Audit of patients switching therapy

This complex audit formed the subcommittee’s main project for 2004–5, and involved a survey of clinicians’ opinions and case-note review of patients switching antiretroviral therapy (ART) for the first time after at least three months on ART. A total of 134 clinical centres took part, supplying data on 504 patients of which 67 were excluded as ineligible, leaving 437 for analysis. The patients were diverse, having been on a wide range of regimens before switching ART, for durations ranging from the three-month cut-off point for eligibility to upwards of five years.

A full report of this study is being prepared for publication, but some of the main findings were that:

- Most responding centres (100, 75%) rely on BHIVA Guidelines for the treatment of HIV-infected adults with antiretroviral therapy with a further 28 (21%) having local guidelines in addition to the BHIVA guidelines.
- Cost did not appear as a major factor in the choice of ART drugs, with 44% of respondents saying it was not taken into account and none saying it was a main or major consideration. It’s possible that this question may have been interpreted as referring to choices when prescribing for an individual patient, whereas cost may have a greater influence at the level of setting clinic guidelines and protocols.
- Toxicity remains the most common reason for changing ART even among patients established on therapy for over three months, with 148 (35%) patients having switched ART solely because of toxicity. In total, toxicity was cited as a reason for switching for 223 (51%) patients, including 71 (16%) with metabolic toxicity.
- Virological failure was the next most common reason given for switching ART, being cited for 132 (30%) patients.
- Other common reasons for switching included adherence difficulties (63 patients, 14%), patient choice (43, 10%) and treatment simplification (42, 10%).
- A significant proportion of patients with virological failure remained on ART with detectable viral load (VL) for long periods before switching. There were 70 whose VL rebounded after previous undetectability and, of these, 24 (34%) had consistently detectable VL for more than six months before changing ART. Of the remaining 62 who appeared never to have achieved undetectability, 23 (37%) had been on ART for more than a year before switching.
- A resistance test result was obtained before switching therapy for 95 (72%) patients with virological failure, in line with guidelines recommending such testing. A further 12 (9%) switched while resistance testing was being done but before results were obtained. For 14 (11%) patients, resistance testing was known not to have been done at the time of switching for virological failure, although eight of these had a VL too low for such testing.

In conclusion, this study yielded a wealth of information about patterns of ART switching. While uncertainties remain, the results suggest that procedures may need to be reviewed so as to respond promptly to virological failure, including appropriate use of resistance testing.

BHIVA’s national clinical audit subcommittee expanded its work programme in 2004–5, completing three separate projects:

- An audit of patients switching ART for the first time;
- A re-audit of patients starting ART from naive; and
- A survey of the management of HIV and TB co-infection.

Another landmark was the publication of the results of the 2003 audit of new HIV diagnoses in the British Medical Journal, the subcommittee’s first article in a general journal. This audit highlighted the extent of potentially preventable morbidity due to late recognition and diagnosis of HIV disease; therefore, it was particularly important for it to reach a wide audience.
Managing tuberculosis co-infection

As part of the process of developing BHIVA’s recent guidelines on TB/HIV co-infection, the subcommittee surveyed clinicians about their practice in this area. The 132 responding centres had looked after at least 543 co-infected patients, although most clinicians had limited experience in this area with 80 centres reporting five or fewer such patients over the past year. Some of the key findings are listed, as follows:

• Only 60 (45%) respondents were able to confirm that the TB patients at their hospitals were routinely offered HIV testing. A further 41 (31%) said testing was targeted to selected patients such as those from countries with a high prevalence of HIV. This is worrying because it raises the possibility that significant numbers of HIV infections are being missed. The British Thoracic Society is revising its guidance to recommend routine HIV testing of all adults aged 18–65 years with a TB infection.

• Although nearly all respondents said they worked in multi-disciplinary teams when managing TB/HIV co-infection, 29 of these teams did not include a TB specialist nurse, and ten did not include either an infectious diseases or a respiratory specialist physician.

• There was some dissatisfaction with access to facilities, including 41 (31%) respondents who were not satisfied with local access to negative pressure isolation rooms and 18 who were dissatisfied with the availability of TB PCR testing.

• Only 84 (63%) respondents said that results of sputum smears for acid-fast bacilli were available on the same or next working day at their centres.

• Most clinicians use the standard four-drug, six-month regimen for TB therapy in HIV-positive patients, in line with guidance.

• Routine tuberculin (PPD) screening is not widely used for newly diagnosed patients with HIV. This was reported by only six clinicians with a further three offering screening to patients without documented BCG immunisation.

