TB:HIV Study
Instructions for HIV form 12 Months Follow-up

NOTE: Information in this form should only be completed if data on HIV infection CANNOT be provided electronically from a database.
For electronic data transfer please contact CHIP on hivtb@cphiv.dk

Please read these instructions and the list of definitions for the various diseases carefully before you start filling out the form. Please use black ink when filling out the form.

At 12 Months Follow-up, please complete data closest to the date of 12 months after TB diagnosis and up to the date.

1. In general:

- **Please cross-check the information provided on the form and complete where missing.**

- Complete this form by entering either "*X*", by filling out a numeric field, or by completing the information about the day, month, and year for time-variables. If the month is unknown write only the year. If the month and year are both unknown write " 02/79 ".

- If information is incorrect, please draw a single line through the incorrect information, write correct information, circle the correction, write your initial and date.

2. Section A: Demography; Section B1: HIV serology and Section B2: Screening for TB:

- Complete "Most recent visit". Cross-check information provided previously and complete where missing.

3. Section C1 and C2: Laboratory values:

- Results of most recent to **12 months after TB diagnosis** haemoglobin, platelet, transaminases (ALT/AST), bilirubin, serum-creatinine, albumin and basic phosphatase should be given.

- If patient has initiated antiretroviral therapy, please provide CD_4 count and HIV-RNA measurements at the time of treatment initiation.

- The **8 most recent** CD_4 cell counts and HIV-RNA measurements performed should be reported. Please indicate the method used for the HIV-RNA measurements, as well as the detection limit (DL) for the tests with a HIV-RNA below DL. Please code measurements below DL as "*<DL*" (e.g. " *<20* " if DL is 20 copies/ml) rather than " 0 ". Such values will be listed at the next form as " *DL - 19*", for example "*19* " for " <20 ".

- If CD_4 count was not measured close to the date of TB diagnosis, please make sure that it is indicated why.

- Cross check the information provided for HIV and HCV-subtyping and resistance tests as well as information on hepatitis B and C virology/serology and complete where missing.

- Results of HBV and HCV antibody tests are " *positive* " if at least one (of several different supplementary tests) is positive; in the presence of a positive result of either an anti-HBs, anti-HBc and/or HBe antibody test, the HBV antibody test is considered positive.

4. Sections D: Antiretroviral treatment:

- **Please cross-check and update the entire history of antiretroviral drugs**.
  "Date of start" should be completed for all drugs used.
  "On drug at present visit" should be completed if a patient started a drug and still receives it.
  "Date of stopping" and "reason for discontinuation" should be completed if the patient discontinues a drug, also if a patient dies. If the patient has received the drug in several intervals, provide all available start and stop dates.
  Information on blinded trial(s) should only be completed if the study drugs are still blinded. Otherwise, only information on active drugs should be completed.

- For drug names please use abbreviations provided at the bottom of the page.

- Please indicate reasons of discontinuation by using codes at the bottom of the page.

- Information on compliance to cART therapy should be filled out if available.

- If the patient has not initiated cART within 2 months of TB diagnosis **please make sure that the question 4 is answered.**

- Please indicate the reason for the chosen cART regimen by answering **question 5**.

5. Section E: Treatment/prophylaxis against opportunistic infections:

- Should only be completed for drugs used from the time of enrolment and thereafter. Please fill out which drugs have been used. Complete start and stop dates, also if the patient dies. If no drugs have been used, please tick "no".

- **Please do not insert here TB drugs used for treatment of the current TB case. They should be provided on TB form, not on HIV form**

6. Section F and G: Severe opportunistic infections and AIDS defining malignancies:

- If the patient has had any severe opportunistic infections or AIDS defining malignancies **at any time,** it should be noted. Both "Time of onset" and "Way of diagnosis" should be completed for all events listed. Diagnoses methods for these events should fulfil criteria listed below.

- **Current TB case should not be reported here, only on TB form**

Presumptive diagnoses are allowed for the following diseases: AIDS dementia complex, recurrent bacterial pneumonia, oesophageal candidiasis, CMV chorioretinitis, mycobacterioses (check carefully), PCP, PML, toxoplasmosis, Kaposi's sarcoma, and primary brain lymphoma.

As for *focal brain lesions not specifically identified by histology/cytology* check whether the patient fulfils the criteria for presumptive diagnosis of either PML, toxoplasmosis or primary brain lymphoma. In case of other severe opportunistic infections not listed in section F, item 20 should be completed. Also cases of pulmonary aspergillosis and nocardia should be listed here. Generally data on the initial diagnosis of a given disease is requested though data on recurrent cases of some opportunistic infections (specified in the form) is also requested.

