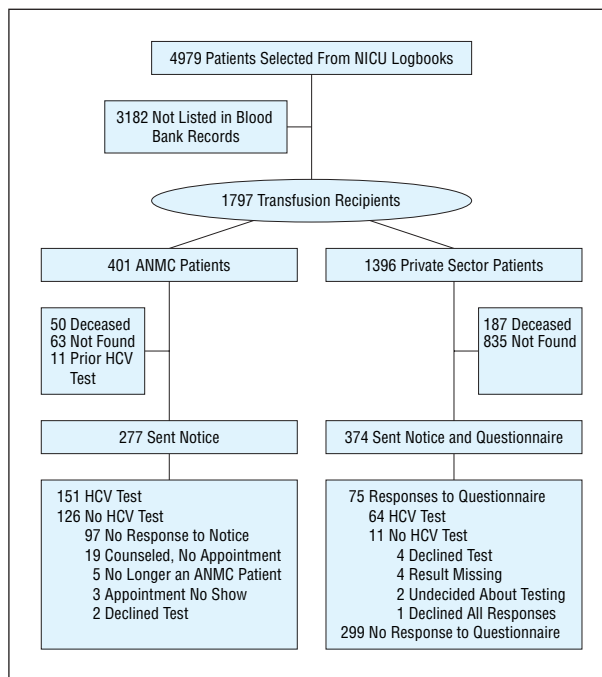


Figure. Patient flow for general hepatitis C virus (HCV) lookback program for persons who received transfusions in a neonatal intensive care unit (NICU) between January 1975 and July 1992. ANMC indicates Alaska Native Medical Center.

ANMC and 1396 (78%) were from the private sector. Persons targeted for notification lived throughout Alaska.

Current locator information was unavailable for 63 ANMC patients (16%; includes 19 letters returned undeliverable), and 50 (12%) were deceased. Eleven patients (3%) were screened for HCV prior to this lookback program (10 anti-HCV negative, 1 anti-HCV and HCV-RNA positive) and thus were not notified or rescreened. Two hundred seventy-seven ANMC patients (69%) were sent a notice; 55% (151/277) of patients were tested for HCV infection.

Of the 1396 private sector patients identified, complete name or current locator information was unavailable for 835 (60%; includes 14 letters returned undeliverable), and 187 (13%) were deceased. Of the 374 private sector patients sent a notice, 75 (20%) returned the questionnaire. The proportion of private sector patients who could not be located (60%) was significantly greater than that of ANMC patients (16%; $\chi^2=242.37$; $P<.001$).

Table 1 illustrates HCV test results for patients screened under this program. For ANMC patients, 6 (4% [95% CI, 1%-8%]) of 151 patients were anti-HCV positive, with 5 (3% [95% CI, 1%-8%]) of those being HCV-RNA positive. The anti-HCV-positive patients were aged 13, 14, 16, 16, 21, and 26 years at the time of screening. By self-report, 1 (2%) of 64 private sector patients, aged 16 years, was anti-HCV and HCV-RNA positive; laboratory results were missing on 11 questionnaires. All anti-HCV-positive ANMC patients were referred to the ANMC Liver Clinic for evaluation, and it was recommended that the private sector patients make an appointment with a community specialist. All ANMC patients were unaware of their anti-HCV status prior to notification and screening.

Using the timeline for implementing HCV screening of donor blood by blood banks^{2,3} and the date of the

Table 1. HCV Infection in ANMC and PS Patients With Positive HCV Antibody Test Results

	No./Total No. (%)	
	ANMC Patients	PS Patients
Confirmatory testing	6/151 (4)	1/64* (2)
RIBA results not reported, HCV-RNA positive†	2 (33)	1 (100)
RIBA results indeterminate, HCV-RNA positive	1 (17)	0
RIBA results positive, HCV-RNA positive	2 (33)	0
RIBA results positive, HCV-RNA negative	1 (17)	0

Abbreviations: ANMC, Alaska Native Medical Center; HCV, hepatitis C virus; PS, private sector; RIBA, recombinant immunoblot assay.

*Self-reported.

†For ANMC patients, HCV RNA was by quantitative polymerase chain reaction; method is not known for PS patient.

