

INTRODUCTION TO FORM 22 - QUARTERLY MEDICAL RECORD ABSTRACTION FORM

These data are the result of medical record abstraction for “VATS events”. Form 22 was only to be completed if triggered by certain responses on Form 21. For each reported event, documentation was sent to NERI and was forwarded to two reviewers (from sites other than the site reporting the event). If there was disagreement, even after further documentation may have been requested and reviewed, the case went to a third reviewer for final arbitration. Data were updated as a result of the review, so the definitive events in the Public Use Data Set represent confirmed VATS events.

QUARTERLY MEDICAL RECORD ABSTRACTION FORM -- FORM 22 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.
- A2.** Enter the visit number.
- 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 -- HIV RELATED COMPLICATIONS

The prompts on Form 21 will lead to completion of Form 22 if there is an answer of "yes" or "don't know" to any of the serious HIV-related complications in Form 21, Section C, and/or if the patient was hospitalized since his/her last quarterly visit (Form 21, Section D).

B1. THROUGH B3.

These questions provide a space to document specific HIV-related complications. For each condition reported "yes" or "don't know" on Form 21, Section C, complete a new entry in Section B of Form 22, reporting the outcome of a medical record search. For example, if the patient reported a new diagnosis of invasive cervical cancer on Form 21, but upon search of medical records none is found or only noninvasive cancer is found, complete an entry with complication code 03 (invasive cervical cancer) and confirmation code 03 (no diagnosis found). Give the source of information code for the most reliable source searched.

If the patient was hospitalized, report any new serious HIV-related complication(s), as listed in the “HIV Related Complication Codes” chart, which were diagnosed during that hospitalization. If none were found, it is not necessary to make any entries corresponding to that hospitalization in Section B.

Only report diagnoses of new complications on this form. Progression of existing CMV disease counts as a new event. For example, if there is a second definitive diagnosis of a previously reported lymphoma, do not report it a second time. 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. Do report progression of existing CMV disease.

Each question contains 4 parts.

For **part a**, enter the code of the new HIV related complication.

For **part b**, record the code that corresponds with the most reliable source of this 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.

Note that the protocol (Section 7.4.2) distinguishes upper and lower GI CMV disease. 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 22 -- QUARTERLY MEDICAL RECORD ABSTRACTION

SECTION A -- GENERAL INFORMATION

- A1. Subject ID: (ENTER ID NUMBER OR AFFIX LABEL AT THE RIGHT) _____ - _____ - _____
- A2. Visit number: _____
- A3. Subject initials: _____
- A4. Form version: 0 7 / 1 5 / 9 5
- A5. Today's date: _____ / _____ / _____
- A6. Initials of person completing form: _____

SECTION B -- HIV RELATED COMPLICATIONS -- New diagnoses since last quarterly visit.

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
 04= No Source Available

DIAGNOSIS CONFIRMATION CODES

If more than one source confirms diagnosis, but reports conflict regarding definitive or presumptive, record definitive.

- 01= Definitive
 02= Presumptive
 03= No Diagnosis Found

- B1. 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: _____ / _____ / _____
- B2. 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: _____ / _____ / _____
- B3. 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 FORM IF ADDITIONAL SPACE IS REQUIRED.

END OF FORM

QUARTERLY MEDICAL RECORD ABSTRACTION FORM – FORM22DATA CODEBOOK

PUB_ID ----- SUBJECT ID

type: numeric (float)
 range: [1,528] units: 1
 unique values: 300 coded missing: 0 / 849
 mean: 264.567
 std. dev: 153.064
 percentiles: 10% 25% 50% 75% 90%
 46 137 269 397 480

VISNUM ----- A2.VISIT NUMBER

type: string (str2)
 unique values: 15 coded missing: 0 / 849
 tabulation:

Freq.	Value
166	"03"
139	"06"
99	"09"
84	"12"
66	"15"
53	"18"
46	"21"
39	"24"
35	"27"
27	"30"
34	"33"
33	"36"
13	"39"
11	"42"
4	"45"

VISNUM:

1. This form is only used at quarterly visits (QU 03, QU 06, QU 09, etc.). Therefore, this variable is always coded as 03, 06, 09, etc.

FORM_V ----- A4.FORM VERSION DATE

type: numeric (float)
 label: FORM_V
 range: [12979,12979] units: 1
 unique values: 1 coded missing: 0 / 849
 tabulation:

Freq.	Numeric	Label
849	12979	07/15/95

COMP_D ----- A5.DATE FORM COMPLETED

type: numeric (float)
range: [12,1357] units: 1
unique values: 507 coded missing: 0 / 849
mean: 453.876
std. dev: 334.157
percentiles: 10% 25% 50% 75% 90%
95 182 359 660 1010

COMP_D:

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)

QUARTERLY MEDICAL RECORD ABSTRACTION FORM – FORM22DATB CODEBOOK

PUB_ID ----- SUBJECT ID
 type: numeric (float)
 range: [1,527] units: 1
 unique values: 149 coded missing: 0 / 312
 mean: 279.676
 std. dev: 156.846
 percentiles: 10% 25% 50% 75% 90%
 42 152 315 409.5 488

VISNUM ----- A2.VISIT NUMBER
 type: string (str2)
 unique values: 13 coded missing: 0 / 312
 tabulation: Freq. Value
 117 "03"
 83 "06"
 27 "09"
 33 "12"
 10 "15"
 13 "18"
 4 "21"
 13 "24"
 4 "27"
 4 "30"
 2 "33"
 1 "36"
 1 "42"

VISNUM:

1. This form is only used at quarterly visits (QU 03, QU 06, QU 09, etc.). Therefore, this variable is always coded as 03, 06, 09, etc.

COMPLIC ----- B1a.HIV RELATED COMPLICATION

type: numeric (float)
 range: [1,22] units: 1
 unique values: 20 coded missing: 0 / 312

tabulation:	Freq.	Value
	47	1
	27	2
	2	5
	3	6
	82	7
	5	8
	12	9
	12	10
	9	11
	8	12
	5	13
	6	14
	4	15
	30	16
	8	17
	3	18
	25	19
	1	20
	1	21
	22	22

COMPSPEC ----- B1a.HIV RELATED COMPLICATION SPECIFY

type: string (str30), but longest is str29
 unique values: 30 coded missing: 281 / 312
 examples: ""
 ""
 ""
 ""
 warning: variable has embedded blanks

SOURCE ----- B1b.SOURCE OF INFO - HIV COMPLIC

type: numeric (float)
 label: SOURCE
 range: [1,3] units: 1
 unique values: 3 coded missing: 0 / 312

tabulation:	Freq.	Numeric	Label
	291	1	01:Medical Record
	15	2	02:Physician's Report
	6	3	03:Other Source

