HALT-C Trial Q x Q

Death Report

Form # 64 Version A: 06/15/2000 (Rev. 11/17/2000)

Purpose of Form #64: The Death Report documents the death of a patient enrolled in the HALT-C trial.

When to complete Form #64: This form should be completed immediately after learning there has been a patient death, regardless of the reason. Complete this form for patients enrolled in the Lead-in Phase, the Week 20 Responder Phase, and the Randomization Phase. This form should also be completed for patients being followed after stopping medication. This information should be collected for six months after the patient completes treatment.

Reporting procedures: All deaths must be reported to the Data Coordinating Center (DCC), by telephone, within 24 hours of the clinical centers' notification. The Death Report Form must also be faxed or e-mailed to the DCC within 24 hours. See the box on the last page for phone and fax numbers. A death must also be reported in accordance with local law and regulations.

All supporting documents should be sent to the DCC when they become available. Every attempt should be made to obtain information from outside sources. If additional information becomes available, edit the form to reflect these changes and send source documentation as instructed below.

Note on dates:
- All dates in this section should be recorded using MM/DD/YYYY format.
- Enter the 2-digit number for the month in the first 2 spaces provided (i.e., January = “01”, February = “02”, etc.), the 2-digit number for the day of the month in the second 2 spaces provided, and the 4-digit number for the year in the final 4 spaces provided.

Note on cause of death:
- In several places, this form asks for the immediate and contributory cause(s) of death as recorded on various reports. Please record exactly what the supporting documents list as the cause(s) of death.

SECTION A: GENERAL INFORMATION:

A1. Affix the patient ID label in the space provided.
- If the label is not available, record the patient number legibly.

A2. Enter the patient’s initials exactly as recorded on the Trial ID Assignment form.

A3. Enter the initials of the person completing the form.

A4. Record the date the form was first completed.

SECTION B:

B1. Enter the date the clinical center was notified of the patient's death using MM/DD/YYYY format.

B2. Enter the date of death using MM/DD/YYYY format.

B3. Circle the number corresponding to the place of death.
- For place of death at HOME, WORK, EXTENDED CARE FACILITY, or HOSPICE, skip to Section C.
- For place of death at HOSPITAL, circle 3 and continue to question B4.
- For OTHER, specify the place of death. Forty characters (including punctuation and spaces) are provided. Skip to Section C.

B4. The death may have occurred before admission (i.e. in the ER or clinic) or after admission to the hospital. Indicate if the patient was admitted to the hospital prior to his/her death.
- If the patient was admitted to the hospital, circle 1 for YES and continue to question B5.
- If the patient was not admitted to the hospital, circle 2 for NO and skip to question B7.

B5. Enter the date of hospital admission using the MM/DD/YYYY format.

B6. Record the hospital admitting diagnoses.
- Sixty characters (including punctuation and spaces) are provided for each possible diagnosis.
- Enter the code(s) for the corresponding diagnosis(es) from the ICD-9 code list.

B7. Indicate if the Hospital Record Summary Report is available. A Hospital Record Summary is any document that summarizes the course of the patient's hospitalization. Other medical records from a hospitalization may be used to document the causes of death, (for example, an ER report or ICU note [see question C8]) but only information from the document that summarizes the hospitalization should be recorded here.

- If the Hospital Record Summary Report is available, circle 1 for YES and continue to question C8.
  - File a copy of the report with the patient's records.
  - A copy of the Hospital Record Summary Report should be sent to the DCC. Black out all identifying patient information, such as name and medical record number, and replace with the patient ID number (labels provided by the DCC may be used). See Fax number and address for DCC in the box on the last page.
- If the Hospital Record Summary Report is not available, circle 2 for NO and skip to Section C.

B8. Record the cause(s) of death as reported on the Hospital Record Summary Report.
- Specify the cause(s) of death. Sixty characters (including punctuation and spaces) are provided for each possible cause.
- Enter the code(s) for the corresponding cause(s) of death from the ICD-9 code list.

