Introduction

A quality management system provides the integration of organisational structure, processes, procedures and resources needed to fulfil the quality policy and thus meet the needs and requirements of users.

Laboratory management has established a quality management system and the roles, responsibilities and authority of all personnel are defined to ensure the establishment, implementation and maintenance of the quality management system.

Laboratory management has been responsible in 2013 for:

a) Setting quality objectives and undertaking quality planning
b) Preparing a quality manual
c) Continuing the procedure for document control
d) Continuing a procedure for control of process and quality records
f) Continuing a procedure for completing audits
g) Continuing in development of a system to perform the management review

Q Pulse System has been utilised for document control, people, audit, Non conformance, assets, suppliers and analytical modules in 2013.

2013 Quality Objectives for Pathology Barnet and Chase Farm Hospitals

- To provide an high quality customer focused, accurate, safe and cost effective service
- To remain CPA accredited
- To remain MHRA/HTA/London QA compliant
- All staff to be familiar with and work to the current version of the departmental Quality Manual and all procedures therein.
- To achieve continual quality improvement by operating a robust Quality Management System
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2013 Quality Indicators

1. Operate according to departmental policies.
   (Monitor acknowledgement levels on Q pulse)

2. (a) Participate in all NEQAS/CQAS schemes appropriate to the department’s repertoire.
   (b) Achieve EQA compliance
   (Monitored at quality management meetings monthly)

3. Maintain an IQA system as part of the department’s workload.
   (Monitor at senior departmental meetings)

4. Perform audits on a planned and regular basis.
   (Monitor at QRM meetings via Q pulse)

5. (a) Conduct an annual ‘User’ survey.
   (b) Implement change according to User needs as and when appropriate.
   (Monitored by production of User Survey Report)

   (Monitor in T Drive/Pathology Meetings/Departmental/)

7. Perform regular reviews of the Quality system and the service.
   (Q pulse messaging reminder will alert document owners)

8. Raise CAPA (Corrective action/Preventive action) against all non-conformances and action them.
   (Monitored at quality management meetings monthly)

9. Measure turnaround times of routine tests
   (Monitored at quality management meetings monthly)

See table below
## Table 1 Quality indicators

<table>
<thead>
<tr>
<th>Quality Indicator</th>
<th>Measurand</th>
<th>Timed Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operate according to departmental policies</td>
<td>Monitor acknowledgement levels on Q pulse by monthly audit, reported to directorate and QRM meetings.</td>
<td>Monthly over 12 months</td>
</tr>
<tr>
<td>(a) Participate in all NEQAS/CQAS schemes appropriate to the department’s repertoire.</td>
<td>(a) Monitored at quality management meetings monthly. 100% compliance of registered for eligible schemes</td>
<td>Monthly over 12 months</td>
</tr>
<tr>
<td>(b) Achieve acceptable EQA compliance score</td>
<td>(b) Monitored at quality management meetings monthly. % compliance of EQA registered for eligible schemes</td>
<td>Monthly over 12 months</td>
</tr>
<tr>
<td>Maintain an IQA system as part of the department’s workload</td>
<td>Monitor at senior departmental meetings.</td>
<td>Monthly over 12 months</td>
</tr>
<tr>
<td>Perform audits on a planned and regular basis</td>
<td>Monitor at QRM meetings via Q pulse. Measure % compliance against documented audit schedule.</td>
<td>Monthly over 12 months</td>
</tr>
<tr>
<td>Conduct an annual ‘User’ survey</td>
<td>User Survey reported</td>
<td>Monthly over 12 months</td>
</tr>
<tr>
<td>Hold regular meetings as listed in the Quality Manual</td>
<td>Monitor in T Drive/Pathology Meetings/Departmental. Achieve quality manual meeting targets</td>
<td>Monthly over 12 months</td>
</tr>
<tr>
<td>Raise CAPA (Corrective action/Preventive action) against all non-conformances and action them</td>
<td>Monitored at quality management meetings monthly. CA/PA completion within 8 weeks of start date</td>
<td>Monthly over 12 months</td>
</tr>
<tr>
<td>Measure test turnaround times of routine tests</td>
<td>Monitor turnaround time against hand book expected value in days, report variance monthly at QRM and Directorate.</td>
<td>Monthly over 12 months</td>
</tr>
<tr>
<td>Measure free mortuary space</td>
<td>Monitor free space against expected space.</td>
<td>Monthly over 12 months</td>
</tr>
</tbody>
</table>
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Quality Indicators/performance targets

These have been monitored over a 12 month period using various quality indicators to reflect the practice of each department. Table 2 indicates the Turnaround Time indicators monitored, details of which can be found in the departmental quality review meetings on the T Drive.

