

Record 01

Patient ID: IDFLD01

Interviewer's Initials: INTINJT

Name of Center: CNTR

Date of Introduction and Screener (Section A)... Not Keyed
MO DA YR

Date of Telephone Interview (Section B)
MO DA YR
TELINTMO DA YR
TELINTDA YR
TELINTYR

Time Began:
HRBEG MINBEG AMPMBEG
am / pm

Time Ended:
HREND MINEND AMPMEND
am / pm

NATURAL HISTORY OF TRANSFUSION-ASSOCIATED
NON-A, NON-B HEPATITIS

PROXY TELEPHONE QUESTIONNAIRE

INTERVIEWER PLEASE READ:

Assurance of Confidentiality

All information which would provide identification of the individual will be held in strict confidence, and will be used only for purposes of and by persons engaged in the study, unless it is otherwise required by the law.

Section A is not keyed

SECTION A

INTRODUCTION AND PROXY SCREENER

A1. Hello. This is (YOUR NAME) from Westat, Inc. I am calling on behalf of (NAME OF MEDICAL CENTER) in (CITY). May I please speak to (NAME OF PROXY)?

- PROXY AVAILABLE 1 (GO TO A2)
- PROXY TEMPORARILY UNAVAILABLE 2 (GO TO A1a)
- PROXY MOVED/LIVES ELSEWHERE 3 (GO TO A1b)
- PROXY DECEASED OR
PERMANENTLY UNAVAILABLE 4 (GO TO A1c)
- OTHER CONTACT PROBLEM (REFUSAL, LANGUAGE PROBLEM,
OTHER PROBLEM) (FILL OUT A NON-COMPLIANCE FORM)

A1a. When will (he/she) be available? (ATTEMPT TO ARRANGE A TIME TO CALL BACK) Thank you very much for your help.

A1b. Could you please give me (his/her) new address and telephone number? I will try to contact (him/her) there. (RECORD INFORMATION ON RIS) Thank you for your help.

A1c. This is (YOUR NAME) from Westat, Inc. I am calling about an important health study that the (NAME OF MEDICAL CENTER), in cooperation with the U.S. Public Health Service, is conducting with people who were previously enrolled in blood transfusion studies. We contacted (NAME OF PATIENT) in (DATE OF LAST CONTACT) in order to interview (him/her). Now we are calling these patients again to get an update on their health history since last year. If we can't reach the patients, we attempt to interview someone in their place. I would like to speak to a close relative or acquaintance who would be familiar with (Mr./Ms.) (LAST NAME OF PATIENT)'s medical history.

OBTAIN FULL NAME, ADDRESS, TELEPHONE NUMBER, AND RELATIONSHIP TO PATIENT. RECORD INFORMATION ON RIS.

IF PROXY IS DECEASED, RECORD ON RIS. IF THERE IS NO ALTERNATIVE PROXY TO INTERVIEW, CLOSE OUT THE CASE AS AN "0." FILL OUT A NON-COMPLIANCE FORM.

When do you think would be the best time to call? (RECORD ON CALL RECORD) Thank you for your help.

2. (NAME OF PROXY), this is (YOUR NAME) from Westat, Inc., calling on behalf of the (NAME OF MEDICAL CENTER). I am calling about an important health study that the (NAME OF MEDICAL CENTER), in cooperation with the U.S. Public Health Service, is conducting with people who were previously enrolled in blood transfusion studies. I would like to conduct a telephone interview in order to obtain information about (PATIENT)'s health history since last we spoke with (him/her). I understand that you are (the/a) (RELATIONSHIP FROM RIS) of (PATIENT). Is that correct?

YES 1 (GO TO 3)
NO 2

2a. How are you related to (PATIENT)?

RECORD RELATIONSHIP

a. _____ (GO TO 3)
b. DON'T KNOW PATIENT

There seems to be a problem. We may have contacted the wrong person.
Thank you for your help.

COMPLETE A NON-COMPLIANCE FORM.

3. Our records indicate that (PATIENT) was last contacted for this study in (DATE OF last contact).

Is that correct?

YES 1 (GO TO 4)
NO 2
DON'T RECALL 3

IF THE PROXY ANSWERS NO TO QUESTION 3 OR DOES NOT RECALL THE PATIENT'S PARTICIPATION IN THE STUDY, IT WILL BE NECESSARY TO DO SOME PROBING.