ANMC patient's first transfusion, 3 groups were defined: group 1, transfusion prior to 1986 and before HCV surrogate testing; group 2, between 1986 and 1990 during the period of surrogate testing; and group 3, between 1990 and 1992 when the first- to second-generation anti-HCV test was used. **Table 2** illustrates frequencies for each of these groups by anti-HCV result. The association between a positive anti-HCV test result and group (1-3) was not statistically significant, nor was the association between group 1 and groups 2 and 3 combined ($P = .66$ and $P = .42$, respectively).

Table 3 illustrates the distribution of number of transfusions (range, 1-238) ANMC patients received by anti-HCV result. There was a trend for anti-HCV positivity with increasing number of transfusions, which approached statistical significance ($P = .06$).

During counseling sessions completed at ANMC or by anonymous questionnaire, patients or their parents were asked, "Were you aware that you had received a transfusion before someone from our program contacted you?" or "Prior to receiving the notification letter, were you aware that you (or your child) had received a transfusion?" Overall, 75 (51%) of 147 patients (or parents) who responded were unaware of their transfusion history; of these, fewer private sector patients (28 [37%] of 75) than ANMC patients (47 [65%] of 72) were unaware ($\chi^2 = 11.48$; $P < .001$).

COMMENT

The goal of this lookback program was to inform NICU transfusion recipients from 2 distinct groups, those who received care in an integrated health care system and the private sector, of their risk for HCV infection. There were significant differences in our ability to locate patients cared for by the integrated health care system compared with the private sector, with 84% of recipients locatable from the former and only 40% from the latter. The primary difference was that for a majority of ANMC patients we had access to a continuous medical record and could therefore identify, for example, name changes due to adop-

tion or marriage and a recent or current mailing address. In contrast, for many private sector patients, their stay in the NICU was the end point of their medical record that was available to us, thereby limiting our ability to resolve incomplete or outdated name and address information. Although we have no way to confirm this, it is possible that persons cared for in the private sector moved out of state more frequently than those who were Alaska Native and received their care at ANMC.

There were also significant differences in the NICU patient's response to notification as 55% of those cared for by the integrated health care system vs only 20% of those from the private sector were screened for HCV infection and/or returned the questionnaire. One limitation is that a potential bias may be present in that there could be differences in persons who responded to the notification letters regarding anti-HCV screening compared with those who did not respond. This bias could be more prevalent in recipients from the private sector since only a minority returned questionnaires. In addition, we have no way of determining what proportion of private sector patients obtained screening and chose to not return the questionnaire, potentially resulting in a misjudgment of the effectiveness of this program in the private sector.

The prevalence of HCV infection among ANMC patients (3%) was slightly higher than that found in a previous general lookback program performed in adults and older children at ANMC (2%)¹³ and twice that (1.4%) found in a Canadian lookback program involving persons who received transfusions as a neonate.⁹ We found the risk of HCV infection was significantly associated with increasing number of transfusions, but we were unable to show a statistically significant increase in risk between periods before and after surrogate screening was implemented, as has been previously reported.¹⁸⁻²⁰ Our finding is likely due to the fact that the number of patients tested in this lookback program was too small to detect any differences. However, over these periods, there was a decline in the percentage of those anti-HCV positive (before surrogate testing in 1986, 6%; after surrogate testing, 4%; first- and second-generation testing, 0%), which may be attributable to a practice implemented around 1985 at the Providence Alaska Medical Center NICU to reduce donor exposure by having a limited number of designated donors and fractionating units of blood into aliquots for multiple use in the same NICU patients. Determining the existence of other risk factors for HCV was not part of this lookback program. However, subsequent to it, 4 of the 6 anti-HCV-positive ANMC patients enrolled in a population-based HCV study,²¹ 3 of whom reported no additional risks and 1 who reported a history of injection drug use (unpublished data). Data on risk factors for the other 2 ANMC patients and 1 private sector patient are not available.

In this lookback program, we found that 51% of persons asked were unaware that they or their child received transfusions as a neonate. Similarly, 49% of those queried in a Canadian NICU lookback program denied knowledge that their child had received transfusions.⁹ It is possible that some parents never knew about their child's transfusion since obtaining consent for blood product transfusions was not standard practice during some

Table 2. Prevalence of Anti-HCV in Alaska Native Medical Center Patients by Date of First Transfusion

Anti-HCV Test Result	No. (%) of Patients			
	Group 1*	Group 2†	Group 3‡	Total
Negative	67 (94)	50 (96)	28 (100)	145
Positive	4 (6)	2 (4)	0	6
Total	71	52	28	151

Abbreviation: anti-HCV, hepatitis C antibody.

