B12 and £4.05 for folate. Reducing the number of inappropriate requests does have cost-saving implications, which could add up to a significant saving if laboratory tests are rationalised across the whole range of investigations provided by the laboratory (approximately £750 per month for B12 and folate alone).

Conclusions and recommendations

The majority of repeat requests (within 90 days for B12 and 30 days for folate) are blocked by the laboratory and this should continue.

A large proportion of requests continue to be inappropriate, but it would be impractical for the laboratory staff to screen requests prior to testing.

It would appear that electronic requesting may help to reduce the number of inappropriate requests; we are rolling out the Tquest system to more GPs and await the arrival of e-requesting within Salisbury District Hospital.

It is important to have clinical guidelines available. However, these are unlikely to have a significant impact on day-to-day test-requesting practice.

Action plan

Implementation of electronic requesting within Salisbury District Hospital, due June 2012.

Re-audit once electronic requesting is in use, likely early 2013.

Dr Emma-Jane McDonald
Haematology SpR
Salisbury District Hospital

Dr Jonathan Cullis
Consultant Haematologist
Salisbury District Hospital

Reference

1. British Committee for Standards in Haematology. Investigation and diagnosis of cobalamin and folate deficiencies. *Clin Lab Haematol* 1994;64:101–115.
2. Smellie WSA, Wilson D, McNulty CMA *et al.* Best practice in primary care pathology: review 1. *J Clin Pathol* 2005;58:1016–1024.

Re-audit on verification of blood-borne viruses serology

Introduction

Errors in reporting of blood-borne viruses (BBV) serology and its interpretation have widespread implications. BBV including HIV serology interpretation helps clinicians in the management of patients including psychosocial aspects. Reporting errors cause mismanagement and have legal implications.

Errors can be minimised by checking previous samples performed on the same patient and interpreting the current result accordingly.

According to national guidelines,[1,2] BBV should always be confirmed by testing a second specimen. For example, if a patient sample is HIV antibody positive, a second sample is requested for further confirmation.

Following a 'Red Box' complaint (Ref No X0298/06) in October 2006, changes to the 'Duty Virologists Standard Operating Procedure (SOP) – verification of BBV serology results'[3] included the following - "Duty virologist should review the previous results of patient with positive result and add appropriate comments during verification."

This was first audited in July 2009 and this re-audit aims to assess compliance of duty virologists in meeting these reporting standards as recommended in the first audit report (2009). It was a successful audit submitted to the College's audit certification scheme in 2010.

Objectives

To monitor quality of BBV serology results verification by duty virologists.

To complete the audit cycle by re-auditing against July 2009.

Sample

All screening reactive HIV and HBV serology results over a one-month period between 1–30 October 2010 were included in the study to represent BBV serology.

Exclusions

All negative screening HIV and HBV serology results were excluded from the study.

Method

All HIV and HBV screening reactive results were extracted from the Meditech database between 1–30 October 2010. All previous HIV and HBV test

results from positive patients were reviewed from the Meditech database. The appropriate comment for the first sample was to request another sample for confirmation. The appropriate comment for the second sample was to say the result is confirmed. There are canned comments available for use in Meditech database for the first and second positive serology result. Appropriate comments also included clinical interpretation depending on the clinical details. Clinical interpretation can be written as free text in the comment box.

Standards

The duty virologist should look for results of previous specimens when verifying BBV positive results and add appropriate comments 100% of the time.

Results

A total of 89 final results were included in the study. Of these, 43 were HIV results and 46 were HBV results (Table 1).

Of the HIV samples, 38 out of 43 (88%) samples were compliant with standards.

Of the HBV samples, 45 out of 46 (98%) samples were compliant with standards.

Overall, 83 out of 89 (93.3%) samples were compliant with standards.

Discussion

This audit shows 98% of HBV reports are compliant with reporting room standards. This was previously un-audited in 2009.

This audit shows 88% of HIV reports are compliant with reporting room standards. This has decreased from 92.5% in 2009.

Overall compliance of BBV reports with reporting room standards has remained largely unchanged at 93.3 % compared with 92.5% in 2009.

Non-compliance in reporting HIV was higher than HBV. Upon discussion among duty virologists, two possibilities are recognised. One is that duty virologist forgot to add a comment or add a final comment having done the additional comment on screening reactive result; the other is that occasionally Meditech failed to reflex the final 'Comment' line for duty virologist to verify.

