British HIV Association

National Clinical Audit:

Changing Initial HIV Therapy (case note review)
Management of TB and HIV Co-Infection
Re-audit of Starting HIV Therapy from Naïve (case note review)

To take part in the 2004-5 national audit of HIV therapy, please complete and return the attached forms to arrive by ***Friday 7 January 2005*** . Please keep the patient summary sheets together with the main form. The forms should be returned to the following address:

British HIV Association (Audit)
Mediscript Ltd
1 Mountview Court
310 Friern Barnet Lane
London N20 0LD

In some areas there is an option to submit data for local/regional audit as well as inclusion in the national audit. If you are a member of a local/regional audit group, then release of your data to that group is on an opt-out basis.

The forms are machine readable. Please follow these instructions carefully.

- Please send your completed form by post. Because of problems with electronic reading, we are sorry we cannot accept faxed copies.
- Please use black ink.
- Please only write in the spaces provided on the form.
- Please mark the box corresponding to your chosen answer with a tick: ☑

- If you make a MISTAKE and wish to change your answer, completely fill in the box corresponding to the **WRONG** answer: ■
- If a question does not apply or you do not wish to answer it, please just leave it blank - do **NOT** cross it out.

This form is designed to enable confidential data processing, such that no one outside the BHIVA secretariat will be able to link information which identifies participating centres to the audit data they have submitted. If you would like further information about this, please see the confidentiality protocol at www.bhiva-clinical-audit.org.uk.

Please also COMPLETE and RETAIN the enclosed check-sheet to keep a record of which patients you have included in the audit. This may help you to interpret the audit results.

If you have any queries about how to complete the audit forms, please contact the BHIVA audit coordinator, Hilary Curtis, 020 7624 2148 (home) 07984 239556 (mobile), hilary@regordane.net.

Thank you for your participation.

BHIVA acknowledges the contribution of the Department of Health towards the funding of the BHIVA National Clinical Audit programme

Section A: Identifying information

Office use only	Centre code:
BHIVA secretariat: Retain this page, send other pages and Patient Summary Sheets to data entry bureau.	999000

Please complete this page either by hand or by using clinic address sticker or stamp.

Question:

A1 Name of lead clinician for this audit: .....

A2 Job title: .....

A3 Department/unit: .....

A4 Hospital or trust: .....

A5 Address: .....

.....

A6 Town/city: .....

A7 Postcode: .....

A8 Telephone: ..... Fax: ..... Email: .....

A9 Local primary care trust, health authority or board: .....

A10 Does your department/unit offer adult out-patient HIV care?

- ☐ Yes, we offer such care
- ☐ No, we do not offer adult HIV out-patient care

If you answered YES to question A10, then please continue to complete the questionnaire.
If NO, we apologise for taking up your time and will remove your unit from our list.

Regardless of your answer, PLEASE RETURN THE QUESTIONNAIRE.

A11 ☐ Please tick this box if you are NOT willing for your centre to appear on a published list of centres taking part in this audit.

A12 ☐ Please tick this box if you are NOT willing for your data to be released to your regional audit group for local analysis, identified by your centre code only. Now please go to question B1.

Signature: .....

Clinicians collaborating in the audit

Please give details of consultants whose patients have been included in audit data submitted with this form, and other clinical staff who have contributed significantly to the conduct of the audit (continue overleaf if necessary).

This is to enable BHIVA to provide individual certificates of audit completion.

Name: .....

Job title: .....

Address if different from that given on page 2:

.....

Name: .....

Job title: .....

Address if different from that given on page 2:

.....

Name: .....

Job title: .....

Address if different from that given on page 2:

.....

Name: .....

Job title: .....

Address if different from that given on page 2:

.....

Centre code: 999000

This page is blank. Please use it for additional details of participants, if necessary.

Centre code: 999000

Centre code: 999000

Section B: Profile of participating centre

Question:

B1 Is the centre located:

☐ In NHS London region ☐ Outside NHS London region ☐ Don't know

B2 How many patients are currently receiving care for HIV at your centre?

