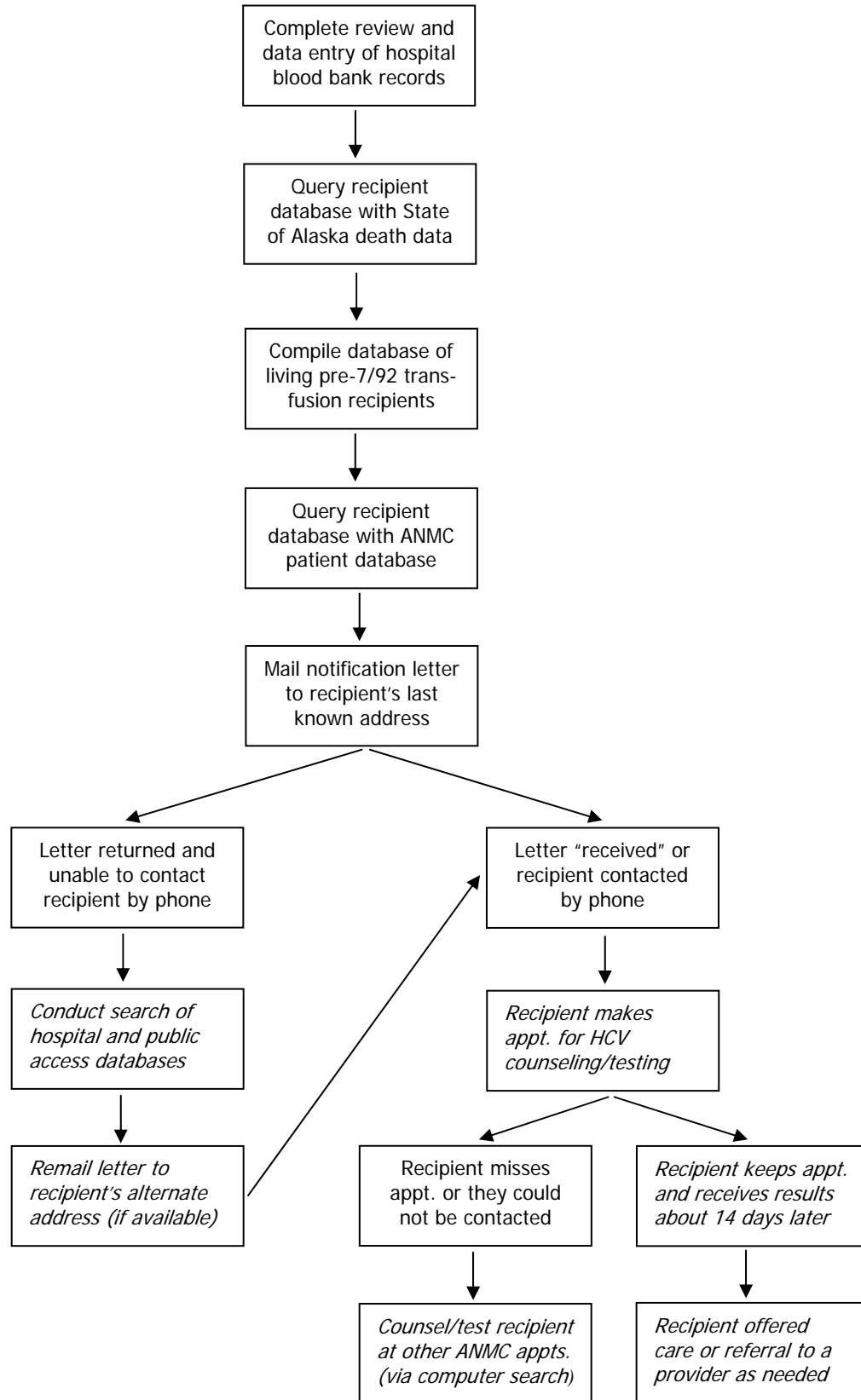


Alaska Native Medical Center (ANMC), Transfusion LookBack Project:  
 Recruitment of Pre-July 1992 Transfusion Recipients for Hepatitis C (HCV) Screening\*



\*This procedure was used for transfusion recipients receiving care at ANMC and it was recommended for the recruitment of those receiving care at other hospitals or through private practice physicians.

