British HIV Association
Clinical Audit Report 2001–2

Registered Charity 1056354

October 2002

About the clinical audit committee

The BHIVA clinical audit committee began work in early 2001 and is currently developing a rolling annual programme of audits. The audits will:

- evaluate the usefulness of BHIVA clinical guidelines;
- yield national aggregate data on treatment patterns; and
- enable individual units to compare their data with national aggregates in confidence.

A detailed report of the first audit is available on the BHIVA website (http://www.bhiva.org)

A successful first year

IN THIS ANNUAL REPORT, the BHIVA clinical audit committee presents conclusions from the first annual UK national audit of the quality of treatment offered to people living with HIV and AIDS. The audit was a resounding success, with a total of 2044 patients reviewed from 146 clinical centres. It was conducted in partnership with three regionally-based audit groups, the North and South Thames and West Midlands, enabling these groups to follow up on the national project at a regional level.

The audit has shown that, once diagnosed, most people receive a high standard of care in accordance with current BHIVA clinical guidelines. However, many people start treatment late because their HIV infection is not diagnosed until after they have developed severe immune deficiency. This reinforces the need for a more strategic approach to promoting uptake of HIV testing, as recognised in the government's national strategy for sexual health and HIV. By diagnosing patients earlier, serious illness could be avoided and the need for costly hospital admissions significantly reduced.

The BHIVA clinical audit committee plans to follow up these results through its activities. Two further projects are in the pipeline: the second national audit will look in detail at patients who are starting treatment for the first time and gather information about HIV in pregnancy, while a prospective audit will examine why so many patients are diagnosed late and what action needs to be taken to tackle this problem.

Implications of the audit's findings

A summary report of the first national BHIVA audit for treating HIV-infected people with antiretroviral therapy is given overleaf. The results show broad support for and adherence to BHIVA's clinical guidelines and good outcomes for antiretroviral therapy. This indicates that most clinicians working at centres of all sizes, inside and outside London (**Figure 1**), are providing a high standard of care for their patients with HIV/AIDS.

The overwhelming majority of audited patients on antiretroviral therapy were receiving highly active combinations of three or more drugs. Most had viral load values below the limit of detectability, indicating success in suppressing HIV. There were some areas for improvement, however:

- Most patients started treatment late (at a CD4 count <200 cells/μl). In 82% of cases, this reflected the patient's CD4 count at the time of HIV diagnosis. Hence, the problem is late diagnosis. Action needs to focus on promoting uptake of HIV testing in a range of clinical settings.
- Of patients who had been successfully tested for HIV drug resistance, more than half were already resistant to two or more classes of antiretroviral drugs. This suggests scope for detecting resistance at an earlier stage, before multiclass drug resistance emerges. Patients might then benefit from a wider range of treatment options with less risk of failing expensive therapy.
- About 13% of centres said that they could not use resistance tests as often as they judged clinically desirable. While better access to these tests could help, clearer guidelines on when to use resistance tests may also be warranted.
- Access to some other specialised tests could also be improved.

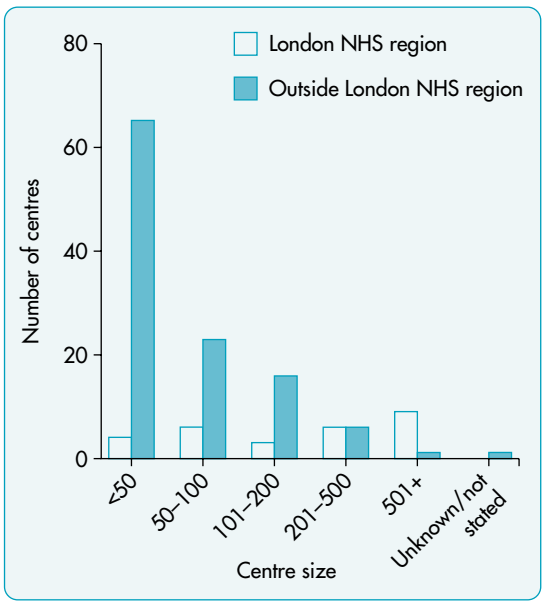

Figure 1. Participating centres by size (number of HIV patients).

Summary of the audit findings

THE AUDIT comprised first, a survey that examined clinicians' views and the availability of drugs and investigations at treatment centres, and second, a case note review assessing:

- adherence to guidelines on when to start treatment;
- adherence to guidelines on what treatment to use;
- outcomes of therapy; and
- patterns of use of resistance testing.