We have (PATIENT) on record as participating in a study that was headed by Dr. [NAME OF MD PI] at [CENTER]. At that time (he/she) received a blood transfusion for a certain condition, and was then followed for a few months afterwards to see if (he/she) developed hepatitis or not. Do you remember this study? Several years later (he/she) was contacted again to do another study and then again (he/she) was contacted last year to do an interview.

YES 1 (GO TO 4)
NO 2

There seems to be a problem. I think that I might have the wrong person. Let me check with my supervisor. We may be contacting you again.

4

Recently you were sent a letter by Dr. (NAME OF MD PI) explaining this study. Did you receive the letter?

YES 1
NO 2

INTERVIEWER: CHOOSE APPROPRIATE WORDING BELOW DEPENDING ON WHETHER THE PROXY RECEIVED THE LETTER.

[(IF YES) As you may remember from the letter/(IF NO) In the letter we explained that] – this important study is an extension of the study (PATIENT) participated in/was contacted about in (DATE OF LAST CONTACT). At that time (he/she) was asked about certain health conditions (PATIENT) may have had, particularly hepatitis, after (his/her) blood transfusion many years ago. Now, Westat, Inc., is calling a family member or a friend of (PATIENT) who will be able to answer a few questions for us about (PATIENT'S) health history from (DATE OF LAST CONTACT ON THE STUDY) including (his/her) death. [FOR INCOMPETENT PATIENTS, USE "and today."] Although your participation is voluntary and there will be no penalty if you decide not to do the interview, your cooperation is very important to us. All information you give in the interview will be kept completely confidential in accordance with the law and (his/her) or your name will not be used in any report of the study.

ASK FOR DECEASED PATIENTS.

Before I go any further with this interview, could you please tell me the date that (Mr./Ms.) (LAST NAME OF PATIENT) died and the state that (he/she) died in (RECORD INFORMATION BELOW)

Date of Death: |__|__| . |__|__| . |__|__|__|__|
MONTH DAY YEAR

State of Death: _____

At this time, I would like to verify your address and telephone number(s) at which you may usually be reached.

VERIFY AND MAKE ANY CORRECTIONS ON THE RIS.

In order to complete the second part of this interview I would now like to arrange a time which would be convenient for you to be interviewed on the telephone. Is it possible to do the interview now? It will only take about a half of an hour.

YES 1 (CONTINUE TO SECTION B)
NO 2 (GO TO APPOINTMENT SECTION)

INTERVIEWER: IF PROXY REFUSES OR CANNOT PARTICIPATE FOR SOME REASON DURING ANY PART OF TELEPHONE CONTACT, TRY TO DETERMINE WHY AND ANSWER PROXY'S CONCERN(S) AS BEST AS POSSIBLE. SOME HELPFUL ANSWERS ARE IN YOUR PROCEDURE MANUAL

IF PROXY CONTINUES TO REFUSE, OR IF YOU DECIDE NOT TO CONTINUE, THANK HIM/HER FOR HIS/HER TIME AND COMPLETE A NON-COMPLIANCE FORM.

APPOINTMENT SECTION

During this interview, I will ask you some questions about (PATIENT)'s health history.

I would like to call you next week. Times I have available are: (CONSULT CALENDAR)

INTERVIEWER: RECORD APPOINTMENT TIME ON RECORD OF CONTACTS AND IN PROFESSIONAL APPOINTMENT BOOK. IF PROXY REFUSES TO MAKE AN APPOINTMENT, TRY TO ANSWER HIS/HER CONCERN(S) AS BEST AS POSSIBLE. IF PROXY STILL REFUSES, OR IF YOU DECIDE NOT TO MAKE AN APPOINTMENT, COMPLETE A NON-COMPLIANCE FORM.

I want to thank you, Mr./Ms. (LAST NAME OF PROXY), for your interest and willingness to cooperate in this study. I look forward to talking with you on (DATE AND TIME).

END OF SECTION

INTERVIEWER: RECORD TIME AND OUTCOME OF TELEPHONE CONTACT ON RECORD OF CONTACTS.

SECTION B: MAIN INTERVIEW

MEDICAL HISTORY INFORMATION

I'd like to ask you about some health conditions that (PATIENT) may have had since the time (he/she) was last contacted on the study [DATE].

B1. Since (he/she) was last contacted on [DATE] was (he/she) told by a doctor or other medical personnel that (he/she) had hepatitis or yellow jaundice?

