Safeguarding public health

Blood Bank Inspections
Common Deficiencies

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2008/9 Inspection Summary

• 72 sites were selected for inspection during 2009/10
• 9 further sites were selected as controls
• The type of deficiencies cited were generally in line with those of previously reported to this group, i.e.
  • False & Misleading Information
  • Quality Management
  • Deviation Reporting and Management
  • SABRE reporting & Recall
  • Maintenance
  • Training
  • Validation and Change Control
  • Documentation
  • Controlled temperature Storage
• This presentation does not include MHRA expectations however these will be discussed as necessary.
False and Misleading Information

This is an area where we are observing an increased level of non compliance.

Background:
Assertions have been made in Blood Compliance Reports indicating that systems are in place and active which has proved not to be the case during inspection.

Following inspection, once a site has agreed a remediation plan with the inspector, any variation in the proposed actions or timeframe should be discussed and agreed with the inspector before a situation of non compliance is reached.

Failure to provide accurate information constitutes the provision of false and misleading information which is a criminal offence (SI 2005/50 Section 18). This often results in referral of the site to the MHRA’s Inspection Action Group (IAG) where regulatory action will be considered.
Quality Resource

• There was insufficient resource available to develop and maintain a Quality System for blood banks based on the principles of good practice in compliance with the standards set out in the Annex to Commission Directive 2005/62/EC.

• The metrics used to determine the resource required to operate the Quality System were unclear, however the number and severity of deficiencies relating to key aspects of the quality system are indicative of an operation which is unable to manage both its Regulatory and service provision commitments.

• Trust risk register entries dating back to April 2008 describe a range of laboratory non-compliances relating to resource difficulties. There was a lack of evidence available during the inspection to demonstrate that the Trust had taken action to address these risks.
Investigation of Deviations (1)

• There was no formal deviations procedure

• Although all staff were required to report deviations, there was no evidence available to demonstrate that MLA’s had received any training or other suitable guidance in this area

• There was no system in place for reporting significant deviations out of hours to ensure that actions were appropriately managed by senior staff

• There was no criticality assessment of deviations to enable suitable prioritisation

• There was no escalation mechanism or link to the recall procedure within the deviations management procedure
Investigation of Deviations (2)

- There is no formal process for dealing with “complaints” i.e. incidents raised elsewhere which have implications for the blood bank.

- Required actions identified in deviation reports were not suitably prioritised within the trust as evidenced by the required IT system blood group amendment emulating from a critical deviation in May 2009 which was still unresolved with no clear timeframe for completion. The patient record advised that the patient's group was both O+ and A+.

- There is no formal process for ensuring outstanding corrective and preventive actions are carried through to completion once the incident has been closed.

- No target dates are set for incident investigations and closures.
Investigation of Deviations (3)

• Incident risk scores were calculated on the basis of outcome of the particular reported event, rather than considering the potential outcome. This approach does not ensure that appropriate resource is directed at preventing recurrence of potentially high risk incidents.

• One incident observed pertaining to two patients blood components being mixed up during labelling was assigned a risk score of 3 (low risk) on the basis that the error was detected at ward level and therefore assigned an outcome of “insignificant”.
Laboratory Operations

• The concurrent labelling of component units for 3 patients on the same bench posed serious risks of mix-up and thus mislabelling of the units. Whilst there was no clear evidence observed within the incidents log of mislabelled units being allocated, the practice observed was not in accordance with the procedures in place and was unacceptable. It was noted that the incident observed included multiple whole blood units for each of 3 patients all with different ABO group requirements.
The control of documentation was not compliant in that:

- The documentation control procedure provided (ver 2.1) failed to incorporate an effective date as required by the procedure.

- The documentation control procedure presented to the inspector was newly created and was not the active document.

- Following a request for the active documentation control procedure, the site provided the superseded version 1.1 rather than active version 2.0 indicating a lack of suitable documentation control.

- A significant number of other procedures presented as active documents were recently created and not in current usage.
Self Inspection (1)

- Self Inspection processes were deficient in that:
  
  - Self inspections were significantly behind schedule with no self inspection activity completed since September 2008. This is a recurrent finding from previous inspections
  
  - The self inspection plan had not been assessed against the BSQR’s to ensure all required areas were addressed
  
  - The quality management system was not subject to audit.
Self Inspection (2)

- No self inspections against the requirements of BSQRs and relevant GMPs are currently carried out.
- There is no SOP on self inspections or the following up of required actions to completion.
SAE and SAR Deficiencies

- SABRE reports were not made in a timely manner; a number of events were seen that took approximately two months to report.

