

FOIA MARKER

This is not a textual record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

Collection/Record Group: Clinton Presidential Records
Subgroup/Office of Origin: Office of Science and Technology Policy
Series/Staff Member: Jerold Mande
Subseries:

OA/ID Number: 13034
FolderID:

Folder Title:
Hepatitis C

Stack:	Row:	Section:	Shelf:	Position:
S	66	4	3	2

To: Donna Shalala
From: Chick Koop
Re: My Concerns About Hepatitis C
Date: December 15, 1997

General

Thank you for the role that you, personally, and the Department have played in convening the NIH Consensus Conference on Hepatitis C in March, 1997 and having the Advisory Committee on Blood Safety and Availability look at Hepatitis C in August, 1997. I am particularly pleased that you moved so quickly to make a decision on the Advisory Committee's recommendations.

Although the epidemic of Hepatitis C does not pose the same kind of threat to the population that was the case with AIDS, my experience on the front line during the first eight years of that epidemic leads me to raise several concerns that I would feel better about if I knew I had shared them with you.

The epidemic of Hepatitis C is not contained and there are a tremendous number of things we do not know about the disease itself, its epidemiology, its mode of transmission, its treatment, and the management of information to put the government in the best light possible both domestically and internationally.

- There is great political advantage in visibly taking control of a Hepatitis C campaign: Hepatitis C is a major disease affecting about four times as many people as are now HIV-positive and unfortunately most of whom are unsuspecting. The European Economic Community, for example, rates it as one of the ten major health problems facing Europe in the next decade.
- It is estimated that 4 million people in the United States are infected but only 5% of them know it. Many of these are not folks with deviant behavior but are mothers and children who received transfusions without knowing the implication of disease. This is a huge reservoir of disease in this country about which we are doing nothing in the chronic phase.
- The public health community is justifiably very concerned as it becomes clear that many mainstream Americans are HCV-positive; mothers who had cesarean sections and received transfusions, low birth weight babies who receive transfusions, young people with serious surgical problems or injuries that were treated by blood transfusion.

- The management of information about the HCV epidemic is a public relations nightmare. Activists in Canada have succeeded in putting the government in a bad light because they have convinced the man in the street that the government entered the Hepatitis C arena too late. There will be class action suits here in the not-too-distant future and the government must avoid the appearance of having either covered up the significance of HCV or being too late in appreciating its danger. No one else in the public health community is going to provide leadership and so it remains for the Department to do so. The lookback at transfusion as a cause of HCV infection provides the opportunity to play such a role.
- It is estimated that in the early years of the next century more people will die of HCV infection than from AIDS. Yet only acute Hepatitis C, which is very hard to detect, is reportable; indeed CDC specifically warns practitioners against reporting chronic HCV infections.
- There is some evidence that we might be on the verge of new treatments for Hepatitis C with a far greater potential for cure and we therefore need to look for ways to screen and offer treatment.
- The economic and health impact of prevention in HCV disease is extraordinarily important. The cost to the government of liver failure, liver cancer, and liver transplants are enormous and the rates are growing.

DHHS Efforts

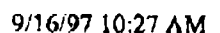
- HHS needs to assume the leadership role for the management of HCV infections.
- The effort of the Department in coming to grips with the lookback at transfusions before 1992 should not be the only strategy used in getting a handle on the management of HCV risk and its consequences. There are things about HCV that are reminiscent of my experience with HIV in the early days. With four times as many people now infected with HCV than with HIV, HCV will require the same kind of coordinated federal agency response that we used in the management of AIDS.
- We have a window now, before those infected with HCV in the 1960s and 70s who have not yet shown evidence of chronic liver disease begin to do so. Education, screening, and treatment is possible to prevent premature death and further spread of the disease.
- There is so much we do not know about the disease that in addition to the aforementioned, we do have a commitment to do research into as many aspects of HCV as possible.

