

INTRODUCTION TO FORM 48 – DEATH REPORT

Note that the causes of death (inset box in Question C.1.a) include more HIV-related complications than are used as primary VATS events. Also, causes of death were not reviewed as VATS endpoint events were. Finally, any VATS events reported in Section D underwent the same review process as described for Form 22.

DEATH REPORT -- FORM 48 QxQ

SECTION A -- GENERAL INFORMATION

- A1.** Affix the subject ID label. If label is not available, write the subject ID number in the space provided. If this is a multiple page form, affix an ID label or write the ID number on the top of each page in the space provided.
- A3.** Enter the subject's first initial in the first space provided, middle initial in the second space provided and last initial in the third space provided. If the subject does not have a middle name, enter the first initial in the first space provided, a "--" in the second space provided, and the last initial in the third space provided. If the person has a hyphenated last name or 2 last names, enter the initial of the first last name in the appropriate box
- A5.** Record the date that this form is completed.
- A6.** Enter the initials of the person completing the form. Enter the first initial in the first space provided, middle initial in the second space provided and last initial in the third space provided. If the person completing this form does not have a middle name, enter the first initial in the first space provided, a "--" in the second space provided, and the last initial in the third space provided. If the person has a hyphenated last name or 2 last names, enter the initial of the first last name in the appropriate box.

SECTION B -- DEATH REPORT SUMMARY

- B1.** Enter the patient's date of death. If exact date not known, enter approximate date, but write a note on the form indicating that the date was estimated.
- B2.** If autopsy was performed, attach a copy of it to this form, or mail it to NERI whenever it becomes available.

SECTION C -- CAUSE OF DEATH

- C1a.** If the principal cause of death is AIDS/HIV, but specific HIV-related complication(s) causing the death are not known (e.g., the patient died at home but little additional detail is available), check progressive HIV disease. If specific HIV related complications were felt to have caused the death, check HIV related complications and fill in complication codes below.
- C2.** If death was thought to be directly or indirectly related to a transfusion event, give details.

SECTION D -- MEDICAL RECORD ABSTRACTION OF NEWLY DIAGNOSED HIV RELATED COMPLICATIONS

The purpose of this section is to fill in any new diagnoses since the date of the last quarterly visit report. The diagnoses reported need not have caused death. Use all available sources, including autopsy information.

D1. THROUGH D5.

These questions provide a space to document specific diagnoses of new HIV-related complications. Only report diagnoses of new complications on this form; for example, if there is a second definitive diagnosis of a previously reported lymphoma, do not report it a second time. But if there is a new episode of pneumocystis carinii pneumonia (PCP), report it again, since second occurrences of a previous infection which has cleared are considered separate events. Progressive pre-existing CMV disease is also considered a new event.

Each question in this section contains 4 parts.

For part a, enter the code for any newly diagnosed HIV related complication.

For part b, use the codes on the form to record the most reliable source of information. Generally speaking, a medical record is considered more reliable than physicians report. Discuss with your Clinical Center PI if there is a question.

For part c, if there are both definitive and presumptive diagnoses, code as definitive. Criteria for definitive diagnosis appear in the protocol, Section 7.5.

For part d, give the first date of diagnosis of the most definitive diagnosis. For example, if there was a presumptive diagnosis and a definitive diagnosis in a single site, code 01 (definitive) in part c and give the date of the definitive diagnosis in part d. If a diagnosis is made definitive at autopsy, but there were prior presenting symptoms/signs, give the date of the presenting symptoms/signs.

Note that the protocol (Section 7.4.2) distinguishes upper and lower GI. Upper GI extends from the mouth to the proximal duodenum. Lower GI is everything distal to the proximal duodenum.

**VIRAL ACTIVATION TRANSFUSION STUDY (VATS)
FORM 48 -- DEATH REPORT**

SECTION A -- GENERAL INFORMATION

A1. Subject ID: (ENTER ID NUMBER OR AFFIX LABEL AT THE RIGHT)

_____ - _____ - ____

FOR NERI / INTERNAL USE ONLY:

A2. LAST VISIT: _____

A3. Subject initials: _____

A4. Form version: _____

0 7 / 1 5 / 9 5

A5. Today's date: _____

____ / ____ / ____

A6. Initials of person completing form: _____

____. ____.

SECTION B -- DEATH REPORT SUMMARY

B1. Date of death. If exact date not known, give approximate date of death:

____ / ____ / ____

B2. Was autopsy performed?