These results show that the compliance with BBV does not meet the current reporting standards and has not changed since previous audit. Suggestions to improve the compliance could include:

1. Increase awareness of adding HIV comment to both screening 'Reactive' line and final 'Comment' line. This could be achieved by discussing audit results at the duty virologists meeting and running brief induction and refresher training sessions on adding comments to BBV serology results. A new canned comment (MHIVLLR) has been developed to save typing and help improve HIV reporting of screening reactive HIV specimens that are negative on further confirmatory testing. This comment reads "Low level reactivity was detected by a component of the test panel but is non-specific and should be regarded as negative. No evidence of HIV infection". This will come into effect in November 2010.
2. Duty virologist should report to senior biomedical scientist when realising that Meditech fails to reflex the 'Comment' line at end of HIV LIA assay result and not authorise the result until it is rectified and a comment is added.
3. Setting up the Meditech system not to release any results unless they have an entry in the comment lines. It is recognised that the technical feasibility of this will need to be assessed and may not be available on the current pathology computer system.

Recommendations

1. Increasing awareness of the process of adding a 'HIV comment' line and review the reporting room SOP for clear instructions.
2. Considering formal 'work-based assessment' for trainees on verification of BBV verification by consultants.
3. Consult lab and IT managers on how to eliminate/minimise failure in reflexing the 'Comment' line.
4. Re-auditing HIV serology verification in 12 months.

Table 1: BBV final results

	Positive	Negative	Indeterminate	No of Samples
HIV	22	18	3	43
HBV	35	9	2	46
Total				89

Table 2: Sample interpretation issues

	Non-compliant samples*	Interpretation issues
HIV	5	3 samples no comment
		2 samples – an appropriate comment was placed near the screening test result, but there was no comment in the final comment line for the user.
HBV	1	No comment

* All non compliant BBV reports that were identified during the audit were corrected and reissued.

Ruramayi Rukuni
Kathryn Rolfe
Mubby Husain

Project Leads
Hongyi Zhang
Hamid Jalal

Patient Safety Co-ordinator
Gemma Whiting
Addenbrooke's Hospital, Cambridge

Re-audit report: November 2011

Introduction

Each year, the microbiology laboratory at Addenbrooke's Hospital performs over 26 000 HIV tests and 25 000 hepatitis B virus (HBV) tests, with an overall pickup rate of 1.20%. Samples are initially screened using high-sensitivity first-line assays, followed by confirmatory testing of reactive specimens.

In the case of HIV, initial screening is with a fourth generation HIV antigen (Ag)/antibody (Ab) assay and reactive samples go through further confirmation testing using a second-line HIV 1+2 Ag/Ab 'combo' test and an HIV line immunoassay (LIA). Since April 2011, an Immunocomb assay has been used as a second-line test. Patients that test positive on these platforms are requested to send a repeat blood specimen to confirm the diagnosis.

Screening for HBV is carried out using an ADVIA centaur hepatitis B surface antigen (HBsAg) assay (Bayer Health Care). This test has an analytical sensitivity of 0.1 ng/ml and clinical sensitivity of 100% (EU clinical trial data from French and German clinical trials, September 2002). Reactive samples are further examined using a polyclonal HBsAg assay and tests for hepatitis B core antibody (aHBc) IgM and IgG, hepatitis B e antigen (HBeAg) and anti-HBe IgG (aHBe). These procedures are based directly on the UK national guidelines for blood-borne virus (BBV) testing.[1,2]

The laboratory duty virologist uses these results, while simultaneously also reviewing outcomes from tests carried out previously on the same patient, to provide a diagnostic interpretation. In the case of HBV, and based on the presence of aHBc IgM or the existence of two tests positive for HBsAg carried out six months apart respectively, this includes classifying the infection as acute or chronic. HBV infectivity is determined by the presence HBe antigenaemia and/or the presence of aHBe antibody. Neonatal prophylaxis guidance is also provided for cases of HBV detected in pregnant women.

Both HIV and HBV are chronic blood-borne virus infections and, as such, errors in the reporting and interpretation of serological tests for these agents carry significant public health, medico-legal and patient management implications. For these reasons, and following a 'Red Box' complaint (Ref No X0298/06) in October 2006, changes were made to the laboratory Duty Virologists Standard Operating Procedure (SOP) 'Verification of BBV serology results'[3] to include the following: "The duty virologist should review the previous results of patients with positive results and add appropriate comments during verification." Specifically, by ensuring that duty virologists always 'look back' to review the results of any relevant tests carried out previously on a patient, it is hoped that the interpretation error rate may be minimised. Compliance with this guidance was first audited in July 2009 and re-audited in 2010.

