

I. General Instructions

The Death Investigation Form is completed for all fatal events, whether or not a death certificate was obtained.

Within the "form header" (top section of the form) the Completion Date, Staff ID, a complete Event ID Number, and the Event need to be filled in.

If no death certificate is available, another source of data will need to be specified to allow data entry in subsequent fields. Even if no reliable data sources can be identified, the form still needs to be created and completed in the data management system (CDART).

When data is entered in the DTH form in CDART, the Death Investigation Tracking Report will update based on the responses to Items 1, 4, and 5, indicating which forms need to be completed. These include the HOE/S Hospitalization and ED visit form, the IIE/S Informant Interview, and the PQE Physician Questionnaire.

Record as "Missing" any responses to questions for which no information is provided on the death certificate or other specified data source.

II. Detailed Instructions

Item 0a. The form Completion Date is entered for the date on which the DTH form is first created and completed by study staff. Update this field every time the form is accessed to update information.

Item 0b. Enter your Staff ID upon form creation and update this field every time the form is accessed to update information.

Item 0c. The Event ID is the participant's Subject ID (8 characters) plus a suffix of 4 characters. The Death Investigation Tracking report will not function properly unless the Event ID has 12 characters. If staff do not yet know if there is a medical record case associated with the fatal event, they should add the suffix 0001 to the subject ID.

If investigation later shows the death was associated with a report of hospitalization on the HOE/S form, DTH0c should be updated with a suffix matching the Annual Follow Up Year and Occurrence.

For example, if the Event ID was initially entered as X12345670001 and then a hospitalized death is discovered and entered in YR10, Occurrence 3, staff would update the DTH0c to X12345671003

For a death occurring during an acute care hospital admission, in the ER, or for a DOA to an ER, the Event ID should match the rest of the forms for that event, following the standard follow up year and occurrence numbering. For deaths occurring outside of the acute care hospital or ER, the Event ID suffix will remain 0001.

You may find on the Death Investigation Tracking Report that some Event IDs have been entered with a suffix of 0099. This was used as a device for identifying deaths reported as being hospitalized but for which we had no formal information. If you encounter a 0099 case, please update it to 0001.

Item 0d. For a death occurring during an admission, in the ER, or for a DOA, the Event Date should match the medical records arrival date for that event. For deaths occurring outside of the hospital for which there is no documentation, the Event Date should be the date of death on the death certificate.

Item 1. The first question asks if a death certificate was obtained. If the answer is "No", then record the answer. If a certificate is received at a later date, this answer can be updated, enabling the user to complete the rest of the DTH form.

Item 1a. Did the death occur outside of the U.S.? Record No/Unknown if the country of death is the USA or if it is not known. If the participant is known to have died outside the US, answer Yes.

Item 1a1.This field should be entered/updated by the field center staff when new NDI data is sent out that contains a possible match for the participant in question. If a positive match is confirmed by selecting "**Match Confirmed**", the NDI data will be loaded by the CC, and the FC staff can consider this DTH complete unless they obtain a death certificate or other valid data source they didn't previously have access to. This participant will not be included in future NDI requests (or at least if they are, that data will not be re-sent to the FC). If the match is incorrect and there is no further information the FC can provide the CC to include in the next NDI query, "**No Match**" should be selected, and this participant will also not be included in future NDI request, "**Update Participant Information and Resubmit**" should be selected, the additional information should be sent to the FC should wait until the next NDI submission to see if a better match is found, at which point they should update this field to confirm or deny the match.

NOTE: Once an NDI match is confirmed, data will be loaded into the form automatically by the CC. These data will not overwrite any data you have already entered from the death certificate. NDI data will only be used to complete missing data fields.

Item 1b. Answer Yes if you have obtained death data, such as a death date or an Underlying Cause of Death (UCOD) ICD code from a reliable source other than a death certificate or an NDI search. Reliable sources will be considered on a case-by-case basis; please contact the CC to confirm your source before completing this question as Yes or entering data in Q11 on the DTH form.

Item 1b1. If a reliable source is accepted, provide the name of the source.

Item 2. Date of Death: Record as listed on the death certificate or by NDI or confirmed Other reliable source.

Item 2a. Indicate if the death date was collected from the death certificate, NDI or Other source (in this hierarchy).

Item 2a1. If Other source, provide the name of the source.

Items 2b – 2b3. Provide the city, state, and country of death.

Item 2c. Indicate the source of the death location.

Item 2c1. Provide the Other location of death source.

Item 3. Time of Death: Record as listed on the death certificate.

Item 4. Answer "Yes" or "No" or "Unknown". Deaths occurring outside a regular acute care hospital, e.g. at home, at work, in an outpatient clinic not physically located within a hospital, in a nursing home or independent hospice etc. would be answered "No". Answer "Yes" for deaths occurring in a hospital emergency room or if the patient was dead on arrival to the hospital (DOA) or during a hospital admission. If the answer to Item #4 is "No", skip to Item #6.