AIDS Defining Events & Severe HIV-associated Diseases – definitive and presumptive way of diagnosis

AIDS dementia complex

Definitive	Disabling cognitive and/or motor dysfunction, or milestone loss in a child, and no other causes by CSF exam and brain imaging or by autopsy
Presumptive	same as above but no CSF and brain imaging performed

Aspergillosis, pneumonia (should be indicated under 'other severe opportunistic infections') (not AIDS defining)

Definitive/autopsy	Culture of Aspergillosis from BAL or lung biopsy in a patient with abnormal chest X-ray

Bacterial pneumonia, recurrent (› 2 episodes within 1 year)

Definitive	New X-ray evidence not present earlier and culture of pathogen that typically causes pneumonia (other than P .carinii or M. tuberculosis)
Presumptive	Acute radiological findings (new X-ray evidence not present earlier) and acute clinical findings

Candidiasis (tracheal, bronchial, lung)

Definitive/autopsy	Gross inspection at endoscopy/autopsy or by microscopic evaluation of tissue, not only culture

Candidiasis (oesophageal)

Definitive/autopsy	Gross inspection by endoscopy/autopsy or by microscopy (histology)
Presumptive	Recent onset retrosternal pain on swallowing and confirmed oral or pharyngeal candidiasis

Cervical cancer (only females)

Definitive/autopsy	Histology

Coccidioidomycosis, disseminated or extrapulmonary (should be indicated under 'Other severe opportunistic infections')

Definitive/autopsy	Microscopy, culture or detection of antigen in tissue/fluid from affected organ

Cryptococcosis, extrapulm.

Definitive/autopsy	Microscopy, culture of, or antigen detection in affected tissue

Cryptosporidiosis, › 1 month

Definitive/autopsy	Microscopy. Duration of diarrhoea for more then 1 month

Cytomegalovirus retinitis

Presumptive	Loss of vision and characteristic appearance on serial ophtalmoscopy, progressing over serial months

Cytomegalovirus (pneumonia, oesophagitis, colitis, adrenalitis, other organs)

Definitive/autopsy	Microscopy (histology or cytology)

Herpes simplex ulcers (duration › 1 month) or pneumonia/oesophagitis

Definitive/autopsy	Microscopy, culture of, or antigen detection in affected tissue

Histoplasmosis (extrapulm.)

Definitive/autopsy	Microscopy, culture of, or antigen detection in affected tissue

HIV wasting syndrome

Definitive	Weight loss (over 10% of baseline) with no other cause, and 30 days or more of either diarrhoea or weakness with fever

Isosporiasis, duration › 1 month

Definitive/autopsy	Microscopy (histology or cytology). Duration of diarrhoea for more than 1 month

Kaposi's sarcoma

Definitive/autopsy	Histology
Presumptive	Characteristic erythematous/violaceous plaque-like lesion on skin or mucous membranes

Leishmaniasis, visceral (not AIDS defining)

Definitive/autopsy	Histology or culture of Leishmania amastigotes in bone marrow or detection of amastigotes in tissue/fluid from affected organ in a patient with symptoms and signs consistent with disseminated Leishmaniasis

Malignant lymphoma

Definitive/autopsy	Histology
Presumptive	(only primary brain lymphoma) Recent onset of focal neurological symptoms and signs or reduced level of consciousness, CT/MR scan evidence of a lesion or lesions having mass effect, no response to toxo therapy, no evidence of lymphoma outside the brain

Microsporidiosis (not AIDS defining)

Definitive/autopsy	Stool microscopy or rectal biopsy in patient with persistent diarrhoea (› 2 weeks)

Mycobacterium tuberculosis and MAC/ Kansasii (pulmonary and/or extrapulm.) (Pulmonary MAC/Kansassii not AIDS defining)

Definitive	Culture
Presumptive	Acid fast bacteria (species not identified by culture) on microscopy of normally sterile body fluid/tissue

Mycobacterium other type (pulmonary) (not AIDS defining)

Definitive	Culture (indicate type)
Presumptive	Acid fast bacteria (species not identified by culture) in sputum

Mycobacterium other type (extrapulm.)

Definitive	Culture (indicate type)

Presumptive	Acid fast bacteria (species not identified by culture) on microscopy of normally sterile body fluid/tissue

Nocardiosis pulmonary (should be indicated under 'other severe opportunistic infections') (not AIDS defining)

Definitive/autopsy	By culture
Presumptive	Microscopy of sputum/pus showing irregular or breaded, narrow, branching filaments

Pneumocystis carinii pneumonia

Definitive	Microscopy (histology or cytology)
Presumptive	Recent onset of dyspnoea on exertion or dry cough, and diffuse bilateral infiltrates on chest X-ray and pO2 ‹70 mmHg and no evidence of bacterial pneumonia

Progressive multifocal leukoencephalopathy (PML)

Definitive/autopsy	Microscopy (histology or cytology)
Presumptive	Progressive deterioration in neurological function and CT/MR scan evidence

Salmonella (non typhoid) bacteriaemia (› 2 episodes)

Definitive	Culture

Toxoplasmosis, brain

Definitive	Microscopy (histology/cytology)
Presumptive	Recent onset focal neurological abnormalities or reduced level of consciousness, and mass effect lesion on scan, and specific therapy response

Toxoplasmosis, chorioretinitis (should be indicated under 'other severe opportunistic infections') (not AIDS defining)

Presumptive	Based on characteristic morphology and response to specific therapy

Copenhagen HIV Programme
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