1. Yes →
 2. No

**ATTACH AUTOPSY REPORT OR
SEND TO NERI AT LATER DATE.**

HIV RELATED COMPLICATION CODES

- | | |
|--|---|
| 01= Bacteremia, catheter related | 16= Kaposi's sarcoma (skin, oral cavity, GI, other) |
| 02= Bacteremia, non-catheter related | 17= Lymphoma, Non-Hodgkins |
| 03= Candidiasis of bronchi, trachea or lung | 18= Lymphoma, primary, of the brain |
| 04= Candidiasis, esophageal | 19= Mycobacterium avium complex or M. kansasii, disseminated or extrapulmonary |
| 05= Cervical cancer, invasive | 20= Mycobacterium tuberculosis, any site, pulmonary or extrapulmonary |
| 06= Coccidioidomycosis, disseminated or extrapulmonary | 21= Mycobacterium, other species or unidentified species disseminated or extrapulmonary |
| 07= Cryptococcosis, extrapulmonary | 22= Pneumocystis carinii pneumonia |
| 08= Cryptosporidiosis, chronic intestinal (>1 month's duration) | 23= Pneumonia |
| 09= Cytomegalovirus disease (other than liver, spleen or nodes) | 24= Progressive multifocal leukoencephalopathy (PML) |
| 10= Cytomegalovirus disease (retinitis) | 25= Salmonella septicemia |
| 11= Encephalopathy, HIV-related | 26= Toxoplasmosis of the brain |
| 12= Herpes simplex: chronic ulcer(s) (>1 mo's duration) or bronchitis, pneumonitis, or esophagitis | 27= Wasting syndrome due to HIV |
| 13= Histoplasmosis, disseminated or extrapulmonary | 28= Other serious bacterial infection |
| 14= Isosporiasis, chronic intestinal (>1 mo's duration) | |
| 15= Kaposi's sarcoma (lung, lymphedema) | |

SECTION C -- CAUSE OF DEATH

C1. Primary cause(s) of death in opinion of physician:

1. AIDS/HIV →
 2. Unknown
 3. Other, specify below ↓:

a.

1. Progressive HIV disease
 2. HIV related complications ↓

Principal HIV related cause(s) of death from (codes above):

____ _
____ _

C2. Was death thought to be related - (directly or indirectly) to transfusion event?

1. Yes → Specify: _____
 2. No _____

SECTION D -- MEDICAL RECORD ABSTRACTION OF NEWLY DIAGNOSED HIV RELATED COMPLICATIONS

COMPLETE THIS SECTION, ABSTRACTING FROM MEDICAL RECORDS ANY NEWLY DIAGNOSED HIV RELATED COMPLICATIONS SINCE LAST QUARTERLY VISIT. NOTE THE CODES THAT FOLLOW ARE NOT THE SAME CODES AS APPEAR ON PAGE 1 OF THIS FORM. PLEASE USE THE CHART BELOW WHEN COMPLETING SECTION D.

HIV RELATED COMPLICATION CODES	
01= Bacteremia, catheter related	14= Lymphoma, non-Hodgkins
02= Bacteremia, non-catheter related	15= Lymphoma, primary, of the brain
03= Cervical cancer, invasive	16= Mycobacterium avium complex or M. kansasii, disseminated or extrapulmonary
04= Coccidioidomycosis, disseminated or extrapulmonary	17= Mycobacterium tuberculosis, any site, pulmonary or extrapulmonary
05= Cryptococcosis, extrapulmonary	18= Mycobacterium, other species or unidentified species, disseminated or extrapulmonary
06= Cryptosporidiosis chronic intestinal (> 1 month's duration)	19= Pneumocystis carinii pneumonia
07= Cytomegalovirus, eye	20= Progressive multifocal leukoencephalopathy (PML)
08= Cytomegalovirus, central nervous system	21= Toxoplasmosis of the brain
09= Cytomegalovirus, upper GI	22= Other serious bacterial infection (normally sterile site)
10= Cytomegalovirus, lower GI	
11= Cytomegalovirus, Other	
12= Histoplasmosis, disseminated or extrapulmonary	
13= Kaposi's sarcoma (lung, lymphedema)	

SOURCE OF INFORMATION CODES	
If more than one source reports diagnosis, record the most reliable.	
01=	Medical Record
02=	Physician's Report
03=	Other Source

DIAGNOSIS CONFIRMATION CODES	
If more than one source confirms diagnosis, but reports conflict regarding definitive or presumptive, record definitive.	
01=	Definitive
02=	Presumptive