Turnaround Times

Table 2 Turnaround times monitored 2013

<table>
<thead>
<tr>
<th></th>
<th>Biochemistry</th>
<th>Cytology</th>
<th>Microbiology</th>
<th>Haematology</th>
<th>Histology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routine Test Turnaround</td>
<td>Most requested 20 tests, referred tests and immunology tests</td>
<td>Cytology smears and non Gynae work</td>
<td>HIV, Serology, MRSA, C.Diff., Chlamydia and urines, referred tests,</td>
<td>Most requested 20 tests and referred tests</td>
<td>Histology average turnaround time and 0.75 percentiles. Breast, prostate and colonic biopsies have been measured</td>
</tr>
<tr>
<td>A/E Turnaround Times</td>
<td>0.95 Percentile for U/E requests, Percentage of A/E routine tests available in 60 minutes</td>
<td></td>
<td>0.95 Percentile for FBC requests. Percentage of A/E routine tests available in 60 minutes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Haemoglobinopathy Screening</td>
<td>National guideline of 3 days to initial report</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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Figure 1 Microbiology Annual Turnaround Time

Green Line = Acceptable level below which performance should not fall.

No quality issues occurred all performances were above 97% for In-laboratory to validation.
Figure 2  Haematology Biochemistry and Immunology annual Turnaround Times

Above Green Line = Acceptable for Haematology FBC and Biochemistry U/E 12 hour target and for Serum electrophoresis percentage reporting.

Above Blue Line = Acceptable for RCPath A\E “60 minute in laboratory” turnaround times for FBC and U/E.

Biochemistry and Haematology have maintained 95% of U/E’s and FBC’s completed within 12 hours. Introduction of “Lean Process” has significantly improved this.

The RCPath guidelines on urgent turnaround times from A/E (less than 60 minutes) have been maintained.

Immunology was out-with for maintaining 95% serum electrophoresis reported within 7 days from July to September. It continues to be challenged on this target. This indicates the need for proactive workforce planning in Immunology.
The previous reduced turnaround times within Histology, with over 75% of reported within 7 days has slipped in 2013 to 8 days. Staffing issues at the yearend has created a larger slippage in turnaround time. Breast biopsies were monitored from request to first report, the median days achieved has consistently fallen within the national target of 3 days in 2013.
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Figure 4 Histology 7/3 day Turnaround & Cytology & Non Gynae Turnaround

Histology Cytology Turnaround Times

Above Red Line = Acceptable Histology 3 day turnaround
Above Blue Line = Acceptable Histology 7 day turnaround
Above Purple Line = Acceptable Cytology Non Gynae 95% reported in 7 days
Above Green Line = Acceptable Cytology 10 day turnaround for screening

Histology has struggled to meet the national 3 and 7 day turnaround times in 2013. Intra laboratory processes have been audited to define hold up and “sample/specimen waits” time. Histology is tasked to attain this target in 2014.

Cytology screening programme continues to attain national targets, however due to exceptionally low staffing levels in March Cytology failed to attain the levels required. Short to medium term staffing levels must be monitored to negate this happening in 2014.

Non Gynae 95% reported in 7 days fell outside the acceptable limits in September and October when key personnel were unavailable. Reporting cover for this work must be available at all times to ensure timely reporting.
Figure 5 Monitoring of Haemoglobinopathy Screening

The national target of Haemoglobinopathy screening has been attained for most of 2013. Slight over targets noticed on 3 occasions.
Audit Schedules

It is a quality requirement that both Quality Management Systems and laboratory processes are audited to assess if the laboratory is compliant with ISO15189/CPA, London QA, HTA and MHRA. The annual audit schedule was introduced for 2013 and department’s progress was monitored at the monthly quality review meetings. Figure 5 shows the cumulative progress of audit completion for 2013.

**Figure 6 Audit progress for 2013**

There has been a systematic approach to audit in 2013, with audits occurring regularly throughout the calendar year and scheduled in the audit module of Q Pulse. From Figure 6 evidence points to a steady progress of audit completion during 2013 in all but one department. Transfusion has had difficulty attaining the required level of audits consistently as it did in 2012. Management must ensure resource is allocated to maintain compliance with the set audit schedule.
Non Conformance
Non conformance was used as a quality indicator in 2013. The target of 8 weeks closure from the initial reporting of a non conformance to completion was the agreed timescale. The non conformances were documented on Q Pulse and remedial and corrective actions applied. Root cause analysis was determined on all non conformances. This is in line with CPA/MHRA/HTA requirements as follows:

There shall be a process for continual quality improvement. This shall include remedial action, corrective action, and preventive action, monitoring of quality indicators and improvement processes.

Corrective action shall be taken to eliminate the root causes of non conformities. Corrective actions shall be appropriate to the effects of the nonconformities encountered. The process shall include:

a) Investigation of the root causes of nonconformities and recording of results
b) Determination of and responsibility for corrective action
c) Implementation of corrective action within an agreed time scale
d) Monitoring of corrective action taken.