Methods and participation

BHIVA sent questionnaires in October 2001 to clinicians at all centres identified as possibly providing clinical care to adults with HIV infection, based on BHIVA and Association for Genito-urinary Medicine membership data, regional haemophilia centres and other data sources. A total of 148 centres responded, 147 of which submitted centre data and 146 submitted analysable data on 2044 patients. Although there is no definitive list of HIV clinical centres for comparison, this suggests a high participation rate. As expected, London centres tended to be larger than those elsewhere (Figure 1).

The method of sampling patients was not designed to be representative of the UK HIV population and probably under-represented people receiving care at very large centres. However, the demography of the audit sample was similar to that of the Survey of Prevalent Diagnosed HIV Infection (SOPHID).

Adherence to clinical guidelines

The audit showed clear support for BHIVA's clinical guidelines, with 138 of 147 respondents saying that they had seen and read the guidelines prior to the audit. Of these, 109 (74%) reported that the guidelines had influenced care at their centre. This finding was supported by data on adherence to specific standards drawn from the guidelines.

Standard on when to start treatment

The BHIVA guidelines recommend initiation of antiretroviral therapy at a CD4 count in the range 200–350 cells/μl, when severe symptoms develop, on sero-conversion or, possibly, at a viral load of >30,000 HIV-1 RNA copies/ml. This is based on evidence of a high risk of serious illness at CD4 counts <200 cells/μl. Moreover, full immune recovery is less likely if treatment is delayed to a very low CD4 level.

At first sight, the audit data on this standard are very disappointing. Of the patients who started treatment during 2000–2001, the period covered by the guidelines, only about a quarter did so while in the recommended CD4 range (Figure 2). More than half started at <200 CD4 cells/μl, including a quarter who started extremely late at <50 cells/μl. But 77% of those who started treatment at between 50 and 200 CD4 cells/μl and 90% of those who did so at <50 cells/μl had shown no change in CD4 category between diagnosis and starting treatment. Overall, 82% of cases of late treatment could be attributed to late diagnosis.

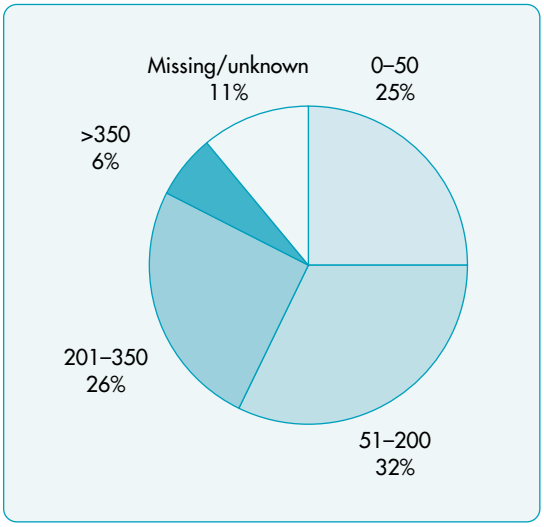

Figure 2. CD4 count measured in cells/μl just before starting treatment for patients who began in 2000 or 2001 (total 577 patients).

In addition, among the 513 audited patients who were not on treatment, 86 were apparently eligible on grounds of a history of severe symptoms/AIDS and/or a CD4 count <200 cells/μl. However, 26 of these patients, including 11 who were newly diagnosed, were described as considering or being about to start treatment, and there were other reasons for non-treatment (including patient choice) in a further 45 patients. There were only 15 cases of unexplained non-treatment, and even these may have been partly due to incomplete information.

Standard on what treatment to use

The BHIVA guidelines recommend that patients starting antiretroviral treatment should ordinarily take three or more drugs. Patients already taking an incompletely suppressive regimen (for historical reasons) may continue this if their viral load is stable and their CD4 count is at a clinically safe level.

Of 1516 patients receiving antiretroviral therapy, 1479 (98%)