☐ 1-50 ☐ 51-100 ☐ 101-200 ☐ 201-500 ☐ 501+ ☐ Don't know

B3 How has the number of patients receiving HIV care at your centre changed over the past year?

☐ Down/same ☐ Up 0-5% ☐ Up 5-10% ☐ Up 10-15% ☐ Up >15%

B4 Please enter the actual number of HIV patients who have attended your centre for care at least once in the past six months. This is optional but enables us to estimate the proportion of the UK HIV population covered by the audit:

Section C: Management of patients on initial therapy

Question:

Please answer the following questions as they relate to your centre's current practice in relation to patients on starting and taking their initial antiretroviral therapy.

C1 Does your centre have a local policy or guidelines on antiretroviral therapy (ART)?

☐ BHIVA guidelines only ☐ BHIVA plus local policy/guidelines

☐ Local policy/guidelines only ☐ No policy/guidelines ☐ Not sure

C2 If your centre has a local policy/guidelines on ART, does this explicitly address support for adherence?

☐ Yes ☐ No ☐ Not sure ☐ No local policy/guidelines

C3 What is your centre's practice with regard to assessing adherence to ART?

☐ Assess at every clinic visit for patients on treatment

☐ Assess routinely, but less often than every clinic visit

☐ Assess only if difficulties are suspected or reported by the patient

C4 What is your preferred way of managing virological rebound after previous undetectability?

☐ Switch as soon as rebound confirmed by second viral load (VL) over 50 copies/ml

☐ Switch as soon as rebound confirmed by second viral load (VL) over 400 copies/ml

☐ Delay switch until VL over 1000 copies/ml to allow resistance testing

☐ Delay switch until VL over 1000 copies/ml for other reasons

☐ Not sure or no preferred approach

C5 In what circumstances would your centre arrange therapeutic drug monitoring (TDM) in a patient with virological failure?

- ☐ Only if drug interactions leading to reduced concentrations are suspected
- ☐ Routinely if adherence is suspect
- ☐ Never/rarely because not available at this centre
- ☐ Never/rarely for other reasons
- ☐ Other
- ☐ Not sure

C6 To what extent does cost influence your choice of ART drugs?

- ☐ Main or major consideration
- ☐ Taken into account, but not a major consideration
- ☐ Not a consideration
- ☐ Not sure

Section D: Management of HIV and TB co-infection

Question:

Please answer the following questions as they relate to your centre's current practice in relation to patients who are or may be co-infected with HIV and TB.

D1 Please estimate the number of patients co-infected with HIV and TB seen at your centre in the past year:

☐ 0-5 ☐ 6-10 ☐ 11-30 ☐ 31-100 ☐ more than 100

D2 Of these patients, please estimate the proportion who had HIV and MDRTB (multi-drug resistant TB, ie resistant to at least isoniazid and rifampicin):

☐ 0-10% ☐ 10-20% ☐ 20-50% ☐ more than 50%

D3 Are you satisfied with:

a	Local availability of isolation facilities:	☐ Yes	☐ No	☐ Don't know
b	Local availability of negative pressure facilities:	☐ Yes	☐ No	☐ Don't know
c	Access to PCR testing for TB	☐ Yes	☐ No	☐ Don't know

If you ticked "No" in any of the above cases, please say why not:

.....

D4 What is your view of your hospital's infection control arrangements as they apply to TB?

- ☐ Arrangements are satisfactory
- ☐ Not familiar with arrangements
- ☐ Not sure
- ☐ Arrangements are unsatisfactory, please comment:

.....

D5 Do you work with a multi-disciplinary team when managing patients with HIV and TB?

a ☐ Yes ☐ No ☐ Don't know

b If yes, please tick all disciplines represented among the team:

- ☐ HIV specialist physician(s)
- ☐ Infectious diseases (ID) specialist physician(s)
- ☐ HIV specialist nurse(s)
- ☐ TB specialist nurse(s)
- ☐ Respiratory specialist physician(s)
- ☐ Other, please state:

D6 Are all cases of TB among patients with HIV at your centre notified under statutory arrangements to the appropriate Consultant in Communicable Disease Control?