- In the early days of HIV there was a single office within the Secretary's office to coordinate HIV efforts. That might be a commendable procedure in the present situation.
- As always, we have to look at the issues of how to provide and pay for testing and treatment. This would include how Medicare and Medicaid pay for Hepatitis C testing and treatment.

The Role of CDC

- I have met with CDC and it is my belief that they do not have sufficient funding to do the major projects that should be undertaken and to assert the leadership that is really their responsibility.
- Certainly CDC, now reporting only acute Hepatitis C cases, does not have the funding, and perhaps not the inclination, to begin reporting chronic disease. The reporting forms limit the practitioner to reporting only acute cases, of which there are only 4,500 per year. This may be a very low figure because the admonition from CDC not to report chronic Hepatitis C may actually result in an under-reporting of acute disease as well.
- Some states are collecting data on all cases of HIV infection. Perhaps this could be extended more generally and then leave it to CDC to sort out the information collected.
- A few states are already ahead of the federal government in their perception of the gravity of the situation with HCV (Massachusetts, Missouri, New Mexico, Ohio, and New Jersey). With a limitation on funds at CDC perhaps a pilot program with these states would be one of the best ways to assess the technical challenges of a nationwide program.


 The image shows a small, dark, textured object, possibly a seed or a piece of wood, with a rough, irregular surface. It is positioned in the bottom left corner of the page.



The first test, developed in 1989 and 1990, helped blood banks screen out infected donors but had a high "false positive" rate.

The advisory committee concluded that searching back further would bear few returns because there would be many "false positives," many of the transfusion recipients have died or relocated, and most blood banks and hospitals have since destroyed records identifying recipients. The panel also sought a broader education campaign to alert all high-risk groups, including drug users who shared needles and anyone who had a transfusion before 1992, to take a hepatitis C test. Transfusion recipients are believed to account for only about 8 percent of those infected.

But critics fear such a campaign would fall short of reaching many of the 300,000 transfusion recipients believed to have gotten tainted blood because many never knew of or have forgotten about their transfusions. One member of the advisory committee, Michigan State University hematologist John Penner, said that the recommended plan amounts to withholding "life-saving" information from some people. Recent research suggests that hepatitis C progresses more rapidly in people infected through blood transfusions.

Educating the public

Arthur Caplan, a former University of Minnesota bioethicist who chairs the advisory committee on blood safety, acknowledged the shortcomings of the proposal. "You aren't going to reach those people in all likelihood," he said of people who are unaware they had transfusions.

Caplan and Koop both said they hope that an education campaign will seek to point out that women who have had C-sections or people born preterm may have received transfusions and should undergo hepatitis C testing.

Once people become aware they are at risk for the disease, they can ask their doctors to give them a relatively inexpensive blood test. While treatment options for those afflicted are limited, the immune system-boosting drug alpha interferon has worked to control the virus in about 20 percent of victims whose infections have not reached advanced stages. Researchers are optimistic that new experimental therapies combining interferon with other drugs will raise the success rate.

Experts say that until the mid-1980s, when blood banks began to improve donor screening, the risk of contracting the virus from a blood product was as high as 40 percent. For example, an estimated 90 percent of the nation's 20,000 hemophiliacs, who frequently receive donated blood-clotting factor, are infected with hepatitis C.

Women who underwent C-sections, the most common surgical procedure in the United States, are believed to make up one of the larger groups to receive transfusions. The American College of Obstetricians and Gynecologists said that 800,000 to 900,000 C-sections have been performed annually since the early 1980s, up from the 1970s, when 200,000 to 600,000 C-sections were performed each year. There are no figures on the percentage of C-sections that

lead to transfusions, but experts and several studies have suggested that 1 to 5 percent of these women got blood until doctors grew more conservative amid the AIDS epidemic in the mid-1980s.