# **HCV Counseling and Testing Manual: The LookBack Project Risk of Exposure to Blood Transfusion or Blood Products Prior to July 1992**

## **Purpose of Hepatitis C (HCV) Counseling:**

The primary purpose of HCV transfusion risk (Lookback) project is to provide counseling and testing to persons potentially exposed to HCV through transfused blood products prior to July 1992. The program is designed to instruct, educate and motivate persons who respond to a transfusion before 1992 notification letter with goals to:

- Identify persons who have potentially been exposed to HCV infection through a blood transfusion or blood product prior to July 1992.
- Inform persons about the small (about 5%) but potential risk of exposure to HCV from blood product transfusion, solid organ transplant or cardiac surgery with blood transfusion before 1992 when sensitive tests became available to detect HCV.
- Provide basic information about benefits and drawbacks of testing for HCV to persons exposed as defined above and offer testing to these individuals.
- Offer an empathic and supportive environment to pursue and receive HCV antibody test results.

## **After completing HCV transfusion exposure counseling and testing, the program is:**

To provide:

- Counseling, education and appropriate referral services for persons testing positive to HCV.
- Partners of HCV positive persons with prevention information and to assist those partners in obtaining services such as HCV counseling, testing and other support.

## **COUNSELING AND TESTING**

As a response to the HCV **Notification Letter to those who may have received a Blood Transfusion** (See copy of Letter Pg.9) prior to 1992, clients will call for more information and appointments. This counseling and testing manual is designed to address this and to be delivered primarily in-person but may be done over the phone or in written form as circumstances dictate.

## **Introduction**

The client is more likely to retain the information you discuss if s/he has an informational handout to refer to during the session and to take home. The client's language and reading level should be considered in selecting these materials and in your communication with the client. Make reference to the pamphlet sent with the letter and/or offer CDC's "***Get Tested for HEPATITIS C***" pamphlet, use for review/give copy.

**\*Information:** Alternate CDC handout "Hepatitis C-You may be at risk if..." Sample copies on Pg. 9.

- Introduce yourself and explain your professional role. Ask about receipt of notification letter and brochure: "Hello, I'm Your Name of the Hepatitis Program, I am a nurse trained to talk about transfusion risk and HCV infection. We sent you a letter and a pamphlet explaining why we felt it was important for you to come today, do you have any questions to start?"
- Explain the purpose of the session:

"The purpose of speaking with you today is to share information on the potential risk of exposure to hepatitis C virus (HCV) from a possibly contaminated blood product or transfusion or organ transplant before July 1992 when sensitive tests became available to detect HCV."

## General HCV information

Hepatitis C is one of several viruses that cause viral hepatitis. Hepatitis C is spread mostly by human blood-to-blood exposure and 70-85% of persons infected with hepatitis C carry the virus for the rest of their lives. Somewhere around 30% of those infected with HCV will clear the virus naturally. Most people infected with hepatitis C do not know they are infected, have no symptoms, and lead normal lives though they will have some mild damage to their liver over time but not enough to make them sick. About 25% of those infected will develop more severe damage called cirrhosis or scarring of the liver and some of those may progress on liver failure. Being infected with HCV makes a person 20 times more likely to get liver cancer than those with out chronic viral hepatitis. There is no vaccine for hepatitis C at this time though there are some treatment options available and much research with a promise of more potential choices on the horizon.

### **HELP CLIENT DETERMINE NEED FOR TESTING**

#### **Using open-ended questions when possible will help.**

Determine if the client has been tested before.

- “Were you ever tested in the past for Hepatitis C? What were the reason/s? When were you last tested? Where? Do you know the test result?”
- “Were you ever successful in donating blood in the past? Anytime after 1992?”

Determine if the client wants testing and that is the reason for coming here today.

- "Thank you for coming in today to listen to what information we have to offer and to take the test. We feel you've made a good decision."

### **I. Pre-Test Counseling**

- Definitions:

**Hepatitis C Virus:** Hepatitis means *inflammation* of the liver. Hepatitis C is one of *several viruses* that cause viral hepatitis and was *previously called non-A, non-B hepatitis*. The most commonly talked about of the hepatitis viruses are A, B and C. The hepatitis viruses are *not related* and *act differently*. HCV is spread primarily by human blood to blood contact as when a person's blood comes into direct contact with an open or bleeding area on another person, or by a contaminated blood transfusion or tissue/organ transplant, or needle. The most common way to get HCV is injecting drug use (IDU), even 1 time.

