Audit of management of TB in HIV co-infected patients: case note review

Please complete this questionnaire for all HIV-infected adult patients who STARTED a full course of treatment for actual or suspected active tuberculosis (TB, ie disease attributed to Mycobacterium tuberculosis complex comprising *M. tuberculosis*, *M. bovis* or *M. africanum*) between 1 October 2007 and 30 April 2008 and who were under your department/clinic’s care for their HIV infection at the time of starting TB treatment or have been so subsequently.

INCLUDE such patients even if their TB treatment was provided elsewhere.
INCLUDE such patients even if they did not start attending your department/clinic for HIV care until after their TB treatment was completed.
INCLUDE such patients even if they have died since starting treatment for TB.

EXCLUDE: Patients under the age of 16.
EXCLUDE: Patients with disease due to atypical mycobacteria or BCG.
EXCLUDE: Patients without active disease given chemoprophylaxis for latent TB only.
EXCLUDE: Patients who started treatment for suspected active TB which was subsequently discontinued on medical grounds because of a confirmed alternative diagnosis.

Please do not use your browser "Back" or "Forward" buttons while filling in the questionnaire - your answers will be lost if you do. You can move between pages using the "Next page" and "Previous page" buttons at the bottom of the page. Your final answers are not saved until you click on the "Submit form" button at the end.

What information sources are being used to complete this questionnaire for this patient?

- [ ] Review of HIV clinic notes only
- [ ] Review of HIV and TB clinic notes or integrated notes

Please base your answers to subsequent questions only on information recorded in the notes you have selected above. Answer “not known” if information is not available in these notes.

Sex of patient:

- [ ] Male
- [ ] Female
Ethnicity:
- [ ] White
- [ ] Black
- [ ] African
- [ ] Black
- [ ] Other
- [ ] Asian or Asian British
- [ ] Other
- [ ] Not known

Housing circumstances:
- [ ] Single household accommodation
- [ ] Hostel/multiple occupancy/shared accommodation
- [ ] Street or shelter homeless
- [ ] Long term hospital inpatient
- [ ] Prisoner or detainee
- [ ] Not known

Age:
- [ ] 16-19
- [ ] 20-29
- [ ] 30-39
- [ ] 40-49
- [ ] 50-59
- [ ] 60 or over

Where was the patient born?
- [ ] In UK
- [ ] Outside UK, in a high TB incidence country
- [ ] Outside UK, not in a recognised high TB incidence country
- [ ] Not known

Please state actual country of birth if this information is readily available,
Had this patient been treated for active or latent TB at any time previous to the course of treatment started between 1 October 2007 and 30 April 2008 on which this audit is based? Please tick the first answer that applies.

☐ Yes, patient has a history of previous treatment for active TB disease.
Please state year and whether a full course of treatment was completed, if known:

☐ Yes, patient has a history of previous chemoprophylaxis for latent TB only.
Please state year and whether a full course of chemoprophylaxis was completed, if known:

☐ No, patient has no history of previous treatment for TB
☐ Not known whether patient has been previously treated for TB

Is there evidence in the patient’s medical record that statutory notification has been done as required for TB?

☐ Yes, this is recorded (eg via a duplicate of the notification form)
☐ This is not clearly recorded but notification is believed to have been done
☐ Notification has not been done
☐ Not known

If notification has been done, please give the job title or role of the person who did this:

When notifying TB, was the information that the patient is HIV positive also passed on?

☐ Yes ☐ No ☐ Not known ☐ Not applicable because not notified
Has contact tracing been done for TB contacts?
- Yes
- No
- Not known

Is the identity of the patient’s TB key worker/case manager documented in HIV clinic records?
- Yes, name and contact details documented
- No, patient is believed to have had a TB key worker/case manager but details are not documented
- No TB key worker/case manager was assigned to the patient
- Not known whether a TB key worker/case manager was assigned to the patient

Note: A key worker/case manager is usually a specialist TB nurse or (in low incidence areas) a nurse whose responsibilities include TB. His/her role includes risk assessment, patient education and support, promoting TB treatment adherence and completion, coordinating care with other providers, arranging contact management and screening, and reporting on surveillance systems and treatment completion.

What was the timing of the patient’s HIV diagnosis, relative to their active TB disease?
- Patient was diagnosed with HIV before seeking care for symptoms of TB
- Patient was tested for HIV during investigation of symptoms which led to TB diagnosis
- Patient was diagnosed with HIV via routine screening as a consequence of their TB diagnosis
- Patient was diagnosed with HIV after being diagnosed with TB, but NOT as a result of investigation or routine screening related to their TB diagnosis
- Unclear or not known
What was the patient’s CD4 count in cells/µl when measured nearest to the time of their active TB diagnosis?
If TB was diagnosed before HIV infection, this would be the first CD4 measurement.

- 0-50
- 51-100
- 101-200
- 201-350
- 351-500
- Over 500
- Not known

Has the patient attended your clinic regularly for HIV care since his/her TB diagnosis?

