

HALT-C Trial Q x Q

Medications Interview

Form # 12 Version B: 12/03/2001

Purpose of Form #12: The Medications Interview form uses patient interview format to record medications (other than trial medications) that the patient has taken since the previous study visit. Because Form #12 may be used as a source document, data collectors must sign the form.

Peginterferon alfa-2a and ribavirin doses that the patient took for the HALT-C trial protocol are not recorded on Form #12, but are recorded on Forms #10, #28, and #29.

On Form #12, medications are divided into two categories: (1) prescription medications, and (2) non-prescription medications, such as alternative, herbal, dietary supplements and over the counter medications.

To assist in recording medication information, the HALT-C Data Management System (DMS) has been programmed to list medications on the Visit Control Sheet (VCS). The VCS lists all medications the patient reported taking at the most recent study visit. Study Coordinators can use the VCS to ask whether the patient is still taking the same medications as at the most recent study visit. Data entry of Form #12 then allows the DMS to update the VCS for the next study visit.

When to complete Form #12: This form should be completed for all patients at each study visit, beginning with the Week 2 (W02) study visit for Lead-In patients or the Month 9 (M09) visit for Express patients.

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 this visit using MM/DD/YYYY format.
- A5. Enter the initials of the person completing the form.

General Information on Completing Sections B and C: All medications the patient reported taking at the last study visit are listed on the patient's current Visit Control Sheet (VCS). An example of this section of the VCS is shown below:

Medications patient was taking at the last visit:			
<u>Computer code</u>	<u>Medication name</u>	<u>Medication Code</u>	<u>Medication type</u>
105804	maxide	HYD R19	Prescription
116866	celexa	CIT R01	Prescription
112253	acetaminophen	ACE 000	Over Counter

Computer code (column 1): For each medication a patient takes, a DMS-generated patient-specific computer code number is listed on the VCS. This computer code number is generated using the following information:

- Tracked list of non-trial medications that this patient has taken during the course of the trial,
- The name of the medication (as typed in when the medication was data entered the first time),
- The medication code for each type of medication from the HALT-C Medication Code List,
- The more non-trial medications a patient has taken during the course of the trial, the higher this computer-generated code number will be.
 - In the box above, three "Computer codes" are listed, 10584, 116866, and 112253.

Medication name (column 2): The VCS lists the name of each medication as typed in when the medication was data entered the first time.

Medication Code (column 3): For each medication a patient takes, a Medication Code is listed on the VCS. Medication Codes are prepared for HALT-C by the DCC. Each clinical center has a binder entitled "Medication Code Book" with lists of all Medication Codes. The DCC updates this binder periodically.

- Prescription medications have codes of the form XXX_R##. The first three letters are the first three letters of the first ingredient (listed in alphabetic order).
 - In the box above, the Medication Code for celexa is CIT_R01.
- Nonprescription (herbal, alternative, dietary supplements, over the counter) medications have codes of the form XXX_###. The first three letters are the first three letters of the most frequently used common name of the herb or alternative medicine or the first three letters of the first active ingredient (listed in alphabetical order) of the over the counter medication.
 - In the box above, the Medication Code for acetaminophen is ACE_000.

Medication type (column 4): There are two medication types listed on the VCS.

- "Prescription" is medications prescribed by a doctor or nurse practitioner. This includes all prescription medications including pain and inflammation medications that require a prescription. Only oral medications should be included, not lotions, ointments, or topical sprays.
 - In the box above, two "Prescription" medications are listed, maxide and celexa.
- "Over the Counter" are non-prescription medications including herbal supplements, dietary supplements, alternative medications, and over-the-counter medications.
 - In the box above, one "Over the Counter" medication is listed, acetaminophen.

SECTION B: PRESCRIBED MEDICATIONS

- B1. Using Column 4 of the VCS, look for any listed “Prescribed” medications.
- If there are one or more “Prescribed” medications listed on the VCS, circle 1 for YES and continue to Question B2.
 - If there are no “Prescribed” medications on the VCS, circle 2 for NO and skip to Question B4.
- B2. Using Column 2 of the VCS, read the name of each prescribed medication to the patient. Ask the patient if he/she has stopped taking any of these prescribed medications.
- If the answer is YES, circle 1 and continue to Question B3.
 - If the answer is NO, circle 2 and skip to Question B4.
- B3. Using Column 1 of the VCS, record in the table the “Computer code” and the name of each prescribed medication that the patient is no longer taking.
- List one prescription medication name per row of the table.
- B4. Ask the patient if he/she has started taking any prescribed medications since the last study visit.
- Include only prescribed medications that the patient is presently taking.
 - If the patient started and stopped a prescribed medication since the last study visit, it is not necessary to record this medication.
 - If the answer is YES, circle 1 and continue to Question B5.
 - If the answer is NO, circle 2 and skip to Section C.
- B5. Record in the table the name of each prescribed medication that the patient has started taking since the last visit.
- List one prescription medication name per row of the table.
 - After completing the interview, the coordinator or data manager can fill in the Medication Code, using the Medication Code List.
 - After completing the table, continue to Section C.

SECTION C: NON-PRESCRIPTION – HERBAL, ALTERNATIVE, DIETARY SUPPLEMENTS AND OTHER OVER THE COUNTER MEDICATIONS

- C1. Using Column 4 of the VCS, look for any listed “Over the Counter” medications.
- If there are one or more “Over the Counter” medications listed on the VCS, circle 1 for YES and continue to Question C2.
 - If there are no “Over the Counter” medications on the VCS, circle 2 for NO and skip to Question C4.
- C2. Using Column 2 of the VCS, read the name of each non-prescription medication to the patient. Ask the patient if he/she has stopped taking any of these non-prescription medications.
- If the answer is YES, circle 1 and continue to Question C3.
 - If the answer is NO, circle 2 and skip to Question C4.
- C3. Using Column 1 of the VCS, record in the table the “Computer code” and the name of each non-prescription medication that the patient is no longer taking.
- List one non-prescription medication name per row of the table.

- C4. Show the patient Card #10 "Complementary and Alternative Medication", which lists herbal, alternative, or other over the counter medication names. Ask the patient if he/she has started taking any non-prescription medications since the last study visit.
- Include only non-prescription medications that the patient is presently taking.
 - If the patient started and stopped a non-prescription medication since the last study visit, it is not necessary to record this medication.
 - If the answer is YES, circle 1 and continue to Question C5.
 - If the answer is NO, circle 2. The interview is complete.
- C5. Record in the table the name of each non-prescription medication that the patient has started taking since the last visit.
- List one non-prescription medication name per row of the table.
 - The interview is complete.
 - After completing the interview, the coordinator or data manager can fill in the Medication Code, using the Medication Code List.

Signature: The HALT-C staff member who performed the interview that is recorded in **Sections B and C** must sign the form on page 3 to indicate that this form is a source document.