National Blood Transfusion Service

Quality Audit
of the
East Anglian
Blood Transfusion Centre
Cambridge

18 - 19 August 1992

Auditors: Mr John Stivala, NLBTC
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CONFIDENTIAL

INTRODUCTION

This audit was carried out some two years after the previous NBTS audit; it appears that it had not been possible to schedule in an audit during 1991. The East Anglian Blood Transfusion Centre (EABTC) is on the site of Addenbrookes Hospital, Cambridge. EABTC runs its only apheresis clinic at the Centre and mobile collection teams cover the whole of East Anglia. There are plans to site one such team permanently in Norwich in the near future.

The auditors wish to express their thanks to the Director, Professor J-P Allain and his staff for the welcome, hospitality and cooperation offered during the two day audit. Particular thanks are also due to the QA Manager, Mr Alan Slopecki, for his pre-audit arrangements and for his attendance and cooperation throughout the two days.

The audit was structured around selected operations of the Centre and due attention was paid to the dangers of excessive auditing. Thus it was agreed that time spent in Components (which had been audited some 7 times in the past two years) would be reduced in favour of other areas that had not been thus exposed.

As part of this audit, Mr Slopecki provided the auditors with a copy of the response to the previous QA audit together with a verbal update on changes since that time.

VIROLOGY

The Virology function forms part of the Donor Testing Laboratory, which also includes routine serology. The sector is headed by David Wenham who guided us through the Virology Section with the assistance of his staff. It was clear that the staff were fully conversant with procedures and activities in their workplace.

The HCV testing procedures used the Abbott Commander system utilising a manual sample barcode reader combined with a sophisticated sample locating device. Other tests relied on the Tecan positive sample identification linked to barcoded plate ID. All results were transferred electronically and reconciled, prior to deposition in a WORM drive. Release of the data to the COR system was by authorised personnel only. The results were evaluated against manufacturer's specifications, without modification.

All SOPs examined reflected observed working practices and all cleaning, service and calibration records appeared to be available and up-to-date. Training records were also available, though they were a recent addition.

Matters of Concern

1. The room for Virology appeared cluttered. Space could have been better organised, especially under benches. This would improve the impression created in what was otherwise a very professionally run department.

2. A suggestion to improve the training records would be to include a summary of past training received prior to the introduction of this new system.

APHERESIS

The Apheresis Unit operated 8 Autopheresis-C machines and 1 PCS+. With the assistance of Drs Walton and Waterhouse, and their staff, we briefly observed procedures for registration and collection of product from donors.

Matters of Concern

1. Despite the familiarity of donors at the session, we were concerned that their identity was not being checked/challenged by any member of staff.

2. Staff appeared uncertain of the exact procedures for disposal of unused product labels, bearing the date of expiry.

3. There appeared to be a degree of uncertainty regarding the point at which different members of staff should sign the session slip for their responsibilities.

4. We think there is a need for an improved awareness of the hygienic handling of equipment during apheresis procedures.

IMMUNOHAEMATOLOGY

The Immunohaematology Sector was found to be in a state of flux; it is understood that it has undergone many changes, and indeed as we were auditing, furniture was being moved. The manual ABO and Rh testing of donors and ante-natal patients is carried out in the donor testing laboratory and Immunohaematology is responsible for further investigation on these samples. Other responsibilities include anti-D quantitation, phenotyping and leucocyte and platelet antibody investigations.

Matters of Concern

1. There appeared a general lack of appreciation of the importance of the principle of Good Laboratory Practice, e.g. lack of evidence of cleaning and in-house maintenance of equipment and environment.

2. Though there was an appreciation of the need for SOPs, very few were available for inspection. Those that were examined were not comprehensive on the importance of sample identification and document checking procedures.

3. We were made aware of a number of ad hoc changes that have taken place with inadequate planning and supervision. This has resulted in a situation where because of the non-replacement of a failed plate reader combined with the expected introduction of a new computer system, blood groups were being manually entered into the computer. A hard copy of this manually entered information is used to check that the correct group has been written on the patient's record instead of this check being performed using the printout from the grouping machine.