YES 1 (COMPLETE TABLE BELOW)

NO 2 (GO TO B5)

B1

B INUM

| B2. In what year was the hepatitis or yellow jaundice diagnosed? | B3. Did the <u>doctor</u> tell (him/her) that any of the following things caused his/her hepatitis or yellow jaundice this time? (READ CATEGORIES AND CIRCLE ALL THAT APPLY) | B4. What was the name and address of the doctor, and the hospital or clinic where the hepatitis or yellow jaundice was diagnosed this time? | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|--|-----|----|-----------------------------|---|---|-----------------------------|---|---|-------------------------------|---|---|---------------------------|---|---|---|---|---|---------------------|---|---|-------------------------|---|---|-------------------|--|--|---|
| <p>B2A a. 1 9 _ _ YEAR</p> | <table border="1"> <thead> <tr> <th></th> <th>YES</th> <th>NO</th> </tr> </thead> <tbody> <tr> <td>Contaminated water... B3A.1</td> <td>1</td> <td>2</td> </tr> <tr> <td>Blood transfusions... B3A.2</td> <td>1</td> <td>2</td> </tr> <tr> <td>Using a dirty needle... B3A.3</td> <td>1</td> <td>2</td> </tr> <tr> <td>Drinking alcohol... B3A.4</td> <td>1</td> <td>2</td> </tr> <tr> <td>Contact with industrial solvents... B3A.5</td> <td>1</td> <td>2</td> </tr> <tr> <td>Anesthetic... B3A.6</td> <td>1</td> <td>2</td> </tr> <tr> <td>Something else... B3A.7</td> <td>1</td> <td>2</td> </tr> <tr> <td>(SPECIFY) B3A.7SP</td> <td></td> <td></td> </tr> </tbody> </table> | | YES | NO | Contaminated water... B3A.1 | 1 | 2 | Blood transfusions... B3A.2 | 1 | 2 | Using a dirty needle... B3A.3 | 1 | 2 | Drinking alcohol... B3A.4 | 1 | 2 | Contact with industrial solvents... B3A.5 | 1 | 2 | Anesthetic... B3A.6 | 1 | 2 | Something else... B3A.7 | 1 | 2 | (SPECIFY) B3A.7SP | | | <p>DR.'S NAME: B4A</p> <p>HOSPITAL OR CLINIC NAME:</p> <p>ADDRESS (CITY/STATE):</p> |
| | YES | NO | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Contaminated water... B3A.1 | 1 | 2 | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Blood transfusions... B3A.2 | 1 | 2 | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Using a dirty needle... B3A.3 | 1 | 2 | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Drinking alcohol... B3A.4 | 1 | 2 | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Contact with industrial solvents... B3A.5 | 1 | 2 | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Anesthetic... B3A.6 | 1 | 2 | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Something else... B3A.7 | 1 | 2 | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| (SPECIFY) B3A.7SP | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| | YES | NO | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Contaminated water... B3B.1 | 1 | 2 | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Blood transfusions... B3B.2 | 1 | 2 | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Using a dirty needle... B3B.3 | 1 | 2 | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Drinking alcohol... B3B.4 | 1 | 2 | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Contact with industrial solvents... B3B.5 | 1 | 2 | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Anesthetic... B3B.6 | 1 | 2 | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Something else... B3B.7 | 1 | 2 | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| (SPECIFY) B3B.7SP | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