Members of the clinical audit committee

Chairperson: Dr Margaret Johnson, BHIVA Honorary Secretary

Deputy chairperson: Dr Gary Brook, North Thames Regional Audit Group

Audit co-ordinator: Dr Hilary Curtis

Dr Ray Brettle, Edinburgh

Mr Paul Bunting, South Thames Regional Audit Group

Dr James Deutsch, Community Representative

Dr Andrew Freedman, Cardiff

Professor Brian Gazzard, BHIVA President

Dr Fiona Mulcahy, Dublin

Dr Colm O'Mahony, Chester

Dr Anton Pozniak, Medical Society for the Study of Venereal Diseases

Dr Keith Radcliffe, Association for Genito-urinary Medicine

Dr Caroline Sabin, Medical Statistician

Dr Alan Tang, Reading

Dr Jan Welch, Association for Genito-urinary Medicine

Dr Ed Wilkins, Manchester

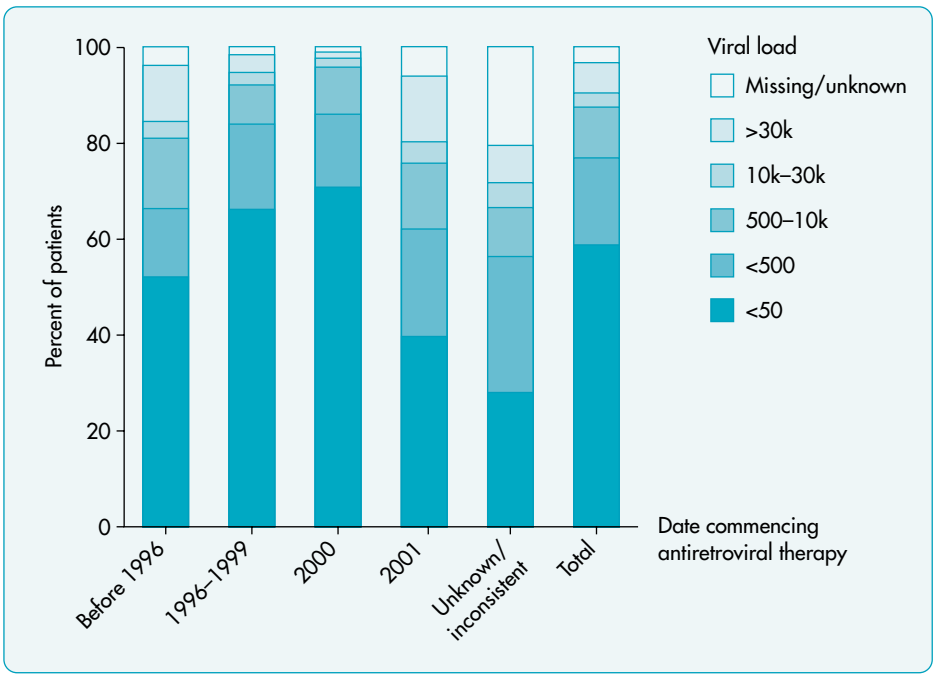

Figure 3: Viral load in RNA HIV-1 copies/ml for patients receiving three or more drugs, by date of first starting antiretroviral therapy (total 1479 patients).

were on three or more drugs, in most cases including a non-nucleoside reverse transcriptase inhibitor, as favoured by the guidelines. Of the remainder, one was taking only one drug but had an undetectable viral load and a CD4 count of >200 cells/µl, and was reported to have declined a switch to triple therapy. Thirty-six were on two drugs, 15 of whom had <200 CD4 cells/µl and/or a history of severe symptoms/AIDS. Reasons were given for not switching to triple-drug combinations for most of these patients.

A possible area of concern is that six previously treatment-naive patients had been started on two-drug combinations during the period covered by the guidelines (2000–2001). These patients were clustered at a small number of clinical centres. This may indicate suboptimal treatment, or possibly experimental use of unusual nucleoside reverse transcriptase inhibitor-sparing combinations.

Standard on outcomes of treatment

According to the BHIVA guidelines, the objective of antiretroviral therapy is to suppress the viral load to <50 HIV-1 RNA copies/ml, as this is predictive of long-term virological and clinical success.

Of the 1479 patients receiving treatment with combinations of three or more drugs, 59% had <50 HIV-1 RNA copies/ml. A further 18% were reported as having <500 copies/ml and this may have included some tested with assays not capable of detecting below this limit. This encouraging picture is confirmed by Figure 3, which shows viral loads for patients on three or more drugs broken down by the date of first starting antiretroviral therapy. For those who started in 2000, an impressive 71% had <50 copies/ml, with a further 15% reported as <500 copies/ml. Figures for those who first started treatment in 1996–1999 were only slightly worse, suggesting sustained responses to treatment. The higher levels for those who started in 2001 or before 1996 were expected: the former may not have reached a viral load nadir by the audit date and the latter are likely to have had previous treatment with incompletely suppressive regimens, leading in some cases to drug resistance.

Specialised tests and treatments

The audit found some problems with use of and access to specialised laboratory tests used in HIV patient management.

HIV drug resistance

Of 2044 audited patients, 395 (19%) had been tested for the presence of HIV resistant to antiretroviral drugs. After excluding 25 in whom the test failed, 20% of those tested showed resistance to drugs from all three classes in common use, 33% showed resistance to two classes, 16% to one class and only 31% showed no resistance. This suggests that more widespread testing may detect resistance earlier when more clinical options may be available. However, only 13% of centres reported no or limited access to these tests. Hence, poor access is not the only reason for the current low level of resistance testing.