- D1. a. HIV related complication: _____ (If 11 or 22, specify site: _____)
 b. Source of information: _____ (If 03, specify source: _____)
 c. Diagnosis confirmation: _____
 d. If Confirmation=01 or 02, Date of diagnosis: _____ / _____ / _____
- D2. a. HIV related complication: _____ (If 11 or 22, specify site: _____)
 b. Source of information: _____ (If 03, specify source: _____)
 c. Diagnosis confirmation: _____
 d. If Confirmation=01 or 02, Date of diagnosis: _____ / _____ / _____
- D3. a. HIV related complication: _____ (If 11 or 22, specify site: _____)
 b. Source of information: _____ (If 03, specify source: _____)
 c. Diagnosis confirmation: _____
 d. If Confirmation=01 or 02, Date of diagnosis: _____ / _____ / _____
- D4. a. HIV related complication: _____ (If 11 or 22, specify site: _____)
 b. Source of information: _____ (If 03, specify source: _____)
 c. Diagnosis confirmation: _____
 d. If Confirmation=01 or 02, Date of diagnosis: _____ / _____ / _____
- D5. a. HIV related complication: _____ (If 11 or 22, specify site: _____)
 b. Source of information: _____ (If 03, specify source: _____)
 c. Diagnosis confirmation: _____
 d. If Confirmation=01 or 02, Date of diagnosis: _____ / _____ / _____

ATTACH COPIES OF THIS PAGE IF ADDITIONAL SPACE IS REQUIRED.

END OF FORM

DEATH REPORT – FM48DATA CODEBOOK

PUB_ID ----- SUBJECT ID

type: numeric (float)
 range: [1,531] units: 1
 unique values: 288 coded missing: 0 / 288
 mean: 267.163
 std. dev: 152.66
 percentiles: 10% 25% 50% 75% 90%
 53 136.5 264.5 397 474

DEATH_DT ----- B1.DATE OF DEATH

type: numeric (float)
 range: [1,1303] units: 1
 unique values: 229 coded missing: 0 / 288
 mean: 248.226
 std. dev: 257.5
 percentiles: 10% 25% 50% 75% 90%
 31 68.5 147 350 641

DEATH_DT:

1. This variable has been coded as the number of days since Randomization (Negative values indicate dates before Randomization, positive values indicate dates subsequent to Randomization).

DEATH_DZ ----- DATE IMPUTATION INDICATOR -- DEATH_DT

type: numeric (float)
 label: DEATH_DZ
 range: [1,2] units: 1
 unique values: 2 coded missing: 0 / 288
 tabulation: Freq. Numeric Label
 286 1 Date not imputed
 2 2 15th of month imputed

DEATH_DZ:

1. Indicator of whether the associated date variable is (1) complete (or entirely missing), or (2) incomplete with day of month missing, or (3) incomplete with day and month of year missing.

AUTOPSY ----- B2.AUTOPSY PERFORMED

type: numeric (float)
 label: AUTOPSY
 range: [1,2] units: 1
 unique values: 2 coded missing: 0 / 288
 tabulation: Freq. Numeric Label
 20 1 1:Yes
 268 2 2:No

P_CAUSE ----- C1.PRIMARY CAUSE OF DEATH

type: numeric (float)
 label: P_CAUSE
 range: [1,3] units: 1
 unique values: 3 coded missing: 0 / 288

tabulation:	Freq.	Numeric	Label
	230	1	1:AIDS/HIV
	7	2	2:Unknown
	51	3	3:Other

AIDS_HIV ----- C1a.AIDS/HIV TYPE

type: numeric (float)
 label: AIDS_HIV
 range: [1,2] units: 1
 unique values: 2 coded missing: 58 / 288

tabulation:	Freq.	Numeric	Label
	124	1	1:Progressive HIV disease
	106	2	2:HIV-related complications

CAUSSPEC ----- C1a.CAUSE SPECIFY

type: string (str30)
 unique values: 45 coded missing: 237 / 288
 examples: ""
 ""
 ""
 ""
 warning: variable has embedded blanks

RELAT_TX ----- C2.DEATH RELATION TO TX EVENT

type: numeric (float)
 label: RELAT_TX
 range: [1,2] units: 1
 unique values: 2 coded missing: 2 / 288

tabulation:	Freq.	Numeric	Label
	1	1	1:Yes
	285	2	2:No

RELAT_SP ----- C2.RELATED SPECIFY

type: string (str30)
 unique values: 1 coded missing: 287 / 288
 tabulation: Freq. Value
 1 "W/ ?ARDS CMPN POST COP TX EPSD"
 warning: variable has embedded blanks