**Reason for testing:** To find out if you are infected with HCV.

#### **Examples follow:**

- Test purpose--*"To determine if you are infected with HCV."*
- What the test can tell you --*"This is a test for HCV infection--it can tell you if you are infected with HCV but it does not mean you have liver disease or predict if you will be ill. The majority of persons with chronic HCV will not develop severe liver disease."*
- HCV diagnosis--Emphasize: *"A positive antibody test does not mean that you still have hepatitis C virus in your blood-remember that up to 30% of those infected clear the virus with their body's own defense system. If you are antibody positive, we will need to test for virus to see if it is still present."*

The transfusion exposure risk is from blood/products prior to July 1992 with the donor status unknown. Counselors need to emphasize the low, ~5% risk for HCV recipients of blood products from donors who were not tested for HCV at that time. Most persons receive at least 2 units of whole blood, platelets, or fresh frozen plasma from different donors. Single donor transfusion is uncommon, though it has a slightly reduced risk.

This includes receiving:

- Blood transfusions or blood components [platelets, (whole blood) red cells, washed cells, and fresh frozen plasma,] including cardiac surgery using bypass technology, before July 1992.
- Recipients of clotting factor produced before 1987
- Recipients of a solid organ transplant before July 1992.

**Testing: Verbal Informed Consent-We do not need to have written consent for testing but it should be noted on the pre-printed PCC form created for HCV counseling, that patient was counseled and agreed to HCV testing.**

## **Benefits of Testing**

- Explain benefits of testing. “ By testing and knowing you have HCV, there are things you can do to reduce liver damage, maintain careful observation over time and get early medical intervention.

## **Risks of Testing**

- Inform client that if he/she test positive for HCV, results will be forwarded to the Alaska State Health and Social Services, Division of Epidemiology.  
*“Your results are confidential and maintained secure within our system. No one will get you test results without your signed release of information through medical records. We are required by Alaska State regulation to forward positive test results to Alaska State HSS, Division of Epidemiology. Mandatory reporting includes this information: Name, DOB, Gender, Race, Date of Onset, and last known address.”*
- Inform client that a positive HCV result may affect future health or life insurance applications or premiums. Once diagnosed as HCV positive, you may be denied health or life insurance or be required to attain these benefits at a higher cost.

\*Documentation: Use Counselor’s Checklist, Pg.10 and Pre-printed PCS encounter form, Pg.11 titled: Counseling and Testing-LookBack. The signed/dated original PCS goes in patient medical record.

**Describe the procedure.** Explain what happens if s/he decides to take the test:

- *“Blood will be drawn from your arm. We will take a small amount of blood, a teaspoonful or two, for testing. These results will be available within 2 weeks.”*
- *“Results will be given to you and no one else, in person or by phone, unless you request otherwise.”*
- *“HCV infection is diagnosed by testing your blood.”*

Test Costs are found in Attachment I, Pg. 8: **Cost Schedule for HCV Testing.**

**Procedure:** Personnel are to:

- Draw 1-7cc (or a second smaller if 1<sup>st</sup> not filled) marble top blood tube. Label as per usual procedure but add **“LookBack-FREEZE”** sticker to the tube and send specimen to the ANMC Laboratory.
- Document date of blood draw in the patient’s medical record on pre-printed PCC.
- Attach lab request for screening from the Viral Hep menu, titled LookBack, choice #39: HCV Ab tests with reflex HCV-RIBA or HCV RNA by PCR. Be sure to apply yellow **“LookBack-FREEZE”** sticker to both the tube of blood and the lab request form.
- Provide patient with an opportunity for more education and information on HCV by:
  - Making a follow-up appointment or arranging to give results either by phone or letter.
- Provide resource and informative material to patients. **See Addendum: Pg.7-Patient Resources, Support & Other Information and Pg.8-Hepatitis C Providers.** Offer a copy to patient/extras in back pocket of manual.
- Record on pre-printed PCC for medical record, keep copy and Counseling Checklist for project file.