*Received transfusion before September 1986 (prior to initiation of surrogate testing [serum alanine aminotransferase and antibody to hepatitis B core antigen]).

†Received transfusion between September 1986 and April 1990 (initiation of surrogate testing to implementation of first-generation anti-HCV test).

‡Received transfusion between May 1990 and June 1992 (time from first- to second-generation anti-HCV test).

Table 3. Anti-HCV Screening by Number of Transfusions Received Among Alaska Native Medical Center Patients*

Anti-HCV Test Result	No. (%) of Patients				Total
	1 Transfusion	2 Transfusions	3 Transfusions	≥4 Transfusions	
Negative	31 (100)	19 (95)	17 (89)	62 (95)	129
Positive	0	1 (5)	2 (11)	3 (5)	6
Total	31	20	19	65	135

Abbreviation: anti-HCV, hepatitis C antibody.

*Number of transfusions received was missing for 16 patients who were anti-HCV negative.

of the periods covered by this program. It may also be possible that they simply forgot because studies have demonstrated suboptimal retention of information by parents during periods of emotional distress.^{22,23} There may have also been a response bias because only the data from patients or their parents who chose to have an HCV test or return the questionnaire were available for analysis.

Although determining the costs associated with conducting this lookback program was not a program objective, we can make an estimate of costs based on previous estimates for a lookback program of children and adults who received a transfusion between 1980 and 1992 at ANMC.¹⁷ This estimate took into consideration personnel and data management time and materials costs for a cost of \$56 per patient sent notification. For the current program, we estimated that personnel and data management time expended were approximately twice that of the previous program because we were required to enter and review data from multiple sources and conduct thorough public access and hospital database searches for private sector patients' mailing addresses. Consequently, based on our previous estimate, a conservative cost per patient sent notification under this lookback program would be \$105.

A majority (64%) of persons selected from the NICU logbooks had no evidence of a transfusion, suggesting that cost savings may have been realized had we conducted a lookback program exclusively using blood bank records. However, Alaska blood bank records did not specify whether a patient was in the NICU and excluded key patient information such as ethnicity, date of birth, intake, and hospital discharge or death.

We found that a general lookback program to identify children and young adults who had received trans-

fusions in an NICU before July 1992 was successful among persons receiving their care in an integrated health care system, but it was much more difficult and not very productive among those in the private sector. Managed care has become an important component in health care delivery in the United States over the last 2 decades, and we recognize that prior to 1992 private practice predominated in the health care environment. Our results suggest that programs would likely be more successful when conducted within managed health care systems vs the private sector. However, under either situation, program success would be dependent on the availability and accessibility of past hospital and blood bank records, searchable public access and medical databases, and, notably, sufficient human and financial resources to carry the program out. Thus, we suggest that the outcome we experienced be considered when determining the efficacy of implementing such a program. Moreover, our experience should demonstrate to others the difficulties and limitations encountered if similar programs were conducted in communities where the private practice of medicine predominated prior to 1992.

In conclusion, the Centers for Disease Control and Prevention recommends HCV screening for persons who received transfusions before July 1992.¹⁴ Given that our data demonstrate that a substantial proportion of former NICU patients are unaware of their transfusion history and potentially their HCV serostatus, health care professionals should similarly consider a history of NICU admission as a potential risk factor for HCV infection. The opportunity for pediatricians to screen persons who received blood transfusions before July 1992 for HCV infection is waning since those who received transfusions as late as this date are now at least 14 years of age. We therefore sug-

gest that it would be prudent for health care professionals to consider screening persons 14 years or older who have a history of an NICU admission before July 1992.

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Correspondence: Henry H Cagle, BS, Liver Disease and Hepatitis Program, Alaska Native Tribal Health Consortium, 4315 Diplomacy Dr, ANC-HEP, Anchorage, AK 99508 (hhcagle@anmc.org).

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Correction

Incorrect Trial Registration Identifier Number. In the article titled "YOUTH: A Health Plan-Based Lifestyle Intervention Increases Bone Mineral Density in Adolescent Girls," by DeBar et al published in the December issue of the ARCHIVES (2006;160:1269-1276) the trial registration identifier number on page 1269 should have been NCT00067600.