• There was a range of views on timing of HAART initiation in relation to TB therapy (see Figure), which reflects the complexity of this difficult issue.

• Directly observed (DOT) and intermittent TB therapy are also rarely used. Only 12 respondents said they used DOT routinely, although a further 47 might use it for patients with multidrug-resistant TB or other complex cases. Only one respondent reported routine use of intermittent therapy, but 23 respondents might use it in selected cases.

![Figure: Preferred timing of HAART initiation in relation to TB therapy, according to CD4 cell count.](image-url)
This year, the subcommittee completed a full audit cycle for the first time, with a re-audit of 495 patients starting ART from naive. This showed a significant increase in reported levels of baseline testing from the previous audit in 2002, although blood pressure, serum lipids and random glucose were still not measured in a significant minority of patients (see Figure). Among diagnosed patients, there was also some improvement in the proportion starting treatment at CD4 counts above 200 cells/µl although, as in 2002, late diagnosis meant that, overall, most patients started at lower CD4 counts.

Resistance testing emerged as a significant area of concern in this re-audit. Less than a third of patients (158, 32%) had a resistance test result prior to starting therapy, despite this being recommended in guidelines since 2003.

Figure: Percentage of patients known to have undergone baseline tests.

Science reports

In addition to reporting its work at BHIVA conferences and through feedback to participating centres, the subcommittee aims to publish all major findings in appropriate peer-reviewed journals. Reports of the 2003–4 projects on HIV and maternity and on management of hepatitis B and C co-infection have been submitted for publication. Reports of earlier audits are as follows:


BHIVA audit projects

BHIVA audit projects are conducted according to a confidentiality protocol by which no one outside the BHIVA Secretariat can link the results to individual participating centres. However, the committee is happy to share data with local and regional audit groups, except where individual centres object.

No patient-identifying data are collected during the audit process – each patient is given an audit code number and only the clinical centre treating the person can match this to his or her identity.
Influencing policy development
A large part of the sub-committee’s work has been concerned with assessing how clinicians view BHIVA’s clinical guidelines and to what extent these are followed in practice. This information feeds into the process of updating and revising each set of guidelines.
In addition, the committee has now established a regular mechanism for presenting its findings to the UK Chief Medical Officers’ Expert Advisory Group on AIDS.

About the national clinical audit sub-committee
The subcommittee has completed several successful audit projects since it was established in 2001, and its position was consolidated in 2004 with the confirmation of three-year funding from the Department of Health. The subcommittee’s terms of reference are subject to revision as part of a wider review of BHIVA’s governance, but its broad aims include agreeing and implementing a rolling programme of national clinical audit of the care of persons infected with HIV, with particular reference to BHIVA’s clinical guidelines, and other clinically important topics where an audit shows deficiencies in care, and advising on necessary change and re-audit as appropriate.

In the pipeline
The subcommittee’s main project for 2005–6 is an audit of mortality among adults with HIV aimed at assessing the extent to which deaths may potentially be preventable through more timely or appropriate diagnosis and management of HIV infection. This will be accompanied by a survey of clinicians’ views on the management of cardiovascular risk factors in HIV-positive patients. Preliminary findings from these studies will be presented in 2006. In addition, a pilot questionnaire is being used to test the software for online surveys, with a view to replacing paper in due course. If successful, this move would save time and costs associated with scanning and inputting data, and will reduce layout and design constraints. It would also make it easier to conduct rapid surveys of opinion, although the committee is mindful of the need to avoid over-burdening busy clinicians with too many questionnaires.
In a new departure, the subcommittee is planning a prospective cohort audit for 2006–7 of virological outcomes among patients starting antiretroviral therapy for the first time. A survey examining service provision and baseline assessment of newly diagnosed patients is also scheduled for 2006.
As part of a wider BHIVA initiative to develop standards for NHS HIV services, the committee has made contact with the Royal College of Physicians’ Clinical Effectiveness and Evaluation Unit. It is hoped that this will lead to closer links with other medical specialties, potentially including future joint audit projects.

Acknowledgement
BHIVA acknowledges the contribution of the Department of Health towards the funding of the BHIVA National Clinical Audit Programme.

Finance details
The overall cost of BHIVA’s national clinical audit for 2004–5 was estimated at £40k. The latest estimates show costs to be within the budget and a minor surplus will be carried over towards current and future audits (see ‘In the pipeline’ on this page). The full cost of the audit is met by the Department of Health.

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More information about the committee’s work is available at: http://www.bhiva-clinical-audit.org.uk.