- **CLIENT'S DECISION ABOUT TESTING**

**Transfusion risk**--"Some people choose not to take the test, and rather take appropriate steps to avoid acquiring or passing the virus. Other people find the test helpful in making meaningful plans for their future. If you take the test and find that you're negative, you'll know that you were not infected by a blood transfusion. If you test positive, you'll know what you can do to protect others and to help yourself to avoid illness, get regular on-going care and delay developing damage to your liver."

**Ask the client if s/he wants to proceed with the test and what plans s/he has for dealing with results.**

**Examples of questions are:**

- What other questions do you have about testing? What would you like to do about taking the test?
- Assess with the client how s/he will react to and/or use the test results. Any HCV antibody test result can have a significant psychological impact on both the individual tested and those who are close to him/her. These or similar questions can help:
  - What are your expectations about the test result?
  - How do you think you will react? What will you do if you feel this way?
  - What would a positive test mean for you?
  - What plans have you made to tell anyone that you've had an HCV test?

**Giving test results:**

- Results are always **best given in person**: "It is best to make an appointment within the next two weeks to give you your test results, could we make that appointment now?"
- If client is reluctant to come back or circumstances make this too difficult/inconvenient to arrange, then offer other alternatives:

**Results can be given verbally; in person or by phone or in writing, ask patient's preference.**

*How would s/he like to receive test results, by phone or written?*

- Results should be available within 2 weeks.
- Would s/he like their results by a letter, be called by us or call us back?
- If the results were back sooner, would you like us to call you sooner?
- Does it matter how we share these results if they are positive or negative?

**Record in the medical chart when and how the results were reported to the patient. Use Pre-printed PCS form for test results. Original goes in chart.**

*If test results are Positive, and given by phone or in writing, suggest patient make a follow up appointment for more information and referral services. Encourage the client to return to discuss his/her situation and the services available to support changes to reduce risk and to monitor health status. Emphasize that s/he should plan to return to clinic, even if s/he has second thoughts about the test results.*

## **Information for Counselors, not for patient information but for better understanding**

**Types of testing usually ordered:** HCV by EIA, HCV by RIBA, and/or HCV RNA by PCR

### **HCV Test Definitions:**

- **HCV by EIA:** The HCV by EIA test refers to an enzyme-linked immunosorbent assay. The HCV by EIA test detects antibodies to HCV, and is the first test performed for serologic screening of HCV infection. A positive HCV by EIA test in a person with known high-risk status for HCV infection or active liver disease has a high positive predictive value and may be the only test necessary to confirm the disease. (It is repeated, ie done twice, on that specimen before reported as positive.) However, a positive result on the HCV by EIA test in a person without known risk factors for HCV infection or active liver disease, may be a “false positive” test and requires a confirmatory test. The potential for a false positive test is much higher in non-injecting drug users (IDU). Therefore, confirmatory testing is highly recommended in non-IDU that test positive by the HCV by EIA test.
- **RIBA:** Recombinant immunoblot assays (RIBA) also tests for antibodies against HCV and is used to confirm a positive ELISA result.
- **PCR:** Polymerase chain reaction (PCR) assays test for HCV RNA in the blood. PCR is used as a confirmatory test, to assess viral load for treatment candidacy and to monitor response to treatment.

You may need to explain the meaning of tests, provide or reinforce information about HCV test results needing verification (RIBA and or PCR.) Know that there are three possible test results with the HCV RIBA: negative, positive or indeterminate. We will use PCR testing to evaluate the indeterminates.

### **Other stuff:**

**Provide information on preventing the spread of HCV infection and to facilitate a person’s ability to identify and modify behaviors that may place him/her at risk for HCV infection.**

- To provide, either directly or through referral, additional prevention services that will enable uninfected persons who are at continuing risk for HCV infection to minimize their risk of acquiring HCV. What makes you think you should be tested for HCV?"
- "When and in what way were you last exposed to someone who might have HCV?"

Reason/s for coming in: assess & record the client’s reason for testing & risk of HCV infection if other than transfusion notification letter: (if the situation warrants, you can use the HCV Natural History Questionnaire as a guide to assessing their other self reported risk factors.)