Here, as recommended in the 2010 audit report, we have assessed ongoing compliance of the duty virologists in meeting these reporting standards.

Objectives

To ensure accurate comments and interpretations are applied to BBV serology results by our duty virologists during February and March 2011.

To ensure ongoing improvement in compliance with our laboratory SOP.

Sample

All screening-reactive HIV and HBV serology results generated between 1 February – 31 March 2011 were analysed. All of our duty virologists were active at some point during this period, meaning that this sampling window was representative of our normal laboratory practice.

Exclusions

HIV and HBV samples with negative screening test results (HIV Ag/Ab and HBV HBsAg) were not examined during this analysis.

Method

Reports for samples testing positive in screening assays for HIV or HBV between the 1 February – 31 March 2011 were retrieved from our Meditech laboratory database. The interpretations and comments that had been applied to the results by the duty virologist were reviewed according to the following standards defined in the SOP:

HIV

In the case of HIV screening, the appropriate comment for a yet-to-be confirmed positive is: "This is a screening result and should not be communicated to the patient or used in patient management. Please await the completion and authorisation of the confirmatory tests below."

Once subsequent confirmatory tests have been conducted on the sample, the comment should be revised to: "HIV antibody positive. If this is the first positive result for this patient, it should be regarded as provisional until confirmed by sending a second blood sample. Please send a repeat sample as soon as possible." Once results are confirmed using a second sample, the comment should be revised to: "HIV antibody positive confirmed."

HBV

For HBV screening, positive tests should be reported as: "This is a screening test result. It must be confirmed by the results that follow to indicate the patient's status." In the case of HBV confirmatory tests, there are relevant pre-written scripts that should be applied based upon the serological profile and the patient's previous test results. In non-acute HBV positive cases (HBsAg positive)

but where there are no past results, the comment should be: "Preliminary result: this patient is infected with hepatitis B virus. As there are no samples dating back more than six months in this laboratory, I am unable to comment on the stage of the infection. Please send further a clotted blood sample to confirm the preliminary result and provide details of symptoms and onset date."

Where previous positive, corroborating results do exist, the comment should instead be: "There are HBsAg positive specimens for this patient dating back more than six months. This is consistent with chronic hepatitis B infection." The comments are also refined according to the HBeAg and aHBe status. Where HBeAg is positive, or aHBe is absent, the comment should be: "Infectivity of blood and blood-stained bodily fluids: HIGH." Samples testing negative for HBeAg and positive for aHBe should instead receive the additional comment "Infectivity of blood and blood-stained bodily fluids: LOW."

Standards

In 100% of cases, the duty virologist should look for results of previous specimens when verifying BBV positive results and add appropriate comments in each case.

Results

A total of 126 positive screening test results were included in the study. Of these, 53 were HIV results and 73 were HBV results (Table 3).

Of the HIV samples, 52 out of 53 (98.1%) were compliant with standard.

Of the HBV samples, 71 out of 73 (97.2%) were compliant with standard.

Overall, 123 out of 126 (97.6%) samples were compliant with standard.

Table 4 shows compliance with the standard in previous years.

All non-compliant BBV reports that were identified during the audit were corrected and reissued.

It was important to determine whether the detected reporting errors are clinically significant. Reassuringly, the only misinterpretation error in the HIV data was a comment field error in the Meditech database. This meant that there was no space for the comment by the duty Virologist. However, based on previously laboratory findings, this patient was already known to be HIV positive, meaning that the omission of an interpretative comment would not carry a clinical impact on this occasion.

Two errors were detected in the data relating to tests for HBV. The first was an interpretation error. The comment applied by the duty virologist included the statement "I am unable to comment on the stage of the infection." However, this was also a non-significant error since the patient was already known to be HBV positive; results going back to November 2007 held by the laboratory Meditech database reflected this. This error was therefore without clinical consequence.

A second error detected amongst the samples tested for HBV was the omission of an interpretative comment altogether. Again, however, investigation revealed that this was the result of a computer error that had removed the comment field from the sample entry in the database, preventing the duty virologist from adding a diagnostic conclusion.

Conclusions

This re-audit of interpretative comments applied to BBV assays by our duty virologists suggests a similar degree of compliance with reporting room standards for HBV between 2011 and 2010, when this practice was last assessed (97.2 % versus 98% respectively).