B9. Record any other significant conditions reported on the Hospital Record Summary Report.
- Sixty characters (including punctuation and spaces) are provided for each possible condition.
- Enter the code(s) for the corresponding condition(s) from the ICD-9 code list.

SECTION C

C1. Indicate if the Death Certificate is available.
- If the Death Certificate is available, circle 1 for YES and continue to question C2.
  - File a copy of the Death Certificate with the patient's records.
  - A copy of the Death Certificate should be sent to the DCC. Black out all identifying patient information, such as name and medical record number, and replace with the patient ID number (labels provided by the DCC may be used). See Fax number and address for DCC in the box on the last page.
- If the Death Certificate is not available, circle 2 for NO and skip to question C4.

- If it is not possible to obtain a copy of the death certificate from a hospital or the patient's family, a copy can often be obtained from the state or county clerk by filing a request for a copy of a public record. There may be a nominal fee for this request. If it is difficult to request checks from your institution, the DCC can issue a check. Please contact the DCC with the amount, the name to make the check out to, and the address to send the check.

C2. Record the cause(s) of death as reported on the Death Certificate.
- Specify the cause(s) of death. Sixty characters (including punctuation and spaces) are provided for each possible cause.
- Enter the code(s) for the corresponding cause(s) of death from the ICD-9 code list.

C3. Record any other significant conditions reported on the Death Certificate.
- Sixty characters (including punctuation and spaces) are provided for each possible condition.
- Enter the code(s) for the corresponding condition(s) from the ICD-9 code list.

C4. Indicate if an autopsy was performed.
- If an autopsy was performed, circle 1 for YES and continue to question C5.
- If an autopsy was not done or it is not known if an autopsy was done, circle 2 and skip to question C8.

C5. Indicate if the Autopsy Report is available.
- If the Autopsy Report is available, circle 1 for YES and continue to question C6.
  - File a copy of the Autopsy Report with the patient's records.
  - A copy of the Autopsy Report should be sent to the DCC. Black out all identifying patient information, such as name and medical record number, and replace with the patient ID number (labels provided by the DCC may be used). See Fax number and address for DCC in the box on the last page.
- If the Autopsy Report is not available or the status is unknown, circle 2 for NO and skip to question C8.

C6. Record the cause(s) of death as reported on the Autopsy Report.
- Specify the cause(s) of death. Sixty characters (including punctuation and spaces) are provided for each possible cause.
- Enter the code(s) for the corresponding cause(s) of death from the ICD-code list.

C7. Record any other significant conditions reported on the Autopsy Report.
- Sixty characters (including punctuation and spaces) are provided for each possible condition.
- Enter the code(s) for the corresponding condition(s) from the ICD-9 code list.

C8. Record how information regarding the circumstances surrounding the patient's death was obtained.
- Circle 1 for YES or 2 for NO for each question C8a-C8f.
- You may answer YES to more than one question.

C8f. If the answer is OTHER, circle 2 for YES and specify how you learned of the death. Sixty characters (including punctuation and spaces) are provided.

SECTION D

Note on section D: The HALT-C Principal Investigator must make these determinations.

D1. Enter the classification of cause of death as determined by a HALT-C site Principal Investigator.
- Circle 1 for YES or 2 for NO for each question D1a-D1f.
- You may answer YES to more than one question.

D2. Record a summary of sequence of events and/or circumstances surrounding the patient's death. Seven hundred and fifty characters (including punctuation and spaces) are available. If necessary, attach a separate page with this information. Include the last date and dosage of ribavirin and peginterferon. This summary will be sent as a report to the DSMB, so the site should ensure that it is data entered correctly in sentence structure.

The Principal Investigator or designee **MUST** sign and date the form.

Send copies of all source documents, including a Hospital Record Summary Report, Death Certificate, and/or Autopsy Report as soon as they become available. Black out all identifying patient information, such as name and medical record number, and replace with the patient ID number (labels provided by the DCC may be used).

DCC Contact Information

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