Discuss the following only if it comes up in the discussion-*for counselor’s information, not to emphasize because will cover more intensely if testing results confirm HCV+ status in HCV Manual Part II: Counseling those at Higher Risk.* If the session was not initiated by the client, but is in response to a notification letter cautioning possible transfusion exposure risk, explain how HCV testing can be of benefit. See benefits/Risks in next section. Remember: Clients may have misconceptions about the test and may actually be seeking (and need to be referred to) other services.

- Concerns about symptom or risk behaviors. Do you have plans to address risk behaviors if you should test HCV seropositive? What changes will you make in your life if you test positive?
- Court ordered, curiosity: Heard, saw, read about in Media, the WEB and concerned may be at risk
- Substantial exposure; needle sharing injecting street drugs or blood exposure to needle sticks or non-intact skin or in mucous membranes, history of snorting cocaine, multiple body piercing or tattoos, sex worker/worked as a prostitute or sex with known HCV + persons/injection drug user.
- History of multiple sexually transmitted diseases
- If you get questions on **Confidentiality**, explain:
  - That information shared in the session will be confidential and what that means.
  - How our institution will use and maintain this information and when it can be shared.

## **Patient Resources and Other Information**

Persons requesting additional information on HCV may be referred to:

- **The American Liver Foundation:** 1-800-465-4837 (or 1-800-GO LIVER); 1-888-443-7222 (or 1-888-4 HEPABC); <http://www.liverfoundation.org>
- **Hepatitis Foundation International:** 1-800-891-0707; <http://www.hepfi.org>
- **Centers for Disease Control, Hepatitis Branch:** 1-888-443-7232; <http://www.cdc.gov/hepatitis/>
- **Alaska Native Medical Center Hepatitis Program:** (907) 729-1560 or 1-800 6554837; <http://www.anthc.org/cs/chs/hep>
- **Public Health-Alaska State HSS, Div. Of Epidemiology:** (907) 269-8000, <http://www.alaska.state.health>
- **National Foundation for Infectious Diseases (NFID):** (301) 656-0003; <http://www.nfid.org/>
- **American College of Gastroenterology (ACG):** (703) 820-7400; <http://www.acg.gi.org/>
- **National Digestive Diseases Information Clearinghouse (NDDIC):** (301) 654-3810 <http://www.niddk.nih.gov>.

## **Hepatitis C Patient Support**

*Requests for information on support groups can be referred to:*

- **Hepatitis Education Project**  
PO Box 95162  
Seattle, WA 98145-2162  
(206) 447-8136  
<http://www.scn.org/health/hepatitis>  
hep@scn.org
- **PATS- Patient Advocacy/Information Telecommunications Systems**  
**Hepatitis Foundation International**  
30 Sunrise Terrace  
Cedar Grove, NJ 07009-1423  
1-800-891-0707  
<http://www.hepfi.org> or [hfi@intac.com](mailto:hfi@intac.com)
- **Local Patient Support Group and Hepatitis C Providers:**

# Lookback Counseling Checklist

Patient Name \_\_\_\_\_

DOB or Chart # \_\_\_\_\_

Transfusion Date \_\_\_\_\_ # Units \_\_\_\_\_

## 1) Purpose of Hepatitis C (HCV) Counseling

\_\_\_\_\_ Identify persons who have potentially been exposed to HCV infection through blood before 1992.

Ask: "Did you know you had a transfusion before?" Yes \_\_\_\_\_ No \_\_\_\_\_

\_\_\_\_\_ Inform persons about the small (about 5%) but potential risk of exposure to HCV

\_\_\_\_\_ Provide basic information about benefits and drawbacks of testing for HCV

2) **Introduction:** "Thank you for coming..." Do the who you are, what you're doing, and why you're here talk.

## 3) General HCV information

\_\_\_\_\_ Ask: "Remember this?" **Show and use pamphlet as you counsel client. Use either CDC handout:**

"Hepatitis C Transfusion Risk..." or "Get Tested for HCV..." Offer a copy to patient.

\_\_\_\_\_ Hepatitis C is virus *previously called non-A, non-B hepatitis*. Best known are A, B, and C. All are different.

\_\_\_\_\_ Hepatitis C is spread mostly in human blood-to-blood contact like a blood transfusion.

\_\_\_\_\_ 70-85% of persons infected with hepatitis C carry the virus in their liver for the rest of their lives.

