

HALT-C Trial Q x Q

Hormones and Women – Risk Factors AS

Form # 144 Version A: 06/15/2000 (Rev. 12/08/2003)

Purpose of Form #144: The Hormones and Women form uses patient interview format to record a female patient's history of pregnancy, history of contraception use, and history of hormone replacement medication. The purpose is to determine if female hormones and pregnancy affect the course of liver disease and hepatitis C.

When to complete Form #144: This form should be completed at Week 8 (W08) for all women in the Lead-in Phase, or at Month 9 (M09) for all women who entered the Trial as Express Patients. Form #144 is data entered at each clinical site.

SECTION A: GENERAL INFORMATION

- A1. Affix the patient ID label in the space provided.
 - If the label is not available, record the ID number legibly.
- A2. Enter the patient's initials exactly as recorded on the Trial ID Assignment form.
- A3. Enter the three-digit code corresponding to this visit.
- A4. Record the date of the visit in MM/DD/YYYY format.
- A5. Enter the initials of the person completing the form.

General Instructions for form: A calendar accompanies this form and may be used as a tool or worksheet to help the patient recall significant times in her life, and to help the patient remember her history of contraception use and hormone replacement therapy. This calendar is optional and should not be data entered.

Use the calendar as a memory probe to elicit the appropriate responses of hormone use, pregnancies, contraception use, and hormone replacement therapy. General probes for all questions would include tying the date to an event in the woman's life that may help her remember the year. For example, the woman does not remember when she started using birth control pills. Interviewer should probe "Do you remember what year in school you were?" The form asks you to pinpoint how old the woman was at the time.

The calendar starts with calculating the birth date of the woman, and then adding 8 years to the birth year and putting that year on the first line of the calendar. This was the year she turned from 7 to 8. Then write in every year until the current year. Record any event (i.e. such as bulleted items) as a reference date as appropriate or needed in order to obtain information on hormone use.

- Date of first menstrual period
- Date of first sexual intercourse
- End of pregnancies
- Date of marriages
- Date of divorces
- Date when stopped having monthly menstrual periods

If after appropriate probing, the patient cannot recall specific dates in her history of contraception use and hormone replacement therapy (i.e. she remembers the year but not the month of an event), **write, "don't know" or "DK" in the space provided** to enter a month.

SECTION B: HISTORY OF PREGNANCY

- B1. If the answer is YES, circle 1 and continue to question B2. If the answer is NO, circle 2 and skip to question B3.
- B2. Record how old the patient was at her first menstrual period using a two-digit number. Age under 10 should start with a 0.
- B3. If the answer is YES, circle 1 and continue to question B4. If the answer is NO, circle 2 and skip to Section C.
- B4. Record the number of times the patient was pregnant using a two-digit number. Any number under 10 should start with a 0. For example, 9 pregnancies would be recorded as 0 9.
- B5a-c. For each time the patient was pregnant, ask questions B5a, B5b, and B5c. As you repeat the questions for each pregnancy, complete the table row by row for each pregnancy. For question B5a insert First Pregnancy, Second Pregnancy, etc. where you see [FIRST/NEXT].
- If the answer to B5c is LIVE BIRTH, ask question B5d. If the answer to question B5c is Miscarriage, Abortion, or Still Birth, DO NOT ASK question B5d; skip to the next pregnancy. When all pregnancies have been completed, continue to Section C.
- B5d. If the answer to question B5d is YES, circle 1 and continue to the next pregnancy. If the answer is NO, circle 2 and continue to the next pregnancy. When all pregnancies have been completed, continue to Section C.

