

HALT-C Data Collection: Completing Forms

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I. Data Collection Supplies

Data Forms:

The HALT-C study records all of its data onto paper data forms. These data forms are all entered into the HALT-C DMS. The Data Coordinating Center (DCC) provides batches of all forms to each study center. If supplies of a particular data form run low, notify the DCC. When sites receive supplies of data forms, the forms should be filed by form number and put in a safe place accessible to data management and data collection staff.

Other Supplies:

- Pens: Forms should be filled out with a black ballpoint pen.
- Pencils: The Block Questionnaire, completed by the patient, must be filled out with a #2 pencil.
- Patient ID labels: These are paper labels, supplied by the DCC, which should be placed on the top of each data form page. See section VII "Routine Data Management Tasks" in C-1, for more information.
- Aliquot labels: These are used for labeling specimens that will be shipped to the central Repository. There are two types of aliquot labels. Patient ID/visit # aliquot labels are supplied by the DCC. Sample ID/sequence # aliquot labels are supplied by the Repository (BBI). See section VII "Routine Data Management Tasks" in C-1, for more information.

II. Types of Forms

The Forms & QxQ's Binder of this manual contains copies of data forms and QxQ's for the main HALT-C Trial and ancillary studies. QxQ's are detailed, question-by-question instructions that explain when and how to complete the questions on each of the data forms.

There are several different types of HALT-C data forms. The following types of forms are expected, per protocol, at specific HALT-C study visits:

- Interview forms: These forms are administered via patient interview. An interviewer reads questions to the patient, and records the patient's responses on the paper form. All interviewers must be certified by the DCC before conducting interviews for HALT-C. See Section J, QC/QA Plan, for information on interviewer certification, and data collection by interview. Examples of interview forms are Form #3, Screening Medical History Interview, and Form #41, the Skinner.
- Patient completed forms: If possible, these forms should be reviewed for completeness while the patient is still present. If some questions are not answered, the data collector should ask the patient to complete the missing information. See Section J, QC/QA Plan, for information on administering forms that are completed by the patient. Examples of patient completed forms are Form #40, Quality of Life, and Form #44, Beck Inventory.
- Lab forms: These forms record the results of lab tests and other procedures done at the local site. Examples of lab forms are Form #30, Local Lab, and Form #22, Ultrasound.
- Forms used at specific visits: An example is Form #4, Screening Checklist.
- Aliquot forms: These forms document specimens collected at specific visits, which will be sent to the central Repository. Entry of aliquot forms is a crucial step in the specimen shipping and tracking process. See section C-5 of this manual, Specimen Shipping and Tracking, for a detailed explanation of completing and using aliquot forms. Examples of aliquot forms are Form #70, Screening 1 Aliquot Form, and Form #72, Lead-in Phase Aliquot Form.
- Results of central lab testing: These forms record the results of lab testing (e.g. HCV RNA) done at central laboratories. Although they are expected at specific study visits, the forms are

completed and entered at the central labs, not at the sites. Examples of forms that record central lab test results are Form #31, Central Lab – HCV RNA and Form #32, Week 20 Quantitative HCV RNA.

The following types of forms are not expected at specific visits, but are completed as needed:

- Trial medication logs: These log forms are used to document trial medications that are dispensed to the patient, dose changes for trial medications, and empty vials returned.
- Adverse event and serious adverse event reports and follow-ups: The adverse event forms are Form #60, Adverse Event Report and Form #61, Serious Adverse Event Report.
- Forms related to clinical outcomes: Examples are Form #63, Clinical Outcome, and Form #64, Death Report.
- Other forms used, as needed: Examples are Form #24, Missed Visit, and Form #5, Trial Ineligibility.

III. Form Versions

HALT-C data forms are tracked by version date. The version date is located on the first page of each form and in the footer of each page. **If a new form version is issued, the DCC will notify the sites, and send a supply of forms to the study sites if necessary. When a new version of a form is distributed, discard all unused, blank copies of the old version of the form.** QxQ's may also need to be updated/replaced. It is very important that all sites complete the same version of each of the data forms at the same time.

IV. Completing Forms

Data collectors should circle or write each answer carefully and legibly. All entries (including numbers, dates, and written text) must be readable, so that the person entering data can easily determine what has been recorded on the form. If the answer to a question is not clearly recorded on a form, the person entering data should clarify what the correct answer is prior to entry. All questions should be completed in black ink. If questions require a choice to be circled, be sure that only one answer is circled. (See the example, below.)

A. Specify Fields

Many questions offer a choice of "OTHER" for responses that are not included or cannot be fit into one of the other categories. Generally, several choices precede the "OTHER" choice. When "OTHER" is chosen as an answer, a "SPECIFY" field must be completed. The form's QxQ may include instructions on what information is requested for the "SPECIFY" field. The example below illustrates this.