☐ Yes ☐ No ☐ Not sure

D7 Who is responsible for notifying cases of TB among patients with HIV at your centre to the appropriate Consultant in Communicable Disease Control?

☐ HIV physician ☐ Respiratory, ID or other TB-related specialist physician
☐ Shared responsibility ☐ Not sure

D8 Is tuberculin (PPD) testing routinely recommended to newly diagnosed patients with HIV infection at your centre?

☐ Yes ☐ Yes if no documented BCG immunisation
☐ No ☐ No policy ☐ Don't know

D9 Is HIV testing routinely recommended to newly diagnosed patients with TB in your hospital?

☐ Yes, all TB patients ☐ Yes, patients with suspected risks for HIV
☐ Yes, patients from HIV-endemic areas ☐ No ☐ Don't know

D10 What chemopreventative therapy would you offer to a patient with newly diagnosed HIV infection and a positive tuberculin skin test?

☐ None ☐ Isoniazid for 9 months ☐ Rifampicin for 3-4 months
☐ Rifampicin + isoniazid for 3-4 months ☐ Rifampicin + pyrazinamide for 2 months
☐ Other ☐ Not sure

D11 How soon are results of smears for acid-fast bacilli usually available within your centre?

☐ Same working day ☐ Next working day ☐ 2-3 working days
☐ More than 3 working days but less than a week ☐ More than a week

D12 What is your preferred regimen for treating fully drug-sensitive pulmonary TB in patients with HIV infection on and off highly active anti-retroviral therapy (HAART)?

a Patients NOT on HAART:

☐ 6 months rifampicin + isoniazid, with pyrazinamide + ethambutol for first 2 months
☐ 6 months rifampicin + isoniazid, with pyrazinamide for first 2 months
☐ 9 months rifampicin + isoniazid, with pyrazinamide for first 2 months
☐ Other, please state: .....

b Patients on HAART:

☐ 6 months rifampicin + isoniazid, with pyrazinamide + ethambutol for first 2 months
☐ 6 months rifampicin + isoniazid, with pyrazinamide for first 2 months
☐ 9 months rifampicin + isoniazid, with pyrazinamide for first 2 months
☐ Other, please state: .....

D13 Please describe how you use protease inhibitors (PIs) in patients being treated for TB:

a Would you use ritonavir-boosting?

☐ Yes ☐ Sometimes ☐ No ☐ Not sure ☐ I avoid PIs if possible

b Would you substitute rifabutin for rifampicin?

☐ Yes ☐ Sometimes ☐ No ☐ Not sure ☐ I avoid PIs if possible

Centre code: 999000

D14 Please describe how you use non-nucleoside reverse transcriptase inhibitors (NNRTIs) in patients being treated for TB:

a What NNRTIs might you use (tick any that apply)?

☐ Efavirenz ☐ Nevirapine ☐ Not sure ☐ I avoid NNRTIs if possible

b Would you substitute rifabutin for rifampicin?

☐ Yes ☐ Sometimes ☐ No ☐ Not sure ☐ I avoid NNRTIs if possible

D15 Is directly observed therapy (DOT) used for patients with HIV and TB at your centre?

☐ Yes, routinely for most patients ☐ Only for patients with MDR TB

☐ For patients with MDR TB and other selected patients ☐ No ☐ Don't know

D13 Do you ever use intermittent therapy for TB in patients with HIV infection?

☐ Yes, routinely ☐ No, never ☐ Only for patients on DOT

☐ For other selected patients ☐ Not sure

D14 How would you initiate anti-retroviral therapy (ART) in a patient presenting with active TB and HIV infection?

a At CD4 <100 cells/μl:

☐ Start ART and TB treatment together
☐ Delay ART for up to 1 month after starting TB treatment
☐ Delay ART until switch to 2 drug phase of TB treatment
☐ Delay ART until completion of TB treatment
☐ Don't know

b At CD4 between 100 and 200 cells/μl:

☐ Start ART and TB treatment together
☐ Delay ART for up to 1 month after starting TB treatment
☐ Delay ART until switch to 2 drug phase of TB treatment
☐ Delay ART until completion of TB treatment
☐ Don't know

c At CD4 > 200 cells/μl:

☐ Start ART and TB treatment together
☐ Delay ART for up to 1 month after starting TB treatment
☐ Delay ART until switch to 2 drug phase of TB treatment
☐ Delay ART until completion of TB treatment
☐ Don't know

D15 Have you ever diagnosed immune reconstitution inflammatory syndrome (IRIS) in a patient with TB receiving HAART?