| B5. Since (he/she) was <u>last contacted</u> on the study in (YEAR), had a doctor told (him/her) that (he/she) had any of the following CONDITIONS? | B6. What date was the [CONDITION] <u>first</u> diagnosed? | B7. Was (he/she) hospitalized for one or more days for the [CONDITION]? | B8. What was the name and the address of the doctor, and the hospital or clinic where the [CONDITION] was diagnosed or treated? |
|--|--|--|--|
| a. Gallbladder disease or Gallstones YES1→ B5A NO2 | B6A MO B6A DA 1 9 YEAR | B7A YES1→ NO2→ | DR.'S NAME: <u>B8A</u> HOSPITAL OR CLINIC NAME: _____ ADDRESS (CITY/STATE): _____ |
| b. Alcoholic Liver Disease YES1→ B5B NO2 | B6B MO B6B DA 1 9 YEAR | B7B YES1→ NO2→ | DR.'S NAME: <u>B8B</u> HOSPITAL OR CLINIC NAME: _____ ADDRESS (CITY/STATE): _____ |
| c. Cirrhosis of the Liver YES1→ B5C NO2 | B6C MO B6C DA 1 9 YEAR | B7C YES1→ NO2→ | DR.'S NAME: <u>B8C</u> HOSPITAL OR CLINIC NAME: _____ ADDRESS (CITY/STATE): _____ |
| d. Cancer of the Liver YES1→ B5D NO2 | B6D MO B6D DA 1 9 YEAR | B7D YES1→ NO2→ | DR.'S NAME: <u>B8D</u> HOSPITAL OR CLINIC NAME: _____ ADDRESS (CITY/STATE): _____ |
| e. Kidney disease requiring dialysis or use of a kidney machine YES1→ B5E NO2 | B6E MO B6E DA 1 9 YEAR | B7E YES1→ NO2→ | DR.'S NAME: <u>B8E</u> HOSPITAL OR CLINIC NAME: _____ ADDRESS (CITY/STATE): _____ |

Record 02

| <p>B9. Since (he/she) was <u>last contacted</u> on the study in (YEAR), did (he/she) have one of the following procedures?</p> | <p>B10. What was the date of this procedure?</p> | <p>B11. What was the name and address of the doctor, and the hospital or clinic where this procedure was performed?</p> |
|--|--|---|
| <p>a. Liver biopsy YES1→ ^{B9A} NO2</p> | <p>^{B10A} MO DA 1 9 YEAR</p> | <p>DR.'S NAME: <u>B11A</u> HOSPITAL OR CLINIC NAME: _____ ADDRESS (CITY/STATE): _____</p> |
| <p>b. Liver spleen scan YES1→ ^{B9B} NO2</p> | <p>^{B10B} MO DA 1 9 YEAR</p> | <p>DR.'S NAME: <u>B11B</u> HOSPITAL OR CLINIC NAME: _____ ADDRESS (CITY/STATE): _____</p> |
| <p>c. Barium swallow YES1→ ^{B9C} NO2</p> | <p>^{B10C} MO DA 1 9 YEAR</p> | <p>DR.'S NAME: <u>B11C</u> HOSPITAL OR CLINIC NAME: _____ ADDRESS (CITY/STATE): _____</p> |

B12. Since (PATIENT) was last contacted on the study in (DATE), had (he/she) been hospitalized?
 (INTERVIEWER: THIS WOULD INCLUDE THE HOSPITALIZATION AT THE TIME OF DEATH.)

B12

YES 1 (COMPLETE TABLE BELOW FOR EACH HOSPITALIZATION)

NO 2 (GO TO INTERVIEWER INSTRUCTION BOX BELOW)

B12 NUM
Record 03 (repeats)

| B13. What was the [CONDITION] for which (he/she) was hospitalized? | B14. What date was the [CONDITION] diagnosed? | B15. What was the name and address of the doctor and hospital or clinic where this [CONDITION] was diagnosed and treated? |
|---|---|--|
| a. <u>B13A1</u> <u>B13A2</u> <u>B13A3</u> | <u>BIHAMP BIHADA</u> MO DA <u>BIHAYR</u> 1 9 YEAR | DR.'S NAME: <u>B15A</u> HOSPITAL OR CLINIC NAME: _____ _____ ADDRESS (CITY/STATE): _____ _____ _____ |
| b. _____ | _ _ MO DA 1 9 YEAR | DR.'S NAME: _____ HOSPITAL OR CLINIC NAME: _____ _____ ADDRESS (CITY/STATE): _____ _____ _____ |

PLEASE ASK THE FOLLOWING:

For the purposes of this study, we would like to review (PATIENT)'s hospital and medical records. In order to do this we need to have your permission. I would like to send you (an/some) authorization form(s) in the mail for your signature.

B20. Did (PATIENT) ever use street drugs by a route other than injection? For example, smoking, inhaling or swallowing?

B20

YES 1
 NO 2 (GO TO B22)

B21. What year did (he/she) start and what year did (he/she) stop?

B21A B21B

| 1 | 9 | _ | _ | to | 1 | 9 | _ | _ |
 YEAR STARTED YEAR STOPPED

B22. Since (PATIENT)'s last contact on the study in (DATE), did (he/she) have any other transfusions of blood or blood components such as red or white blood cells, platelets, or plasma?

B22

YES 1
 NO 2 (GO TO B24)

B23. How many different times was (he/she) transfused?

