

SLATE II CRF Part 2

Study ID

(Scan the study ID barcode on the outside of the randomization envelope.)

Study Clinician: "Hello, my name is _____. I will be collecting the rest of the information we need for the study, to see if you can start ART now, as part of the study, or if you should receive additional care or counseling from the clinic first. I will start by asking you if you have any symptoms of illness today."

Only patients randomized to the intervention arm should continue!

REDCap User

Time started _____

SYMPTOM REPORT

Study nurse: please review symptoms reported by patient in CRF Part 1 and confirm that each symptom reported is correct or that patient has no symptoms.

Does patient currently have a cough?

- Yes
 No
(TB module will open at end of symptom report.)

Does patient have a fever now or in the past 24 hours?

- Yes
 No
(TB module will open at end of symptom report.)

Does patient report having night sweats?

- Yes
 No
(TB module will open at end of symptom report.)

Does patient report losing weight?

- Yes
 No
(TB module will open at end of symptom report.)

Does patient report any other symptoms that may indicate TB?

- Yes
 No
(TB module will open at end of symptom report.)

Does patient have a continuous headache that hasn't gone away for at least two days?

- Yes (screens out of immediate ART initiation)
 No
(If headache is persistent or continuous, answer "yes." If occasional or temporary, answer "no.")

Does patient report any other symptoms of illness?

- Yes
 No

If yes, what other symptoms?

If yes, do any of the other symptoms indicate that further consultation is needed before starting ART?

- Yes
 No

Comments on symptom report

(Describe any symptoms reported by patient (duration, intensity, etc.))

TB MODULE: Patient answered "yes" to one or more of the TB symptoms listed above. The TB module will now open and should be completed before continuing with the symptom report.

If the patient already gave a urine sample for a pregnancy test then the LAM test should be performed using that sample. If no urine sample was collected earlier then do so now.

Has patient been asked for a urine sample for a TB LAM test?

- Yes
 No

If no, why not?

Did patient provide a urine sample for a LAM test?

- Yes
 No

If no, why not?

Was LAM test performed?

- Yes
 No

If no, why not?

LAM test result

- Negative
 Positive

Duration of cough

- 1 day
 2 days
 3-7 days
 8-14 days
 >14 days

Description of cough

- Productive
 Non-productive

Duration of fever

- 1 day
 2 days
 3-4 days
 >4 days

Description of fever

Duration of night sweats

- last night only
 2-3 nights
 4-7 nights
 >7 nights

Description of night sweats

How much weight have you lost, in kg?

For how long have you been losing weight, in weeks?

Description of weight loss

Description of other symptoms that might indicate TB

Do any single symptoms or combination of symptoms suggest that further investigation or a TB test are needed before ART initiation?

- Yes
 No

On the basis of symptoms, this patient screens out for immediate ART initiation and will be referred for additional care. Complete remaining 3 screens and the other sections in CRF Part 2.

MEDICAL HISTORY

Have you been on ART before?

- Yes
 No

If yes, when did you start taking ART before?

 (Enter year YYYY)

If yes, when did you stop taking ART before?

 (Enter month MM and year YYYY)

If yes, why did you stop taking ART before?

Based on timing of or reason(s) for default, what do you recommend for this patient?

- Start ART immediately (today, in the study), no further steps required
 Start ART immediately (today, in the study), refer for additional counseling or other services
 Do not start ART immediately (screens out) (Study nurse completes.)

If you recommended NOT starting ART today due to previous default, explain your decision.

 (Study nurse completes.)

Are you currently on TB treatment?

- Yes
 No

If yes, how many days ago did you start taking TB treatment?

 (Enter number of days. If more than 1 month, enter number of months with "M")

If you started taking TB treatment less than 14 days ago, have you had any health problems or unpleasant side effects from the TB treatment?

- Yes
 No

If yes, describe the problems or side effects.

Is the patient tolerating TB treatment well enough to start ART today?