☐ Yes ☐ No ☐ Not sure

D16 If you have diagnosed IRIS in a patient with TB, have you used steroids to manage it?

☐ Yes ☐ No ☐ Not sure ☐ N/A - have not diagnosed IRIS

D17 If you have diagnosed IRIS in a patient with TB, have you stopped HAART to manage it?

☐ Yes ☐ No ☐ Not sure ☐ N/A - have not diagnosed IRIS

Section E: evaluation of audit

Centre code: 999000

Please complete all other sections before coming back to complete this section

Question:

E1 In your opinion, is this questionnaire:

- ☐ Too detailed or difficult to complete
- ☐ About right
- ☐ Too simple or superficial to give a fair picture
- ☐ Don't know

E2 Please estimate how much time it has taken to complete sections A, B, C and D of this questionnaire

.....

E3 Please comment on how easy or difficult it was to retrieve the information from patient records to complete the case note review sections of this questionnaire, and if possible estimate the time involved:

.....

E4 Which questions were most difficult to answer (give question number(s)), and why?

.....

E5 Please enter any other comments about this audit project including suggestions for improvements for future audits

.....

.....

Please answer the remaining questions in this section if you participated in the 2003-4 audit of HIV maternity patients.

E6 Did your department have a formal feedback session to review your 2003-4 audit results?

☐ Yes ☐ No ☐ Not sure

E7 If yes, who attended (tick all that apply)?

- ☐ HIV physician(s)
- ☐ Obstetrician(s)
- ☐ Midwi(ves)
- ☐ Paediatrician(s)
- ☐ Nurse(s)
- ☐ Pharmacist(s)
- ☐ Other(s)

E8 Did clinical practice change in your centre as a result of the 2003 audit?

- ☐ No, because no need
- ☐ No, other reasons
- ☐ Yes, in following way(s): .....

.....

E9 Have the 2003-4 audit results (your own and/or national data) been discussed with your commissioners/funders?

☐ Yes ☐ No ☐ Not sure

Centre code: 999000

Instructions for reviewing patient case notes

There are TWO sets of patient summary sheets attached to this questionnaire, for two different case note reviews, as follows:

1. Review of Patients who CHANGED initial therapy

Please review the case notes and complete patient summary sheets for up to 25 adult patients with HIV attending your centre who met the following inclusion criteria:

The patient changed anti-retroviral therapy (ART) between 1 April and 30 September 2004.
AND this was the patient's FIRST change of therapy since starting ART.
AND this change in therapy took place more than 3 three months after starting ART.

Count ANY stopping, starting or switching of one or more ART drugs as a change in therapy but do NOT include patients who stopped ALL drugs.

F1 Please enter the number of patients who CHANGED therapy reviewed here (max. 25): [ ][ ]

2. Review (re-audit) of patients who STARTED therapy for the first time

Please review the case notes and complete patient summary sheets for up to 5 adult patients with HIV attending your centre who met the following inclusion criteria:

The patient started anti-retroviral therapy (ART) between 1 April and 30 September 2004.
AND the patient had never previously taken ART.

F2 Please enter the number of patients who STARTED therapy reviewed here (max. 5): [ ]

Please remember to complete section E after you have reviewed patient records.

Case note review: Changing initial therapy
Patient summary sheet

Patient code for scanning: 999013

Include patients who CHANGED initial antiretroviral therapy (ART) between 1 April and 30 September 2004, in accordance with the inclusion criteria on the main questionnaire (page 10). Please do NOT complete until you have read these criteria. If in doubt, contact Hilary Curtis, 020 7624 2148 hilary@regordane.net.