This audit also found that 98.1% of HIV reports are compliant with reporting room standards. This is a marked improvement over the previous two years: previous audits have revealed compliance rates of 88% and 92.5% in 2010 and 2009 respectively.

Overall, compliance in BBV result reporting as a whole has improved. Compliance rates were 92.5% in 2009 and 93.3% in 2010. In the current audit period, the rate is 97.6%.

However, it should also be highlighted that the sample size considered by the current audit is substantially larger than the former, above-cited 2010 assessment, which looked at only 43 HIV results and 46 HBV results. The current audit is therefore likely to be a more reliable indicator of our workplace practice.

We have also discussed our protocols, in the light of this audit, with other diagnostic labs at Ipswich, Colchester, West Suffolk and Kings Lynn, where similar testing practices are used. Surprisingly, none of those that we spoke to had audited their own BBV performance data yet.

The previous, 2010, audit of our performance on BBV testing made the following recommendations:

1. Increasing awareness of the process of adding an 'HIV comment' line and reviewing the reporting room SOP for instructions.
2. Consider formal 'work-based assessment' by consultants of trainees verifying BBV results.

Table 3: BBV final results

Test	No.compliant	Negative	No. non-compliant	No. of samples
HIV	52 (98.1%)	1 (1.9%)	1 (1.9%)	53
HBV	71 (97.2%)	2 (2.7%)	2 (2.7%)	73
Total	123 (97.6%)	3 (2.3%)	3 (2.3%)	**126**

Table 4: Compliance with the standard in previous years

	Compliance (%)		
Standard	2009	2010	2011
HIV	92.5	88	98.1
HBV		98	97.2
Overall	92.5	93.3	97.6

Table 5: Sample interpretation issues

Test	Non-compliant samples*	Issues identified
HIV	1 (1.9%)	**1 x comment field error** The sample lacked an interpretative comment. However, this was owing to an error that removed the comment field, preventing the duty virologist from providing an interpretation.
HBV	2 (2.7%)	**1 x incorrect interpretation** "This patient is infected with hepatitis B virus. As there are no samples dating back more than six months in this laboratory, I am unable to comment on the stage of the infection." However, former HBV results were present dating back to November 2007.
		1 x comment field error A computer error meant that no comment field for the duty virologist's interpretation was provided.

3. Consult lab and IT managers on how to eliminate/minimise failure in reflexing the insertion of an interpretative 'Comment' field in the database.

Clearly, based on the results of this assessment, there has been an improvement in performance, although it is outside the scope of this audit to determine to what extent, individually or together, these recommendations are responsible.

Recommendations

However, the findings of this audit have highlighted some shortfalls that could be addressed to ensure that the present upward trajectory in compliance rates is maintained:

1. Duty virologists will 'look back' within the Meditech database for previous results on any given patient.
2. During induction of new trainees: this audit would be presented to new trainees so that they become acquainted with the process of BBV result interpretation and reporting.
3. Supervision of the duty virologist by senior staff: duty virologists would verify the results and all serology samples to be reviewed by the consultant virologist on a daily basis.
4. Re-audit in six months rather than a year: yearly audits suggest that there is only limited improvement in results over the last three years. A shorter period of re-auditing would make trainees more aware and highlight shortfalls more rapidly.

Finally, in closing, we are pleased to note that, having discussed the IT-issues highlighted by this audit with the relevant service manager, the underlying problems have been resolved.

Project Leads
Afia Asif Zia
Chris Smith

Others involved
Hamid Jalal
Kathryn Rolfe
Hongyi Zhang

References

1. Health Protection Agency. *Anti-HIV screening – minimum testing algorithm.* National Standard Method ,VSOP 11(1), 2007.
2. *UK National Guidelines for HIV Testing*, 2008.
3. *Standard Operating Procedures – Virology, Duty Virologist Routines*, Edition No: VS-OP020e September 2010.
4. *Journal of Clinical Microbiology* 2006;44:2321–2326.
5. ADVIA Centaur Immunoassay manual.

Clinical audit templates

Clinical audit templates on a range of topics in cellular pathology are now available online. These templates provide a step-by-step guide to planning an audit. All the templates can be downloaded and adapted for local or individual use from www.rcpath.org/clinical-effectiveness/clinical-audit/clinical-audit-templates

For further information please contact Maria Marrero Feo, Senior Clinical Effectiveness Coordinator, on maria.marrero@rcpath.org