The National Center for Health Statistics said 20,650 Caesarean sections were performed in Minnesota from 1990-1992, but it has no data available on prior years. Assuming those numbers reflected a long-term trend, thousands of women in the state received transfusions during a period when the hepatitis C risk was high.

Dr. Bruce Flamm, a clinical professor at the University of California, Irvine who is an expert on C-sections, said that "it would be pretty unlikely that they women would get a blood transfusion and not know it. The bag is hanging right above you. . . . The bag is obviously red."

But Koop said that all too frequently, "somehow or other, nobody takes the trouble to say, 'We gave you a transfusion.'"

Looking for victims

Elizabeth Webb, 40, of Iowa City, Iowa, thinks she contracted the disease when she received a transfusion after delivering her first child by C-section in San Francisco in 1981. She said she periodically suffered flulike symptoms for much of the next eight years before she was tested for hepatitis C. Interferon treatment at the Mayo Clinic in Rochester, Minn., appears to be helping her, she said.

Webb now produces an on-line magazine for hepatitis C victims. She said she has heard from other women who think they got the virus from transfusions after delivering babies.

No figures are available on the number of preterm babies who have received transfusions. Since 1981, 6.8 to 7.5 percent of babies born in the United States have been underweight, or below 5.5 pounds, and 9 to 11 percent have been premature, according to the National Center for Health Statistics.

Dr. John Fangman, a neonatologist at Children's Health Care-Minneapolis, said that the percentage of babies born prematurely -- before the 37th week of pregnancy -- has ranged from 5.5 to 6 in Minnesota in recent years, below the national average. He said that "a very high percentage" of babies weighing under 2 1/2 pounds receives blood transfusions, mainly to compensate for blood lost during frequent sampling to monitor their conditions.

Dr. William Hoots, a pediatrician who serves on the federal advisory panel and heads a hemophilia clinic in Houston, said the federal education campaign should "target pediatricians who follow those children" so they can alert them of the hepatitis C risk.

But Fangman said that when he has tried to monitor the development of preterm babies for even two or three years, "people have moved so many times that it's just about impossible to locate them."

Related items

-  [Talk about health issues](#)
-  [What you can do](#)

Koop said it also may be difficult to persuade cost-conscious managed-care networks to assign staff members to comb through records in search of transfusion recipients.

records in search of transfusion recipients.

startribune.com

Nation | World

List

© Copyright 1997 Star Tribune. All rights reserved.

Risk of Hepatitis C Transmission Through Cesarean Section

- There has been growing concern about transmission of hepatitis C through blood transfusions that occurred before 1992, when an adequate screening test first became available.
 - Last week, the HHS Advisory Committee on Blood Safety and Availability recommended a targeted lookback program to identify and notify recipients of blood contaminated with hepatitis C virus (HCV).¹
 - The targeted-lookback would go back only to 1987.
- The lookback will not be adequate to deal with one particularly significant area of transmission of hepatitis C -- Cesarean-delivery surgery.
 - Women who had cesarean-delivery surgery were often given whole blood, and a proportion (risk estimated to be 10.2% during the 1974 - 1981 period) of these would have contracted hepatitis C as a result.²
 - Based on current knowledge of hepatitis C disease, most of the women infected during or following Cesarean-delivery between the late 1960s into the early 1980s are entering the years of greatest risk for developing serious liver disease.³
 - For many of these women, notification and treatment now could prevent more serious illness, liver cancer, liver failure or transplant.⁴
- Transmission of HCV through C-section is significant for a number of reasons:
 - C-section is the most common surgery in the U.S.⁵ -- slightly fewer than 1 million babies each year are delivered by Cesarean surgery⁶. One third (300,000+) of these women have delivered children by Cesarean surgery in the past, placing them at higher cumulative risk⁷.
 - Often C-sections got transfusions
 - In the 1970s and early '80s, as many as 20% of C-section patients were given transfusions during surgical delivery or in the recovery period.⁸

1 Advisory Committee on Blood Safety and Availability. Resolution of the Advisory Committee. August 13, 1997.

2 National Health, Lung, and Blood Institute's Blood Specimen Repository Report. Division of Blood Diseases and Resources. Period of Contract: June 28, 1974 through June 30, 1981.