Question

P1 Please state the patient's sex and ethnic group:

☐ Male ☐ Female ☐ White ☐ Black-African ☐ Other ☐ Not known (NK)

P2 When did the patient first start ART (date of prescribing)? d d m m y y

P3 When did the patient change ART (date of prescribing or of recording if the patient changed therapy without prescription)? d d m m y y: 0 4

P4 Was the patient participating in a clinical trial of any aspect of ART?

☐ No ☐ Yes, please state name of trial: .....

P5 What ART drugs was the patient taking BEFORE changing treatment (tick all that apply)?

☐ Abacavir ☐ Atazanavir ☐ Didanosine ☐ Efavirenz ☐ Emtricitabine ☐ Indinavir
☐ Lamivudine ☐ Lopinavir/r ☐ Nelfinavir ☐ Nevirapine ☐ Ritonavir (full dose)
☐ Ritonavir (booster dose) ☐ Saquinavir ☐ Stavudine ☐ Tenofovir
☐ Zalcitabine ☐ Zidovudine ☐ Others: .....

P6 What ART drugs did the patient take AFTER changing treatment (tick all that apply)?

☐ Abacavir ☐ Atazanavir ☐ Didanosine ☐ Efavirenz ☐ Emtricitabine ☐ Indinavir
☐ Lamivudine ☐ Lopinavir/r ☐ Nelfinavir ☐ Nevirapine ☐ Ritonavir (full dose)
☐ Ritonavir (booster dose) ☐ Saquinavir ☐ Stavudine ☐ Tenofovir
☐ Zalcitabine ☐ Zidovudine ☐ Others: .....

P7 AFTER CHANGING treatment, how many times a day was the patient taking ART drugs?

☐ Once ☐ Twice ☐ Three times ☐ Not clear

P8 What was the patient's baseline viral load (VL) in copies/ml BEFORE STARTING ART, if known?

Date of sample (ddmmyy): ☐☐ ☐☐ ☐☐ Leave blank if not known

VL: ☐ <1000 ☐ 1,000-5,000 ☐ 5-10,000 ☐ 10-50,000 ☐ 50-100,000 ☐ >100,000 ☐ Not known

P9 Please state the patient's VL in copies/ml as measured on the last four samples taken BEFORE the CHANGE in therapy:

a Date of sample (ddmmyy): ☐☐ ☐☐ ☐☐ VL: ☐ 0-50 ☐ 50-400 ☐ 400-1000 ☐ 1000-10000 ☐ >10000

b Date of sample (ddmmyy): ☐☐ ☐☐ ☐☐ VL: ☐ 0-50 ☐ 50-400 ☐ 400-1000 ☐ 1000-10000 ☐ >10000

c Date of sample (ddmmyy): ☐☐ ☐☐ ☐☐ VL: ☐ 0-50 ☐ 50-400 ☐ 400-1000 ☐ 1000-10000 ☐ >10000

d Date of sample (ddmmyy): ☐☐ ☐☐ ☐☐ VL: ☐ 0-50 ☐ 50-400 ☐ 400-1000 ☐ 1000-10000 ☐ >10000

PLEASE DO NOT PHOTOCOPY THIS SHEET

P10 If the patient had EVER had undetectable VL (<50 copies/ml), what was the date of the LAST undetectable sample PRIOR to therapy change?

d d m m y y
leave blank if always detectable

P11 Was a test for HIV drug resistance done at the time of changing therapy?

a ☐ Yes, change made after results received ☐ Sample stored only
☐ Yes, change made before results received ☐ Not done ☐ NK

b If resistance test was done, please give date of sample:

d d m m y y
leave blank if not done

P12 Please state the reason(s) for the change in therapy (tick all that apply):

☐ Undetectable VL not reached ☐ VL increased ☐ VL rebounded from undetectable
☐ Toxicity ☐ Adherence difficulties ☐ Poor CD4 response ☐ Treatment simplification
☐ Potential for drug interaction ☐ Co-morbidity ☐ Pregnant ☐ Planning pregnancy
☐ Therapy not meeting current recommendations (eg non-HAART, 3NRTI, unboosted PI, D4T)
☐ Patient choice ☐ Trial end-point ☐ Other: ..... ☐ NK/not documented

P13 What factors influenced the choice of the new combination of drugs after the change in therapy (tick all that apply)?