\_\_\_\_\_ Somewhere up to 30% of those in Alaska infected with HCV will clear the virus naturally.

\_\_\_\_\_ Most with hepatitis C do not know they are infected, have no symptoms, and lead normal lives.

\_\_\_\_\_ All will have some mild damage to their liver over time but not enough to make them sick.

\_\_\_\_\_ About 25% with HCV will develop severe damage called cirrhosis/scarring of the liver and liver failure.

\_\_\_\_\_ There's a 20 fold increased liver cancer risk (HCC) with severe liver disease(scarring/cirrhosis) and HCV.

\_\_\_\_\_ There is no vaccine for hepatitis C at this time and there is no sustained immunity.

\_\_\_\_\_ There are treatment options currently available and new research on the horizon.

## 4) HELP CLIENT DETERMINE NEED FOR TESTING

\_\_\_\_\_ Any previous testing? "Have you ever been tested for HCV before?"

\_\_\_\_\_ Blood donation accepted after 1992? "Were you allowed to donate blood anytime after 1992

\_\_\_\_\_ "Is a blood transfusion your only reason for HCV testing?" Other?

## 5) Reasons for testing:

\_\_\_\_\_ To find out if exposed to HCV through blood transfusion/s at ANMC prior to 1992.

\_\_\_\_\_ To see if HCV is still an active infection in your body. If active, your PCP can assess how severe the disease is.

\_\_\_\_\_ Review blood transfusion risks before July 1992, you were a recipient of either a:

\_\_\_\_\_ transfusion of (whole blood) red cells, or blood components platelets/washed cells/fresh frozen plasma,

\_\_\_\_\_ cardiac surgery requiring transfusion or use of bypass pump technology.

\_\_\_\_\_ other; a solid organ transplant or clotting factor produced before 1987.

## 6) Verbal Informed Consent: Patient was counseled on:

### Benefits of Testing

\_\_\_\_\_ health benefits of early diagnosis of HCV: there are things you can do to decrease liver damage,

\_\_\_\_\_ keep close medical f/u, careful observation over time and early medical intervention.

### Risks of Testing

\_\_\_\_\_ results are forwarded to the State HHS, Epidemiology Dept. as required by regulation.

\_\_\_\_\_ positive HCV result may affect future health or life insurance benefits.

**7) CLIENT DECISION ABOUT TESTING**

\_\_\_\_\_ Agreed to HCV testing or Refused\_\_\_\_\_ and comment\_\_\_\_\_

**8) Describe the procedure.**

\_\_\_\_\_ Draw 1- 7cc tube of blood for antibody testing/attach ***FREEZE*** Label \_\_\_\_\_ Results reported by 2 weeks

**9) Offered Patient Resource information: \_\_\_\_\_**

**10) Request result F/U by: \_\_\_\_\_ a Telephone call \_\_\_\_\_ a Letter Appointment\_\_\_\_\_**

\*\*If unable to reach client within 2 weeks, contact will be attempted by a letter or a phone call.

Does it matter if results + or -? Yes\_\_\_\_\_ No\_\_\_\_\_ Plans for dealing with results \_\_\_\_\_

**Date:** \_\_\_\_\_

**Time:** \_\_\_\_\_

**Signature:** \_\_\_\_\_

## **Example of Notification Letter to Adults Who Received a Blood Transfusion**

To: «Name»

A search of our hospital records indicates you received a blood product transfusion before July 1992. A small percentage of persons who received a blood product before that date may have been exposed to the hepatitis C virus. It is therefore recommended you be tested for hepatitis C.

To get tested for hepatitis C, please call \_\_\_\_\_ or \_\_\_\_\_ to make an appointment in our special Transfusion LookBack Clinic.

Hepatitis C is a newly discovered disease that can infect the liver. Before July 1992 there was no accurate screening test for this viral infection so hepatitis C infection in donated blood was impossible to find. As a result, some persons who received blood transfusions were infected with hepatitis C virus. You'll find a handout on hepatitis C enclosed for your information.

To protect your health, we strongly encourage you to contact our program about your need to be tested.

Sincerely,

Dr. \_\_\_\_\_

**Call \_\_\_\_\_ for Hepatitis C testing.**