DEATH REPORT – FM48DATB CODEBOOK

PUB_ID ----- SUBJECT ID

type: numeric (float)

range: [1,527] units: 1
 unique values: 106 coded missing: 0 / 168

mean: 231.089
 std. dev: 148.736

percentiles:	10%	25%	50%	75%	90%
	44	110	221.5	350	450

HIV_CODE ----- Cla2.HIV RELATED COMPLICATION CODE

type: numeric (float)

range: [1,28] units: 1
 unique values: 23 coded missing: 0 / 168

tabulation:	Freq.	Value
	4	1
	7	2
	3	4
	2	7
	3	8
	20	9
	10	10
	9	11
	1	13
	1	14
	5	15
	6	16
	17	17
	8	18
	22	19
	2	20
	3	21
	10	22
	15	23
	3	24
	1	26
	15	27
	1	28

DEATH REPORT – FM48DATC CODEBOOK

PUB_ID ----- SUBJECT ID

type: numeric (float)
 range: [1,526] units: 1
 unique values: 65 coded missing: 0 / 80
 mean: 237.738
 std. dev: 154.572
 percentiles: 10% 25% 50% 75% 90%
 27.5 108.5 238 374 453

HIV_COMP ----- D1a.-D5a.HIV RELATED COMPLICATION

type: numeric (float)
 range: [1,99] units: 1
 unique values: 16 coded missing: 1 / 80

tabulation:	Freq.	Value
	9	1
	17	2
	1	6
	6	7
	3	8
	1	9
	2	10
	2	11
	1	12
	6	14
	6	15
	7	16
	1	17
	12	19
	4	22
	1	99

HIV_COMP:

- HIV_COMP=99 for one case with presumptive PML/NHL.

SITESPEC ----- D1a.-D5a.SPECIFY SITE OF COMPLICATION

type: string (str30), but longest is str25
 unique values: 7 coded missing: 73 / 80

tabulation:	Freq.	Value
	1	"BRAIN"
	1	"LUNG"
	1	"LUNGS"
	1	"MENINGITIS"
	1	"MUCORMYCOSIS-- L. ARM"
	1	"PSEUDOMAS SEPSIS"
	1	"SUSPECTED PML VS LYMPHOMA"

warning: variable has embedded blanks

SOURCE ----- D1b.-D5b.SOURCE OF INFORMATION

type: numeric (float)
 label: SOURCE

 range: [1,3] units: 1
 unique values: 3 coded missing: 1 / 80

 tabulation: Freq. Numeric Label
 71 1 01:Medical Record
 4 2 02:Physician's Report
 4 3 03:Other Source

SOURSPEC ----- D1b.-D5b.SOURCE OF INFORMATION SPECIFY

type: string (str30), but longest is str29

 unique values: 3 coded missing: 76 / 80

 tabulation: Freq. Value
 2 "LAB REPORT"
 1 "PARTNER OF PT IN DIFF COUNTRY"
 1 "PT'S PARTNER"

 warning: variable has embedded blanks

DX_CONF ----- D1c.-D5c.DIAGNOSIS CONFIRMATION

type: numeric (float)
 label: DX_CONF

 range: [1,2] units: 1
 unique values: 2 coded missing: 1 / 80

 tabulation: Freq. Numeric Label
 55 1 01:Definitive
 24 2 02:Presumptive

CONF_DT ----- D1d.-D5d.DIAGNOSIS CONFIRMATION DATE

type: numeric (float)

 range: [-31,1051] units: 1
 unique values: 73 coded missing: 1 / 80

 mean: 221.544
 std. dev: 268.146

 percentiles: 10% 25% 50% 75% 90%
 1 18 101 338 682

CONF_DT:

1. This variable has been coded as the number of days since Randomization (Negative values indicate dates before Randomization, positive values indicate dates subsequent to Randomization).

CONF_DTZ ----- DATE IMPUTATION INDICATOR -- CONF_DT
type: numeric (float)
label: CONF_DTZ

range: [1,2] units: 1
unique values: 2 coded missing: 0 / 80

tabulation:	Freq.	Numeric	Label
	77	1	Date not imputed
	3	2	15th of month imputed

CONF_DTZ:

1. Indicator of whether the associated date variable is (1) complete (or entirely missing), or (2) incomplete with day of month missing, or (3) incomplete with day and month of year missing.