4. It appeared not to be possible to reconcile the tests under incubation with adequate identifying information on the worksheet. There was no evidence of

controls being used with the papainised cell panel.

5. Reagents in fridges showed inconsistencies and inadequacies in labelling; there were many hand-written labels with no expiry or preparation dates. Reagents labelled *store frozen* were being kept at 4°C and there were anti-N and anti-M reagents apparently in use which expired in April 1992. These showed no evidence of extension of expiry date.

6. The clarity of the recording documentation for antibody investigations could be improved.

7. The procedure for documenting the extra investigations required on ante-natal samples, e.g. antibody cases, ought to be improved. Only minimal information was presented to the MLSO on the work required.

8. Records of errors for investigation and analysis are not kept.

9. Input of phenotypes was being carried out by one person without a second person checking, contrary to documented procedures.

ISSUES

The Issues area was audited at a time of significant staff shortage, through sickness and leave. Staff who were in attendance appeared to be fully conversant with the necessary procedures and were able to answer all questions informatively. It is a compact area, appearing somewhat congested, although this did not appear to affect its function. Although we were not able to examine all records, there was clear evidence of appropriate monitoring of temperature and alarms both in the department and vehicles.

Matters of Concern

1. The removal of expired units did not appear to have been carried out as frequently as reported, based on the fact that blood which was 6 days past expiry was currently being removed from stock.

2. There was some evidence that occasionally products have been issued without a record in the COR.

3. It is current practice to handwrite the date of issue of FFP on a label attached to outer packaging. This instructs the user to use the product within 3 months of that date. However there is no clear internal policy regarding the age of packs at date of issue.

REAGENTS

The Reagents Laboratory produces red cell reagents and antisera, both for in-house use and supply to hospitals and BPL-D. It is also responsible for the production of buffered salines for laboratory use. A good deal of work had obviously been expended on producing SOPs; those examined by us were quite satisfactory. Both Roger Pepper and Gerry Campbell assisted us during the audit of their area and were able to explain

procedures involved to our satisfaction.

Matters of Concern

1. The quality of labelling of some products was not satisfactory. In particular, there was no expiry date on AB serum and there were a number of items in the cold store bearing handwritten labels consisting only of a number. In one instance this was stuck over another label indicating the tube contained Lows Papain.

2. There was inadequate segregation of issuable stock within the cold store. The store also contained reagents for lab use, items belonging to other departments and even one function that is separate from the Centre. Improved labelling of areas and/or items is indicated. A rack of haemolysed and unlabelled cells was observed and is evidence of questionable laboratory practice.

3. A batch record for anti-Fy^a was examined. Some specificity tests had been performed without recording the cell identity information. Without this, it was not possible to determine the cause of positive reactions which may not have been due to the anti-Fy^a. No satisfactory explanation for these results had been recorded in the batch record.

4. There did not appear to be a formal procedure indicating inspection of batch record and release of the reagent.

5. Batch records covering buffered saline did not always carry an example of label used, as required.

6. One of the buffered saline containers had clear evidence of algal growth.

7. The manual record system that is at present in place is unhelpful for tracing product distribution.

COMPONENTS

We had a brief look at routine QC results which are performed by the Components Laboratory's own staff. These showed evidence of a commitment to the maintenance of standards within production.

The new Components Laboratory was visited but not for audit purposes.

QUALITY ASSURANCE

We visited the QA Laboratory where Fatima Ali and Alan Slopecki outlined the work of the department and provided records for our perusal and inspection. There is considerable activity covering many aspects of QA, including haematological control, environmental monitoring, Factor VIII assays, temperature monitoring.

The department is also engaged in raising the awareness of quality by training and communication. We were impressed by the diversity of the QA Manager's involvement and influence within the Centre.

PRESENTATION

The draft of this report was presented at a meeting attended by the Director, QA Manager and Sector Heads. Each item listed under Matters of Concern was discussed and reviewed, and corrective action suggested, wherever possible.

FOLLOW-UP

Under the terms of the NBTS Audit Procedure, a written response to this report should be sent to the National Directorate within 3 months.

DISTRIBUTION

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Prof J-P Allain, Director, EABTC
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19th August 1992