B. Questions without Answers

Prior to entry, data collectors should check forms for completion. No question should be left

B2. What type of housing are you currently living in? Are you living in	
a private house or apartment,.....	1
a nursing or convalescent home.....	2
a retirement home,.....	3
a boarding house (rooming house or rented room),...	4
a mental health facility, or.....	5
another health facility?.....	6
OTHER.....	(7) SPECIFY: <u>Shelter</u>

blank. Follow the instructions below if there are fields on forms that cannot be completed.

Don't know (on interview forms or patient completed forms only)

If the patient does not know the answer to a question on an interview form or patient administered form, the data collector still needs to document something so that the field does not remain blank. Some interview forms have a "Don't know" choice to circle. If the patient does not know the answer to a question, and there is no "Don't know" choice on the form, the data collector writes in the margin, next to the question, "DK" or "Don't Know", then dates and initials this comment. The example below illustrates this.

B2. During the past six months, have you ever had more than 5 drinks in a single day?	
1. Yes	
2. No	<i>Don't know SES. 07/14/2000</i>

Refused (on interview forms or patient completed forms)

If the patient refuses to answer a question on an interview form or patient administered form, the data collector writes in the margin, next to the question, "Refused", then dates and initials this comment. The example below illustrates this.

B4. Have you been ...	
looking for work	1
not looking for work, or	2 <i>Refused SES 07/13/2000</i>
unable to work because of illness or disability?	3

Other missing answers

A question should be labeled missing only if there are no means available to obtain the data. This may apply, for example, to a lab result that will not be obtained. In this case, write the word "Missing" next to the questions, with a reason explaining why the data are missing, then date and initial this comment. The example below shows this.

D1. Uric Acid _____ . _____ (mg/dl)	<i>Missing - No urine collected. Pt. couldn't void. CER 07/15/2000</i>
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C. Making Corrections to Forms

If there is a recording error on the form, there is a specific procedure that should be followed for making corrections. If an error is found, the form should be returned to the data collector for correction. Using a black ballpoint pen, the data collectors should use a single slash to cross out the incorrect answer. The correct answer should then be circled or written in as closely as possible to the entry space. The data collector must initial and date the correction. The example shown below illustrates how to properly correct an answer.

Yes..... 1	<i>R.N.R. 07/04/2000</i>
No..... 2	

If the data collector accidentally makes a circle that covers two codes, s/he should clearly make the correct answer by putting a single slash through the incorrect code, and initial and date in the margin. Adding a comment to the margin can be done if it is unclear what the answer should be.

Yes	1	<i>The correct answer is 2. CER 07/05/2000</i>
No	2	

V. Skip Patterns

Skip instructions on forms are always printed in **boldface** on forms, enclosed in parentheses, and are located to the right of the response. This format indicates instructions for data collectors. The information in parentheses specifies the next question on the form to be completed. The questions in between should be left blank (skipped).

The example below illustrates that if question C6 is answered “No”, the next question to complete is D1; C6a is skipped. If D1 is answered “No”, then data collection for this form has been completed; D2 is skipped.

C6. Edema	Yes	1
	No	2 (D1)
a. Edema severity	1+	1
	2+	2
	3+	3
	4+	4
SECTION D: NEW FINDINGS		
D1. Are there new findings at this visit?	Yes	1
	No	2 (END OF FORM)
D2. Specify new findings.		
a.	New finding 1: _____	
b.	New finding 2: _____	

In the example above, if question C6 is answered “Yes”, then C6a requires an answer. If there is no skip instruction associated with a question (e.g. question C6a, above), the data collector should move directly to the next consecutive question.

The DMS is designed to recognize skip patterns, and will follow the same protocol during data entry. If the data collector does not follow the skip pattern, but codes unnecessary items (e.g. answering C6a. Edema severity in the example above), it will not be possible to enter the extra items. In this case, the person entering data should provide feedback for the data collector.

On some forms, there are sections that are not completed every time the form is administered. If that is the case, the information on when the section should be completed will be displayed at the beginning of the section. The example below shows this.

<p>SECTION D. SERUM URIC ACID</p> <table border="1"> <tr> <td> <p align="center"><u>When to complete Section D</u></p> <p><u>All patients</u>: Complete at screening (S00), baseline (W00), W20.</p> <p><u>In addition: Week 20 responders</u>: complete at W48.</p> </td> </tr> </table> <p>D1. Uric Acid ___ ___ . ___ (mg/dl)</p>	<p align="center"><u>When to complete Section D</u></p> <p><u>All patients</u>: Complete at screening (S00), baseline (W00), W20.</p> <p><u>In addition: Week 20 responders</u>: complete at W48.</p>
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