- The SABRE procedure did not state the expectation for the timeliness of reporting.
Recall Deficiencies

- There was no reference within the recall procedure with respect to the additional required searches for units (as identified through the deviations system) to ensure that they had not been “purged” from the system.

- There was no requirement to ensure that similarly affected units were considered for recall.

- Incident 2010/02/01 gave rise to a recall of units but no records of the recall process are available.

- Mock recalls were performed using a specific “mock recall procedure” that failed to assess the operational suitability of the recall procedure.
Change Control Deficiencies

• There is no process for the control of change within the unit. A number of recent changes such as the new analyser, the taking on of new work, and the lab refurbishment project have not been subject to change control. Also noted:
  • *The 2009 BCR stated that 12 change controls had been raised in the preceding 12 months. No record of these could be found.*

• There was no requirement to manage changes after the approval to implement had been granted. There was no confirmation that SOP revisions, training, etc. had been completed as part of the change.

• The change control process does not detail and approve the various expected impacts and requirements of a change or include a formal approval that all such points have been addressed satisfactorily.
Validation Deficiencies (1)

- There was no validation procedure available on site.
- The validation SOP does not address the requirements of EU GMP Guide Annex 15 in contradiction to the claims of the 2009 BCR.
- There were no plans in place for revalidation of critical equipment such as the auto analysers.
- The LIMS system had not been subjected to any validation though aspects of its operation were advised by the site to be non compliant.
Validation Deficiencies (2)

• Validation of existing equipment and systems within the laboratory including the LIMS system has not yet been performed.

• Critical equipment such as the Auto Analyser and the Temperature monitoring & alarm system has not been subjected to retrospective validation. Note that this was raised as a deficiency in the last MHRA inspection.
Training

• There was no requirement for out of hours staff to be trained and assessed as competent on key quality management system procedures. In addition a list of required and periodically assessed competencies was not available.
Database Deficiencies

- One incident reviewed identified potential data corruption on merging the trusts two databases, though no actions ensued to quantify the potential wider concern of database corruption. Also though raised in March 2009, this incident remained open at the time of the inspection in December 2009.

- There was no restriction in the electronic issue rules to ensure that records containing two differing blood groups were unsuitable for electronic issue. Such records were observed whilst on site.
Merging Deficiencies

• Procedures for the merging of patient records at the trust level were not adequately controlled in that:

  - There was no reference to ensuring that PAS merges on patients with blood transfusion or testing history were authorised for merger by suitably qualified blood transfusion staff prior to the merger taking place

  - One incident reviewed concerning the misidentification of a patient in the laboratory was directly attributed to the importation / use of incorrect data from PAS to the Laboratory Information System
Controlled Temperature Storage

• Temperature mapping performed on fridges is limited to the movement of the single IceCube probe around the inside of the unit. No comparison back to a reference probe is therefore possible so that a temperature range cannot be ascertained.

• The MDU fridge has not been calibrated since 2007 as the unit was closed on the day that the calibration engineer attended.

• There is some evidence that calibrations have gone overdue in the past. No system in place for ensuring that this doesn’t happen.
Controlled Temperature Storage(2)

• Though a required element within the site's procedures, there was no record of routine fridge or freezer housekeeping for the previous 6 months.

• The temperature chart for the issues fridge identified the unit as being out of specification which was not captured. In addition, temperature charts were not formally reviewed for compliance when removed.

• The use of a domestic fridge for the storage of controlled reagents was inappropriate. Ice was noted on the rear of the fridge indicating a non-compliant temperature <2°C in that zone.
Maintenance & Calibration Deficiencies

• Some key equipment such as the fridges and freezers, and the plasma incubator are not subject to a programme of regular calibration and preventive maintenance.

• Calibration reports from contract engineers are not signed off by blood bank personnel.

• There are no defined limits on the acceptability of any variance between the equipment under test and the calibration device.
Traceability

- Measures employed to ensure that traceability requirements were met were not robust. One week reviewed was noted to contain Ca. 50 untraced units for this site with no clear procedure or rationale for ensuring that these are traceable to their final fate.
Thank You

Questions ?