- Yes, patient attends regularly for HIV care
- Patient has missed some appointments but is still receiving HIV care
- Patient has stopped attending for HIV care, please comment on circumstances:
  
- Not sure

What was the timing of initiation of highly active anti-retroviral therapy (HAART) relative to the patient’s treatment for TB?

- Patient had been on HAART for at least two months before starting TB treatment
- Patient started HAART between two months and two weeks before starting TB treatment
- Patient started HAART within two weeks either before or after starting TB treatment
- Patient started HAART more than two weeks after starting TB treatment but during the intensive (usually 4 drug) phase
- Patient started HAART during TB treatment after completing the intensive phase
- Patient started HAART after completion of TB treatment
- Patient has not started HAART
- Not sure
What type of HAART regimen was used during TB therapy?

- Protease inhibitor (PI) plus nucleoside reverse transcriptase analogues (NRTIs)
- Non-nucleoside reverse transcriptase (NNRTI) plus NRTIs
- NRTIs only
- Other
- Not sure
- Not applicable because HAART not used during TB therapy

What was the site of the TB (tick all that apply)?

- Pulmonary
- Peripheral lymph node
- Meningeal
- Disseminated (including miliary)
- Other

How was TB diagnosed (tick all that apply)?

- Positive sputum smear
- Acid-fast bacilli microscopy other than sputum smear
- Positive sputum culture
- Positive culture other than sputum
- Chest X ray
- Other imaging
- Cytology or histology
- Positive tuberculin skin test
- Positive interferon-gamma test
Positive NAAT (nucleic acid amplification test)
Presumptive diagnosis based on clinical response to TB therapy
Presumptive or suspected diagnosis based on other factors
Other, please describe:

Was a culture-positive specimen sent to a reference laboratory?
☐ Yes ☐ No ☐ Not applicable because no positive culture ☐ Not known

Was rapid diagnostic testing for rifampicin resistance performed?
☐ Yes ☐ No ☐ Not known

At the time when the initial TB therapy regimen was prescribed, what was the status as regards TB drug resistance? Select one answer for each drug.

Isoniazid: [Select answer]
Rifampicin: [Select answer]
Pyrazinamide: [Select answer]
Ethambutol: [Select answer]
Streptomycin: [Select answer]

Did TB drug resistance subsequently emerge or evolve during treatment?
☐ Yes, please describe: ☐ No ☐ Not known
Was the patient assessed for likely adherence to TB therapy before this treatment was started?
☐ Yes ☐ No ☐ Not known

If patient was assessed, what was the outcome?
Please base your answer on assessment prior to starting treatment only, not actual adherence or any subsequent reassessment.

☐ Expected to adhere adequately or well
☐ Likely to be poorly adherent
☐ Not known
☐ Not applicable because not assessed

What drugs were included in the initial TB therapy regimen prescribed, and for what intended duration?
NB base your answer on regimen planned when therapy initiated, not on any subsequent modification. Select one answer for each drug.

Isoniazid:
☐ [Select answer]

Rifampicin:
☐ [Select answer]

Rifabutin:
☐ [Select answer]

Pyrazinamide:
☐ [Select answer]

Ethambutol:
☐ [Select answer]

Streptomycin:
☐ [Select answer]

If any other drug(s) (eg quinolone) was prescribed in the initial TB therapy regimen, please state drug and duration:
Was a steroid also prescribed?

- [ ] Yes
- [ ] No
- [ ] Not known

Was this regimen subsequently extended or modified in any way?

- [ ] Yes
- [ ] No
- [ ] Not known

If yes, please give details and reasons:

What was the outcome of TB therapy?

- [ ] Known to have completed full course of treatment without interruption
- [ ] Treatment is still ongoing
- [ ] Treatment was stopped or interrupted before the full course was completed (even if subsequently completed)
- [ ] Died before completing treatment
- [ ] Transferred care to another UK clinical centre while still on treatment
- [ ] Patient left UK while still on treatment
- [ ] Patient stopped attending while still on treatment, but is not known to have left UK or transferred to another UK centre
- [ ] Outcome not known for other reasons, please state:

- [ ] Outcome not documented
Whether or not treatment was subsequently completed successfully, did cultures remain or become positive at any time after the first four months of treatment?

- Yes
- No
- Not known

Has therapeutic drug monitoring been performed for:*

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<th>Yes</th>
<th>No</th>
<th>Not relevant because</th>
<th>Not sure</th>
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<td>Anti-retroviral (ART) drug levels?</td>
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<td>TB drug levels?</td>
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Would directly observed therapy (DOT) have been appropriate for this patient’s TB medication?

- Yes, please give reasons:  
- No
- Not sure

Was DOT used at any time for this patient’s TB medication?

- Yes
- No
- Not sure

If yes, please state by whom this was supervised:

Please click "Next page" to continue.
If conditions are met hide NEXT question

Did not answer to **What was the timing of the patient’s HIV diagnosis, relative to their active TB ...** with **Patient was diagnosed with HIV after being diagnosed with TB, but NOT as a result of investigation or routine screening related to their TB diagnosis**

Why was this patient’s HIV not diagnosed on routine screening following the TB diagnosis?