Item 5. Death classification: Record as listed on the death certificate. Select #3 outpatient if the death occurred in an outpatient clinic inside the hospital. Responses 1,2 and 4 will require hospital records to be sent to the CSCC.

Item 6. Coroner or Medical Examiner's Case: Record "Yes" or "No" as indicated on the death certificate. (If "No", skip to Item #10)

Items 7-9. Name and Address of Coroner or Medical Examiner: Record the name and address of the coroner or medical examiner who signed the death certificate. Record all details as documented on the death certificate.

Item 10. Autopsy: Record "Yes" if the death certificate indicates that an autopsy was performed. If not recorded, select "No".

Item 11. ICD-10 Code for <u>Underlying</u> Cause of Death (UCOD): The underlying cause of death is the most important or primary cause that led to the death. It may not be the same as the first or "immediate" cause, and is assigned by a certified nosologist working for the State in which the participant died, based on all available information. A Discharge ICD code from hospital records, even from a visit that culminated in the death, is not the same as an UCOD and should never be used for this field.

The Q11 UCOD field is editable, meaning that in order to enter data, you must first click the closed "lock" icon. This will open the field for data entry (green open lock icon). Once an UCOD is entered, the field should remain open. This field can also have data loaded from an NDI search by the CC. If an NDI UCOD has been loaded (red lock icon remains even though there is data in this field), do not open or change the code without consulting with the CC first.

Enter the ICD-10 Code for the UCOD if stated on the death certificate. The first space should be a letter, followed by a two-digit number. There may also be a number to the right of the decimal point. If a digit to the right of the decimal is not given, do not add one. **Do not zero fill.**

Please note: If you do not have a red lock icon on a blank Q11 field, other data entered on the DTH form does not yet meet the criteria needed for entering an UCOD code.

Item 11a. Indicate how the UCOD code was obtained. The most common answers will be Death Certificate, NDI or Confirmed Missing. Do not mark Q11a as Confirmed Missing until all avenues to

obtain the UCOD code have been exhausted. This may require you to leave this question blank until an NDI search has been conducted and it is confirmed there is No Match.

Item 11a1. If the UCOD code was obtained from a confirmed Other source, indicate the source name.

Items 12a – 12t. Record all other ICD-10 codes in the 20 available fields exactly as listed on the death certificate. Enter codes the same way as in Item 11. If there are no codes provided, set the first field (12a) to Missing, and the rest may be left blank. ICD-10 codes may be found at the bottom on the certificate or sometimes along one side if they are not listed with the causes of death. These fields may also be loaded directly from an NDI search result.

Item 12u. Record whether the codes came from a death certificate or not (Yes or No).

Item 12v. This field is completed by a data load of the NDI search results and you do not need to hand enter any data.

Item 12w. Indicate if the codes came from another confirmed source. Item 12w1. Record the name of the Other source for codes.

Item 13. Causes of death recorded on the death certificate? Respond "Yes" or "No". If the answer is "No", skip to Item14.

Items 13a. – 13d. Transcribe the causes of death exactly as recorded on the death certificate. If two causes are listed on one line of the death certificate, record them similarly on the form.

Item14. Other significant conditions recorded on the death certificate? Record "Yes" or "No". If "No", skip to Item 16.

Item 15. Transcribe the other significant conditions contributing to the death, exactly as recorded on the death certificate. If the other significant conditions list is long, record as much as you can in the answer field and enter any remaining data in a Notelog.

Item 16. Interval between onset and death for <u>immediate</u> cause of death - Enter the category for the immediate cause of death, as recorded on the death certificate. Follow this pattern:

If interval is listed as "Minutes" or "Instantaneous", record 1 = 5 minutes or less If interval is listed as more than 5 minutes but less than one hour, record 2 = 1 hour or less If interval is listed as "Hours", record 3 = 1 day or less If interval is listed as "Days", record 4 = 1 week or less If interval is listed as "Weeks", record 5 = 1 month or less If interval is listed as "Months", record 6 = more than 1 month If interval is not recorded or listed as "Unknown", record 7 = unknown or not recorded

Item 17. Name and address of informant recorded? Record "Yes" or "No". If "No", skip to Item 22.

Item 18. Name of Informant: Most death certificates have a line for informant. Often this is the spouse, but it may be a co-worker, friend, etc. Record the name exactly as documented.

Item 19. Record the address of the Informant as documented on the death certificate.

Item 20. Relationship of Informant to deceased: Record as listed on the death certificate. Select "3" if unknown.

Item 21. If the informant is "other" than spouse, specify the relationship. If the relationship is "spouse" or "unknown" CDART will skip this question.

Item 22. Name and address of the certifying physician recorded? Record "Yes" or "No". Do not select "Yes" if this is a coroner/medical examiner's case. That data should be recorded on Items 8 and 9.

Item 23. Record the name of the certifying physician who signed the death certificate.

Item 24. Record the address of the certifying physician as documented on the death certificate.