3 "Management of hepatitis c." NIH Consensus Development Statement 1997 March 24-26;15(3):pp.20.

4 Hoofnagle JH, Di Bisceglie AM. Drug therapy: the treatment of chronic viral hepatitis. The New England Journal of Medicine. 1997;336:347-356.

5 Goer H. Obstetrical Myths Versus Realities, Bergin & Garvey, 1995.

6 MYSR Vol. 45, No. 11(S). Report of Final Natality Statistics, 1995. 80 pp. (PHS) 97-1120.

7 MYSR Vol. 45, No. 11(S). Report of Final Natality Statistics, 1995. 80 pp. (PHS) 97-1120.

8 Bukovsky I, Schneider DF, Langer R, Arieli S, Caspi E. Elective caesarean hysterectomy. Indications and outcome. Aust N Z J Obstet Gynaecol 1989;29:287-90.

- A study from 1984-1987, after blood use decreased significantly, indicated that 5% of all C-sections required transfusion⁹.
 - According to experts in transfusion medicine, modern surgical practice has been "guided by the belief that a hematocrit value of less than 30% indicates a need for perioperative red cell transfusion...although firm evidence to support the practice is difficult to identify."¹⁰
 - 77% of women in the 1984-1987 *Transfusion* study received 2 units or greater, only 12% received a single unit transfusion.¹¹
 - A study by a group of obstetricians contrasting vaginal and cesarean birth considered the need for blood transfusion to be a "minor complication"¹²
 - A 1992 USC study showed that 6.8% of women receiving C-sections were transfused.
- Transmission of HCV through transfusion related to C-sections would have been fairly high
 - HCV population infection rates were higher in the mid-1980s than they are now -- 2.9% of the general population was infected with HCV.¹³
 - An NIH study in the mid-1980s showed that 7-10% of patients getting a transfusion would have developed hepatitis C after surgery.¹⁴
 - Most women getting C-sections would not have known that they got a transfusion. For this reason, a general education campaign for people getting transfusions before 1987 would not alert these women to the need for an HCV test.
 - In a 1993 USC study -- only one-fourth of the women who had transfusions during or following childbirth had knowledge, before the birth, of potential complications in their pregnancy that would result in the need for transfusion.¹⁵
 - Two-thirds of all whole blood transfusions are given during surgery, in other words, during the perioperative period.¹⁶

9 Camann WR, Datta S. Red cell use during cesarean delivery. *Transfusion*. 1991; 1:12-15.

10 Perioperative Red Cell Transfusion. NIH Consensus Conference Consensus Statement. 1988, Jun 27-29;7(4):1-19.

11 Camann WR, Datta S. Red cell use during cesarean delivery. *Transfusion*. 1991;1:12-15.

12 McMahon MJ, Luther ER, Bowes WA, Olsham AP. Comparison of a trial of labor with an elective second cesarean section. *New England Journal of Medicine*. 1996;335:689-695.

13 National Health, Lung, and Blood Institute's Blood Specimen Repository Report. Division of Blood Diseases and Resources. Period of Contract: June 28, 1974 through June 30, 1981.

14 National Health, Lung, and Blood Institute's Blood Specimen Repository Report. Division of Blood Diseases and Resources. Period of Contract: June 28, 1974 through June 30, 1981.

15 Sherman SJ, Greenspoon JS, Nelson JM, Paul RH. Obstetric hemorrhage and blood utilization. *Journal of Reproductive medicine*. 1993; (38) 12:929-34.

16 Perioperative Red Cell Transfusion. NIH Consensus Conference Consensus Statement. 1988, Jun 27-29;7(4):1-19.