☐ Results of resistance test ☐ Possible/suspected resistance not based on testing
☐ Ease of adherence ☐ Cost ☐ Adverse effect profile ☐ Patient request ☐ Clinical trial
☐ Clinic/physician protocol ☐ Other, please state: ..... ☐ NK/not documented

P14 If you ticked "Toxicity" in response to question P12, please state the main problem:

a ☐ Peripheral neuropathy ☐ GI tract ☐ Hepatitis/liver-related ☐ CNS ☐ Renal
☐ Lipoatrophy ☐ Central obesity ☐ Hypercholesterolaemia ☐ Hypertriglyceridaemia
☐ Hyperlactataemia/lactic acidosis ☐ Hyperglycaemia ☐ Drug hypersensitivity
☐ Other, please state: .....

b If you wish, please comment further on this toxicity, eg its duration prior to the change in therapy and any treatment or support given to help the patient manage it:

.....

.....

P15 If you ticked "Adherence difficulties" in response to question P12, please state:

a When patient started having adherence difficulties, if known: Month: ☐☐ Year: ☐☐

b Please describe any steps taken to support adherence prior to the change in therapy:

.....

.....

P16 ☐ Please put a tick in this box if you wish to comment further about this patient, and then do so below (NB comments may not be read unless the box is ticked).

.....

.....

999013

Case note review: Starting therapy from naïve
Patient summary sheet

Patient code for scanning: 999269

Include patients who STARTED antiretroviral therapy (ART) for the first time between 1 April and 30 September 2004, in accordance with the inclusion criteria on the main questionnaire (page 10). Please do NOT complete until you have read these criteria. If in doubt, contact Hilary Curtis, 020 7624 2148 hilary@regordane.net.

Question

Q1 Please state the patient's sex and ethnic group:

☐ Male ☐ Female ☐ White ☐ Black-African ☐ Other ☐ Not known (NK)

Q2 When did the patient first start ART (date of prescribing)? d d m m y y: _ _ _ _ 0 4

Q3 Why did the patient start ART (tick all reasons that apply)?

☐ Advanced disease (eg low CD4/symptoms) ☐ Recent seroconversion
☐ Prevention of vertical transmission ☐ Other reasons ☐ Reasons unclear

Q4 Is the patient in a clinical trial of ART? ☐ Yes ☐ No ☐ Not sure

Q5 When was the patient first diagnosed with HIV?

☐ Less than 3 months before starting ART ☐ 3-6 months before starting ART
☐ More than 6 months before starting ART ☐ NK

Q6 What was the patient's CD4 count just prior to starting ART, in cells/μl?

☐ 0-50 ☐ 51-150 ☐ 151-200 ☐ 201-250 ☐ 251-350 ☐ 351-500 ☐ >500 ☐ NK

Q7 What was the patient's clinical stage just prior to starting ART?

☐ CDC stage A: no history of symptoms ☐ CDC stage B: history of minor symptoms
☐ CDC stage C: history of severe symptoms/AIDS ☐ Not known

Q8 Were the following tests/measurements done prior to starting ART?

Blood pressure:	☐ Yes	☐ No	☐ NK	Liver function:	☐ Yes	☐ No	☐ NK
Serum lipids:	☐ Yes	☐ No	☐ NK	Random glucose:	☐ Yes	☐ No	☐ NK
Hepatitis B:	☐ Yes	☐ No	☐ NK	Hepatitis C:	☐ Yes	☐ No	☐ NK

HIV drug resistance: ☐ Test not done before treatment start but had been done previously
☐ Test done before treatment start ☐ Sample stored only ☐ Not done ☐ NK

PLEASE DO NOT PHOTOCOPY THIS SHEET