- Yes
 - No
- (Study nurse completes.)

Have you been told that you have other diseases or health problems besides HIV?

- Yes
- No

If yes, what other diseases or conditions do you have?

If yes, do any of the diseases or conditions suggest further consultation is needed?

- Yes
- No

Are you currently taking any anti-epilepsy medication?

- Yes (screens out of immediate ART initiation)
- No

Are you currently taking warfarin?

- Yes (screens out of immediate ART initiation)
- No

Are you currently taking any other medications?

- Yes
- No

If yes, what other medications are you currently taking?

If yes, do any of the medications suggest that further consultation is needed?

- Yes (screens out of immediate ART initiation)
 - No
- (Study nurse completes.)

On the basis of medical history, should ART be delayed for this patient?

- Yes
 - No
- (If treatment should be delayed, complete all four screens, blood draw, payment and completion form and then escort the patient to regular clinic visit.)

Comments on medical history

On the basis of medical history, this patient screens out for immediate ART initiation and will be referred for additional care. Complete the 2 screens remaining sections in CRF Part 2.

Physical exam

Temperature

(Number entered must have 1 decimal place. Example - '32.0')

Systolic blood pressure

Diastolic blood pressure

Height (cm)

(Number entered must have 1 decimal place. Example - '160.5')

Weight (kg)

(Number entered must have 1 decimal place. Example - '60.2')

Did the patient report symptoms that should be examined?

- Yes
 No

After examination, do any symptoms suggest that further consultation is needed?

- Yes
 No

If yes, which symptoms should be investigated further?

Does the patient have other conditions that further consultation is needed?

- Yes
 No

If yes, what are the other conditions?

On the basis of the physical exam, should ART be delayed for this patient?

- Yes
 No
(If treatment should be delayed, complete all four screens, blood draw, payment and completion form and then escort the patient to regular clinic visit.)

Comments on physical exam

On the basis of the physical exam, this patient screens out for immediate ART initiation and will be referred for additional care. Complete the last screen below and the remaining sections in CRF Part 2.

Readiness assessment

If you should start ART today, how ready are you?

- Not ready (screens out of immediate ART initiation)
 Thinking about trying, maybe in the next month or so (screens out of immediate ART initiation)
 Almost ready, maybe this week (screens out of immediate ART initiation)
 Ready today
(If response is not ready or thinking about trying, delay required; if almost ready, discuss with patient and decide; if ready, continue)

How will you remember to take your medication every day?

- Mobile phone reminder
 Alarm on a clock or watch
 Ask someone to remind me
 Use a calendar or diary
 Take my tablets at the same time as I do something else every day (like brushing my teeth)
 No reminders, I'll just remember
 Other way (specify below)

If other, specify

Is there anything that will stop you from taking your tablets every day?

Did the patient raise any issues or concerns that lead you to think that ART should be delayed?

- Yes (screens out of immediate ART initiation)
 No
 (Study nurse completes.)

If yes, what were these issues or concerns and how did you respond?

(Study nurse completes. Please write a detailed description)

On the basis of the readiness assessment, should ART be delayed for this patient?

- Yes
 No
 (If treatment should be delayed, complete all four screens, blood draw, payment and completion form and then escort the patient to regular clinic visit.)

Comments on readiness assessment

Time ended

On the basis of the readiness assessment this patient screens out for immediate ART initiation and will be referred for additional care. Complete the remaining sections in CRF Part 2.

CD4 COUNT

Blood drawn for study CD4 count?

- Yes
 No - patient already had bloods drawn today
 Refused blood draw

Blood sample bar code (1)

What labs were bloods drawn for?

- CD4
 CRE
 HBV
 FBC
 RPR
 ALT
 (Check all labs that bloods were collected for)

SPUTUM SAMPLE

All patients in the intervention arm should be told how to produce a sputum sample and asked for one.

Was patient able to produce a sputum sample?

- Yes
 No
 Refused to try

Sputum sample barcode