B23NUM
 | _ | _ | _ |
 NUMBER OF TIMES
 TRANSFUSED

Record 05 (repeats) COMPLETE TABLE BELOW FOR EACH TRANSFUSION.

| | <u>Year of transfusion</u> | <u>Units of blood</u> | <u>Name/Location of hospital</u> |
|----|----------------------------|-----------------------|---|
| a. | B23YR 1 9 _ _ | B23UN _ _ | B23NAME _____ NAME LOCATION (CITY/STATE) |
| b. | 1 9 _ _ | _ _ | _____ NAME LOCATION (CITY/STATE) |
| c. | 1 9 _ _ | _ _ | _____ NAME LOCATION (CITY/STATE) |

Record 06
 B24. Was (PATIENT) ever been rejected as a blood donor?

B24

YES 1
 NO 2
 NEVER TRIED TO DONATE 3

(IF YES) What reason did they give (him/her)? B24A

In what year(s) was this? 1. B24B1 | _ | _ | _ | 2. B24B2 | _ | _ | _ |
 YEAR YEAR

Next, I would like to ask you about (PATIENT)'s smoking and drinking habits over (his/her) entire life.

B25. Did (he/she) ever smoke cigarettes regularly, that is, at least one cigarette per day for six months or longer?

B25

YES 1
NO 2
NEVER SMOKED 3

B26. Did (he/she) ever have at least 12 drinks of any kind of alcoholic beverages in any one year?

B26

YES 1
NO 2
NEVER DRANK 3

IF PATIENT IS DECEASED.
SKIP QUESTIONS B27, B28, AND B29.

Please think about (PATIENT)'s alcohol consumption in a typical week last month:

B27. In a typical week last month, how many cans, bottles or glasses of beer did (he/she) drink?

B27

PER WEEK:
DID NOT DRINK BEER LAST MONTH 95
NEVER DRANK BEER 00

B28. In a typical week last month, how much wine did (he/she) drink?

B28AMT
B28UN
B28SPEC

PER WEEK: _____ GLASSES 01
HALF PINTS 02
PINTS 03
FIFTHS 04
QUARTS 05
HALF-GALLONS 06
GALLONS 07
OTHER (SPECIFY) 08

_____ DID NOT DRINK WINE LAST MONTH 95
NEVER DRANK WINE 00

B29 In a typical week last month, how much hard liquor did (he/she) drink?

| | | | |
|--|-----------------------|----|---------|
| PER WEEK: _____ | SHOTS/DRINKS | 01 | B29AMT |
| | HALF PINTS..... | 02 | B29UN |
| | PINTS..... | 03 | B29SPEC |
| | FIFTHS..... | 04 | |
| | QUARTS | 05 | |
| | HALF-GALLONS..... | 06 | |
| | GALLONS | 07 | |
| | OTHER (SPECIFY) | 08 | |
| DID NOT DRINK HARD LIQUOR LAST MONTH | | | 95 |
| NEVER DRANK HARD LIQUOR | | | 00 |

B30 Did (PATIENT) personally ever have a problem with alcoholism?

| | | |
|-----------|---|-----|
| YES | 1 | B30 |
| NO | 2 | |

Next, I would like to ask you about any travelling (PATIENT) might have done since (he/she) was last contacted on the study.

B31 Did (he/she) ever live or travel outside of North America (contiguous U.S. and Canada) for one month or longer since (he/she) was last contacted on the study (DATE)?

| | | |
|-----------|---|------------|
| YES | 1 | B31 |
| NO | 2 | (SKIP B32) |

B32NUM

B32 What were the names of the countries in which (he/she) lived and during what periods?

| | | | |
|----|-----------------|----------------|----------------|
| a. | <u>B32A</u> | <u>B32AYR1</u> | <u>B32AYR2</u> |
| b. | <u>B32B</u> | <u>B32BYR1</u> | <u>B32BYR2</u> |
| c. | <u>B32C</u> | <u>B32CYR1</u> | <u>B32CYR2</u> |
| | Name of country | From (Year) | To (Year) |

IF APPROPRIATE

I will send (a) Medical Authorization Form(s) in the mail, and would appreciate it if you would sign (it/them) and return (it/them) at your earliest convenience.

READ FOR EVERYONE

Thank you for taking the time to do the interview with me and for cooperating in this study.

END OF INTERVIEW.