Ultrasensitive viral load tests

Over 90% of centres said they used viral load tests able to detect as low as 50 copies/ml routinely or as clinically desirable, with 7% reporting no or limited access to these tests. While this is encouraging on the whole, all centres should have good access to these tests.

Tests for viral subtypes

Only 64% of centres reported access to viral load tests for specific subtypes of HIV; 16% said they lacked access and 18% did not know whether or not they had access. This may be of concern, especially as many patients with heterosexually acquired HIV are infected with non-B subtypes.

Key conclusions

The audit has shown broad support for and compliance with BHIVA clinical guidelines, and good patient outcomes. The only major departure from the guidelines is that most patients starting treatment do so at CD4 counts of less than 200 cells/mµl. This largely reflects late diagnosis.

More than half of patients with an HIV resistance test result already show resistance to two or more drug classes.

More than a third of centres lack access or are unsure whether they have access to viral load tests able to detect HIV subtypes.

Most centres are making extensive use of combinations containing non-nucleoside reverse transcriptase inhibitors.

A small number of centres started treatment-naive patients on two drug combinations during 2000 and 2001.

A positive response

The clinical audit committee's work has been welcomed by clinicians and HIV community organisations. Dr Margaret Johnson's presentation of the audit results at the BHIVA Annual Conference in April 2002 was well-received and attracted widespread attention.

Evaluation questions were also built into the audit itself. These showed that 76% of respondents thought the audit questionnaire was about right, with 7% thinking it was too simple to give a fair picture. Only 3% thought it too detailed or difficult to complete. Many respondents did comment, however, on the amount of time it took to review case notes for the audit; some pointed out that, because of heavy clinical workloads, they had had to do this in their own time.

Financial details

The budgeted cost for BHIVA's first clinical audit was £50,000. All BHIVA's major sponsors agreed to jointly fund this initial project with equal levels of funding. For this, we would like to thank all concerned.

This project has cost £36,000 so far and it expected that the final figure will be less than the amount originally envisaged in the budget. A breakdown of costs to date is shown below:

	£000
Clinical audit coordinator	9
Project handling (secretariat)	13
Data reading, printing, postage	6
Travel and related expenses	1
Payment to health centres	7
Total	36

It is intended to apply any surplus funds towards the follow-up on the 2001 audit via a review of patients newly diagnosed with HIV.

THANKS TO SPONSORS AND PARTICIPANTS

Roche ROCHE PRODUCTS LTD

Abbott Laboratories Limited

Boehringer Ingelheim

Bristol-Myers Squibb Pharmaceuticals Limited

GILEAD

gsk GlaxoSmithKline

MSD Merck Sharp & Dohme Limited

'Commendable and should be repeated annually.'

'Good work, especially for smaller units to compare and evaluate their HIV patient management.'

Comments from participants

Looking to the future

The BHIVA clinical audit committee is currently planning two further audits. The second national audit is due to take place in autumn 2002. It will examine the care offered to patients starting HIV antiretroviral therapy for the first time and HIV clinicians' understanding of arrangements for managing HIV in pregnancy. Then, in early 2003, centres will be invited to follow up on the 2001 audit via a prospective review of patients newly diagnosed with HIV. This will provide a better picture of what needs to be done to promote earlier diagnosis.

Meanwhile, the committee is encouraging clinical centres to join a new venture: the BHIVA clinical audit faculty. Membership of the faculty is open to anyone taking part in the audit of HIV/AIDS care, and the aims are to give recognition to centres participating in the audit and to facilitate exchange of ideas and good practice at both the national and local audit levels. This will be achieved mainly via electronic means, including an email list for sharing information and ideas and a website on which faculty members will be invited to post results and questionnaires from their own audit projects. In this way, the committee hopes to complement its national audits with support for local and regional audit, which can be particularly useful in looking at specific issues in greater depth.

Contact details

BHIVA organising secretariat:

Mediscript Ltd
1 Mountview Court
310 Friern Barnet Lane
London N20 0LD
Tel: 020 8446 8898
Fax: 020 8446 9194
Email address:
bhiva@bhiva.org
Website:
http://www.bhiva.org

Clinical audit co-ordinator:

Dr Hilary Curtis
39 Esmond Road
London NW6 7HF
Tel: 020 7624 2148
Fax: 0870 0567 212
Email: hilary@regordane.net