- HIV screening was offered but patient declined
- HIV screening was not offered
- Not known

Please describe the circumstances of this patient’s HIV diagnosis:

If conditions are met hide NEXT question

Did not answer to **What was the timing of the patient’s HIV diagnosis, relative to their active TB ...** with **Patient was diagnosed with HIV before seeking care for symptoms of TB**

Had the patient been screened for latent TB at the time of his/her HIV diagnosis?

- Yes, please state tests used if known: 
- No
- Not sure

If conditions are met hide NEXT question

Did not answer to **How was TB diagnosed (tick all that apply)?** with **Positive sputum smear**
What was the time interval from taking the sputum sample to receiving the positive sputum smear result?

- Same day
- Next day
- 2 days
- 3 days
- 4 days or longer

If conditions are met hide NEXT question

Did answer to **How was TB diagnosed (tick all that apply)?** with **Positive sputum culture OR**
Did answer to **How was TB diagnosed (tick all that apply)?** with **Positive culture other than sputum**

The answers you selected earlier indicate that a positive culture was not used to diagnose this patient’s active TB. Was culture attempted at that time?

- Yes, on sputum with or without other samples
- Yes, but only on samples other than sputum
- No
- Not known

If conditions are met hide NEXT question

Did not answer to **Was rapid diagnostic testing for rifampicin resistance performed?** with No AND
Did not answer to **At the time when the initial TB therapy regimen was prescribed, what was the sta...** with Rifampicin: equals Not tested

Why was the patient not tested for rifampicin resistance?

- Patient was assessed and considered at low risk for resistance
- No culture or smear positive material was available
- Other reason, please state:
  
  ______________

- Not known
If conditions are met hide NEXT question

Did not answer to **What type of HAART regimen was used during TB therapy?** with **Non-nucleoside reverse transcriptase (NNRTI) plus NRTIs**

You have indicated that this patient was treated with an NNRTI during TB therapy. Was this:

- [ ] Efavirenz
- [ ] Nevirapine

Please state the dose used and reasons for this dosage:

If conditions are met hide NEXT question

Did not answer to **Was DOT used at any time for this patient’s TB medication?** with **Yes**

You have indicated that DOT was used for this patient. What was the frequency of DOT administration?

- [ ] Daily
- [ ] 3 times a week
- [ ] Twice a week
- [ ] Other
- [ ] Not known

If conditions are met hide NEXT question

Did not answer to **What was the timing of initiation of highly active anti-retroviral therapy (HAART... with Patient started HAART within two weeks either before or after starting TB treatment AND**

Did not answer to **What was the timing of initiation of highly active anti-retroviral therapy (HAART... with Patient started HAART more than two weeks after starting TB treatment but during the intensive (usually 4 drug) phase AND**

Did not answer to **What was the timing of initiation of highly active anti-retroviral therapy (HAART... with Patient started HAART during TB treatment after completing the intensive phase**
Did the patient experience immune reconstitution inflammatory syndrome (IRIS) after starting HAART?

- Yes, IRIS was diagnosed
- Possibly, some symptoms worsened but uncertain whether this was due to IRIS
- No
- Not known

If conditions are met hide NEXT question

Did not answer to **What was the timing of initiation of highly active anti-retroviral therapy (HAART)** with Patient started HAART within two weeks either before or after starting TB treatment AND

Did not answer to **What was the timing of initiation of highly active anti-retroviral therapy (HAART)** with Patient started HAART more than two weeks after starting TB treatment but during the intensive (usually 4 drug) phase AND

Did not answer to **What was the timing of initiation of highly active anti-retroviral therapy (HAART)** with Patient started HAART during TB treatment after completing the intensive phase

If IRIS was diagnosed or suspected, were steroids prescribed?

- Patient was already on steroids when IRIS developed
- Steroids were prescribed in response to IRIS
- Steroids were not prescribed
- Not applicable because no IRIS
- Not known

If conditions are met hide NEXT question

Did not answer to **What was the outcome of TB therapy?** with Died before completing treatment
What was the cause of death?

☐ TB  ☐ Other, please state: ☐ Not sure  

If conditions are met hide NEXT question

Did not answer to What was the outcome of TB therapy? with Treatment was stopped or interrupted before the full course was completed (even if subsequently completed)

Why did the patient stop or interrupt treatment before completing the full course?

If conditions are met hide NEXT question

Did not answer to What was the outcome of TB therapy? with Treatment was stopped or interrupted before the full course was completed (even if subsequently completed)

Was treatment subsequently satisfactorily completed?

☐ Yes, a full course of TB treatment has been satisfactorily completed

☐ Treatment has been resumed and is ongoing satisfactorily

☐ Treatment was resumed but not satisfactorily
No, treatment has not been resumed

Not known

If conditions are met hide NEXT question

Did not answer to What was the outcome of TB therapy? with Known to have completed full course of treatment without interruption

Has the patient been followed up for TB since completing treatment?

Yes TB follow-up is scheduled

No planned TB follow-up

Not known

Please add any comments if you wish:

Please click on "Submit form" to complete the questionnaire. Your answers are not saved until you do so.