Figure 7 Non Conformance Quality Indicators Completed within 8 weeks
A quality indicator of non conformance cleared within 8 weeks was set at the beginning of 2013. For some EQA non conformances such as those in Biochemistry, the NC is not cleared until the next correct EQA is assessed. This reflects in the levels for Biochemistry who has a secondary clearance level of 70% in 6 weeks. Cytology struggled over the summer period to maintain an 8 week clearance mainly due to a loss of key management staff. This has been rectified and acceptable non conformance clearance levels are now being attained.

External Quality Assessment

External quality assessment was also used in 2013 as a quality indicator. Each department setting expected compliance for EQA and measured against actual compliance. Figure 6 shows the EQA quality indicators for 2013.

Figure 8 EQA Quality Indicators.

![EQA QI's 2013 graph](image)

Above Green Line = acceptable for Histology
Above Red Line = acceptable for Biochemistry
Above Black Line = acceptable for Haematology & Cytology
Each department set acceptable levels of compliance. Haematology and Cytology set an expected compliance of 95% (black line) the green line indicates the lower limit of acceptance for Histology. Biochemistry’s complex EQA systems require compliance of above 75% (red line). Biochemistry had one blip in November 2013, and struggle with non returns. This is being addressed by management. Immunology had a one point EQA failure in May which has not reoccurred.

Non Conformance Analysis

Q Pulse analysis module is used to trend non conformance in pathology. Total non conformance for each department is shown in figure 9.

**Figure 9 Non Conformances in Pathology 2013**

Pathology overall non conformance closed within 8 weeks was 87.8% in 2013
All departments are reporting via Q pulse allowing analysis of the non conformances.

Table 3 Non conformance closure for each department

Using the CAPA module to monitor non conformances allows definition of root cause of the non conformance. Figure 10 shows the root cause analysis for departments in pathology.

Figure 10 Root Causes of Non Conformances in Pathology 2013
Each department’s non-conformity can be analysed for the resolution to enable trends to be assessed by management.

**Figure 11 Resolution of Non Conformance by Department**

<table>
<thead>
<tr>
<th>Business case implemented</th>
<th>Competency completed</th>
<th>Documentation Update</th>
</tr>
</thead>
<tbody>
<tr>
<td>100%</td>
<td>20%</td>
<td>85%</td>
</tr>
<tr>
<td>Equipment maintenance</td>
<td></td>
<td></td>
</tr>
<tr>
<td>45%</td>
<td></td>
<td>63%</td>
</tr>
<tr>
<td>Lab meeting</td>
<td>Interface cycled</td>
<td>100%</td>
</tr>
<tr>
<td>100%</td>
<td>90%</td>
<td>50%</td>
</tr>
<tr>
<td>No Action</td>
<td>manufacturer’s investigation</td>
<td>100%</td>
</tr>
<tr>
<td>35%</td>
<td>34%</td>
<td>50%</td>
</tr>
<tr>
<td>Product Renewed</td>
<td>Quarantined</td>
<td>RAISED WITH IT</td>
</tr>
<tr>
<td>90%</td>
<td>100%</td>
<td>20%</td>
</tr>
<tr>
<td>Recalibration</td>
<td>Repair carried out</td>
<td>Repeat full assay</td>
</tr>
<tr>
<td>90%</td>
<td>90%</td>
<td>95%</td>
</tr>
<tr>
<td>Report removed</td>
<td>Retrained</td>
<td>Training set up</td>
</tr>
<tr>
<td>40%</td>
<td>10%</td>
<td>10%</td>
</tr>
<tr>
<td>Tutorial set</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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Mortuary QI’s were also monitored in 2013, measuring free body storage space monthly and mortuary audits.

Table 3 Mortuary QI’s 2013

<table>
<thead>
<tr>
<th>Department</th>
<th>Quality indicator</th>
<th>Measured by</th>
<th>Current Indicator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortuary</td>
<td>Free body storage capacity greater than 10% of total</td>
<td>Monthly audit</td>
<td>Free storage &gt; 10% each month in 2013</td>
</tr>
<tr>
<td>BG/CFH</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Monitor Audit</td>
<td>Monitor Audit schedule at QRM</td>
<td>Monthly audit</td>
<td>100% audits completed</td>
</tr>
<tr>
<td>schedule at QRM</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IR1 reporting</td>
<td>IR1 reporting</td>
<td>Expected 8 week</td>
<td>100% closure of IR1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>closure monitored</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>at QRM</td>
<td></td>
</tr>
</tbody>
</table>

Conclusion
The quality objectives for 2013 have been met as evidenced by the measurement of quality indicators which evidence that BCFH has continued to provide a high quality customer focused, accurate, safe and cost effective service. Haematology, Biochemistry, Microbiology, Histology and Cytology remain CPA accredited, Transfusion remains MHRA complaint although a visit is expected on the CFH site. Histology remains HTA complaint and Cytology and Histology London QA compliant. All staffs work to the current version of the departmental Quality Manual and all procedures therein.

S Cooper (Pathology Quality Manager)
13/12/2013