

HALT-C Trial
Baseline History

Form # 6 Version B: 08/20/2001

SECTION A: GENERAL INFORMATION

A1. Affix ID Label Here →

A2. Patient initials: __ __ __

A3. Visit number: S 0 0

A4. Visit Date: MM / DD / YYYY ____ / ____ / _____

A5. Initials of person completing form: __ __ __ **Signatures required**

Note: Information in Section B should be collected by patient interview. Section C should be completed by the investigator. Section D should be completed by the coordinator using chart abstraction and patient interview.

SECTION B: HEPATITIS C RISK FACTORS

ASK THE PATIENT ABOUT HOW THEY WERE POSSIBLY EXPOSED TO HEPATITIS C. ASSURE THEM OF THE CONFIDENTIALITY OF THEIR ANSWERS.

B1. When did the patient first test positive for hepatitis C? (MM/YYYY) ____ / _____

B2. Was the patient first tested for hepatitis C for any of the following reasons: (circle YES or NO for all answers)

- a. Acute symptoms of hepatitis, such as jaundice? Yes..... 1
No..... 2
- b. Result of being evaluated for another illness? Yes 1
No 2
- c. For donating blood? Yes..... 1
No..... 2
- d. After known exposure to hepatitis C? Yes..... 1
No..... 2
- e. During a routine or insurance physical? Yes 1
No 2
- f. Because of a history of injection drug use? Yes 1
No 2
- g. Because of a history of receiving a blood transfusion? Yes 1
No 2
- h. Because of a prior history of non-A, non-B hepatitis? Yes..... 1
No 2 **(B2j)**

____ - ____ - ____

i. When was the patient first told that s/he had non-A, non-B hepatitis? (MM/YYYY) ____ / ____

j. Any other reason? Yes 1 SPECIFY: _____

No 2

ASK THE PATIENT ABOUT POSSIBLE SOURCES OF EXPOSURE TO THE HEPATITIS C VIRUS.

B3. Has the patient ever received a transfusion of blood or blood products, such as platelets or plasma?

Yes..... 1

No 2 (B4)

a. How many times? _____

In what year(s) did s/he receive transfusion(s), starting with the earliest year?

(YYYY)

b. _____

c. _____

d. _____

e. _____

B4. While working at any job, did the patient ever have exposure to or direct contact with human blood?

Yes..... 1

No 2 (B5)

a. In what year did s/he first have exposure to or direct contact with blood? (YYYY) ____

b. In what year did s/he last have exposure to or direct contact with blood? (YYYY) ____

B5. Did the patient ever experience a needle stick or cut that might have exposed her/him to human blood?

Yes..... 1

No 2 (B6)

a. How many times? _____

Approximately what year(s), starting with the earliest year?

(YYYY)

b. _____

c. _____

d. _____

e. _____

____ - ____ - ____

B6. Has the patient ever been tattooed? Yes 1
No..... 2 (B7)

a. How many times? _____

Approximately what year(s), starting with the earliest year?
(YYYY)

b. _____

c. _____

d. _____

e. _____

B7. Has the patient ever had body piercing, not including pierced ears? Yes 1
No..... 2 (B8)

a. How many times? _____

In what year(s) did s/he have body piercing, starting with the earliest year?
(YYYY)

b. _____

c. _____

d. _____

e. _____

THE NEXT FEW QUESTIONS ASK ABOUT THE PATIENT'S EXPERIENCE WITH INJECTION OF RECREATIONAL DRUGS. THESE ARE DRUGS THAT ARE NOT MEDICALLY PRESCRIBED.

B8. Has the patient ever used needles to inject recreational drugs? Yes 1
No..... 2 (B9)

a. In what year did s/he first inject drugs? (YYYY) _____

b. In what year did s/he last inject drugs? (YYYY) _____

c. Approximately how many times has s/he injected drugs during her/his lifetime? Was it ...

less than ten times, 1

ten to fifty times, or..... 2

more than fifty times? 3

____ - ____ - ____

B9. Has s/he ever snorted cocaine? Yes..... 1
No 2 (B10)

a. In what year did s/he first snort cocaine? (YYYY) ____

b. In what year did s/he last snort cocaine? (YYYY) ____

c. Approximately how many times have s/he snorted cocaine during her/his lifetime? Was it ...
less than ten times, 1
ten to fifty times, or..... 2
more than fifty times? 3

B10. Given everything the patient has learned about the causes of hepatitis C, in what year does s/he think s/he was infected?
(YYYY) ____

Signature of Interviewer: _____

SECTION C SHOULD BE COMPLETED BY THE INVESTIGATOR.

SECTION C: INVESTIGATOR'S ASSESSMENT OF ACQUISITION OF HEPATITIS C INFECTION

OTHER POTENTIAL RISK FACTORS:

C1. Based on any sources of information (e.g. medical records, patient interview), do you think the patient may have become infected with hepatitis C as a result of medical care – injections or procedures - inside or outside of the United States?

Yes..... 1
No 2 (C3)

C2. How confident are you of this source of infection? Probable..... 1
Possible..... 2
Unlikely..... 3

ASSESSMENT OF YEAR OF INFECTION:

C3. Based on your assessment of the answers given in Section B, above, and any other information, what was the year that the patient contracted hepatitis C??

(YYYY) ____

C4. How confident are you that this is the correct year? Probable 1
Possible..... 2
Unlikely..... 3 (SECTION D)

C5. Based on your assessment of the answers given in Section B, above, and any other information, do you have an idea of the range of years in which the patient most likely contracted hepatitis C?

Yes..... 1
No 2 (SECTION D)

____ - ____ - ____

C6. What is the range of years in which you believe the patient most likely contracted hepatitis C?

a. From: (YYYY) _____

b. To: (YYYY) _____

C7. What is the probability that hepatitis C was contracted between those years?

Probable..... 1

Possible 2

Unlikely 3

Signature of Investigator: _____

SECTION D SHOULD BE COMPLETED BY THE STUDY COORDINATOR USING CHART ABSTRACTION AND PATIENT INTERVIEW.

SECTION D: PRIOR TREATMENT WITH INTERFERON

D1. The patient's most recent adequate treatment with Interferon prior to the trial was documented on Trial ID Assignment (Form # 1). Did the patient have any other treatments with Interferon before or after that documented course?

Yes..... 1

No 2 **(END OF FORM)**

D2. Not counting the most recent adequate treatment, how many courses of Interferon treatment (with or without Ribavirin) did the patient receive? _____

D3. **Use one row of the table on the following page for each course of treatment.**

Use the Medication Code List, below, for coding type of medication (item b.).

| Medication Code List: |
|-----------------------------------|
| 33. Interferon alone |
| 44. Peg Interferon alone |
| 55. Interferon with Ribavirin |
| 66. Peg Interferon with Ribavirin |
| 99. Other (SPECIFY in item a.) |

| Courses of Interferon | a. Type of interferon (see code list above) | b. Approximate duration of treatment (in weeks) | c. Start Date (for initial course only) |
|------------------------------|---|---|--|
| Initial Course of Interferon | | | ____ / ____ - ____ - ____ M M / Y Y Y Y |
| Subsequent course | | | |
| Subsequent course | | | |
| Subsequent course | | | |
| Subsequent course | | | |
| Subsequent course | | | |