SECTION C: HISTORY OF CONTRACEPTION USE

- C1. If the answer is YES, circle 1 and continue to question C2a. If the answer is NO, circle 2 and skip to question C3.
- C2a. For each time the patient used birth control pills, ask questions C2a and C2b. PROBE for each episode starting at age of first menstrual period and continue to PROBE for each episode. Record the date the patient began taking birth control pills in MM/YYYY format.
- C2b. Answer if use of birth control pills is ongoing or has been discontinued. If use of birth control pills is ongoing, circle 1 and skip to question C3. If use of birth control pills has been discontinued, circle 2 and go on to question C2c.
- C2c. Record the date the patient stopped using birth control pills in MM/YYYY format. When all episodes have been completed, continue to question C3.
- C3. If the answer is YES, circle 1 and continue to question C4a. If the answer is NO, circle 2 and skip to question C5.
- C4a. For each time the patient used birth control shots, ask questions C4a and C4b. PROBE for each episode starting at age of first menstrual period and continue to PROBE for each episode. Record the date the patient began using birth control shots in MM/YYYY format.

- C4b. Answer if use of birth control shots is ongoing or has been discontinued. If use of birth control shots is ongoing, circle 1 and skip to question C5. If use of birth control shots has been discontinued, circle 2 and go on the question C4c.
- C4c. Record the date the patient stopped using birth control shots in MM/YYYY format. When all episodes have been completed, continue to question C5.
- C5. If the answer is YES, circle 1 and continue to question C6a. If answer is NO, circle 2 and skip to section D.
- C6a. For each time the patient used birth control implants, ask questions C6a and C6b. PROBE for each episode starting at age of first menstrual period and continue to PROBE for each episode. Record the date the patient began using birth control implants in MM/YYYY format.
- C6b. Answer if use of birth control pills is ongoing or has been discontinued. If use of birth control implants is ongoing, circle 1 and skip to Section D. If use of birth control implants has been discontinued, circle 2 and go on to question C6c.
- C6c. Record the date the patient stopped using birth control implants in MM/YYYY format. When all episodes have been completed, continue to Section D.

SECTION D: HISTORY OF HORMONE REPLACEMENT

- D1. If the answer is YES, circle 1 and skip to question D7. If the answer is NO, circle 2 and continue to question D2.
- D2. Record the date of last menstrual period in MM/YYYY format.
- D3. If the answer is THEY STOPPED NATURALLY, circle 1 and skip to question D7.
- If the answer is THEY STOPPED AFTER A HYSTERECTOMY, circle 2 and continue to question D4.
- If the answer is THEY STOPPED DUE TO ILLNESS OR MEDICATION, circle 3 and skip to question D7.
- If the answer is BEGAN HORMONES BEFORE NATURAL PERIOD STOPPED, circle 4 and skip to question D7.
- If the answer is HAVE NOT STARTED MENSTRUATING AFTER A RECENT PREGNANCY, circle 5 and skip to question D7.
- If the answer is SOME OTHER REASON, circle 99. Specify the other reason. Skip to question D7.
- D4. Record the date of hysterectomy using the MM/YYYY format.
- D5. If the answer is YES, circle 1 and continue to question D6. If the answer is NO, circle 2 and skip to question D7. If the answer is DO NOT KNOW OVARIAN STATUS, circle -8 and skip to question D7.

- D6. If ONE OVARY REMOVED, circle 1. If BOTH OVARIES REMOVED, circle 2. If unknown, circle -8.
- D7. If the answer is NO, the form is complete. If the answer is YES, continue to question D8.
- D8. For each time the patient used hormone replacement pills or patches, ask questions D8a, D8b, D8d, and D8f. PROBE for each episode starting at age of first menstrual period and continue to PROBE for each episode.
- D8a. Record the date the patient began using hormone replacement pills or patches in MM/YYYY format.
- D8b. If use of hormone replacement pills or patches is ONGOING, circle 1 and skip to question D8d. If use of hormone replacement pills or patches has been DISCONTINUED, circle 2 and continue to question D8c.
- D8c. Record the date the patient stopped using hormone replacement pills or patches in MM/YYYY format.
- D8d. Record the name of the hormone replacement pill or patch used.
- D8e. Record Code from Hormone Code List after the interview is completed. This codebook is located in the HALT-C Trial Manual of Operations, Section K-7: Risk Factor Ancillary Study Appendix A.
- D8f. Record the number of days the hormone replacement pills or patches were taken or worn during the episode. Continue to PROBE for each episode. When there are no more episodes, the form is complete.