2015 Pathology Quality Objectives and Quality Indicators Cumulative Report

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 2014 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 2014.

2014 Quality Objectives for Pathology Barnet and Chase Farm Hospitals

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.

Quality Objectives

1. Deliver a high quality, safe clinical and laboratory service to customers
2. Provide services of the highest quality to all its stakeholders, by continuous improvement and meeting customer needs and requirements
3. Comply with standards ISO 15189:2012, The Blood Safety and Quality Regulations **(**MHRA) and The Human Tissue Authority

2015 Pathology Quality Objectives and Quality Indicators Cumulative Report

Quality Objective	Quality Indicator	Measurand	Timed Period
Quality Objective 1	Operate according to departmental policies	Monitor acknowledgement levels on Q pulse by monthly audit, reported to directorate and QRM meetings.	Monthly over 12 months
Quality Objective 1 Quality Objective 2	(a) Participate in all NEQAS/CQAS schemes appropriate to the department's repertoire.	(a) Monitored at quality management meetings monthly. 100% compliance of registered for eligible schemes	Monthly over 12 months
Quality Objective 1 Quality Objective 2	(b) Achieve acceptable EQA compliance score	(b) Monitored at quality management meetings monthly. % compliance of EQA registered for eligible schemes	Monthly over 12 months
Quality Objective 1 Quality Objective 2 Quality Objective 3	Perform audits on a planned and regular basis	Monitor at QRM meetings via Q pulse. Measure % compliance against documented audit schedule.	Monthly over 12 months
Quality Objective 2	Conduct an annual 'User' survey.	User Survey reported and responses actioned via potential non conformance	Monthly over 12 months
Quality Objective 1 Quality Objective 2 Quality Objective 3	Raise CAPA (Corrective action/Preventive action) against all non-conformances and action them	Monitored at quality management meetings monthly. CA/PA completion within 8 weeks of start date	Monthly over 12 months
Quality Objective 1 Quality Objective 2 Quality Objective 3	Measure test turnaround times of routine tests	Monitor turnaround time against hand book expected value in days, report variance monthly at QRM and Directorate.	Monthly over 12 months

2015 Pathology Quality Objectives and Quality Indicators Cumulative Report

Table 1 Quality indicators

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

	Biochemistry/ Immunology	Cytology	Microbiology	Haematology	Histology
Routine Test Turnaround	Most requested 20 tests, referred tests and immunology tests	Cytology smears and non Gynae work	HIV, Serology, MRSA, C.Diff., Chlamydia and urines, referred tests,	Most requested 20 tests and referred tests	Histology average turnaround time and 0.75 percentiles. Breast, prostate and colonic biopsies have been measured
A/E Turnaround Times	0.95 Percentile for U/E requests, Percentage of A/E routine tests available in 60 minutes			0.95 Percentile for FBC requests. Percentage of A/E routine tests available in 60 minutes	
Haemoglobinopathy Screening	National guideline of 3				

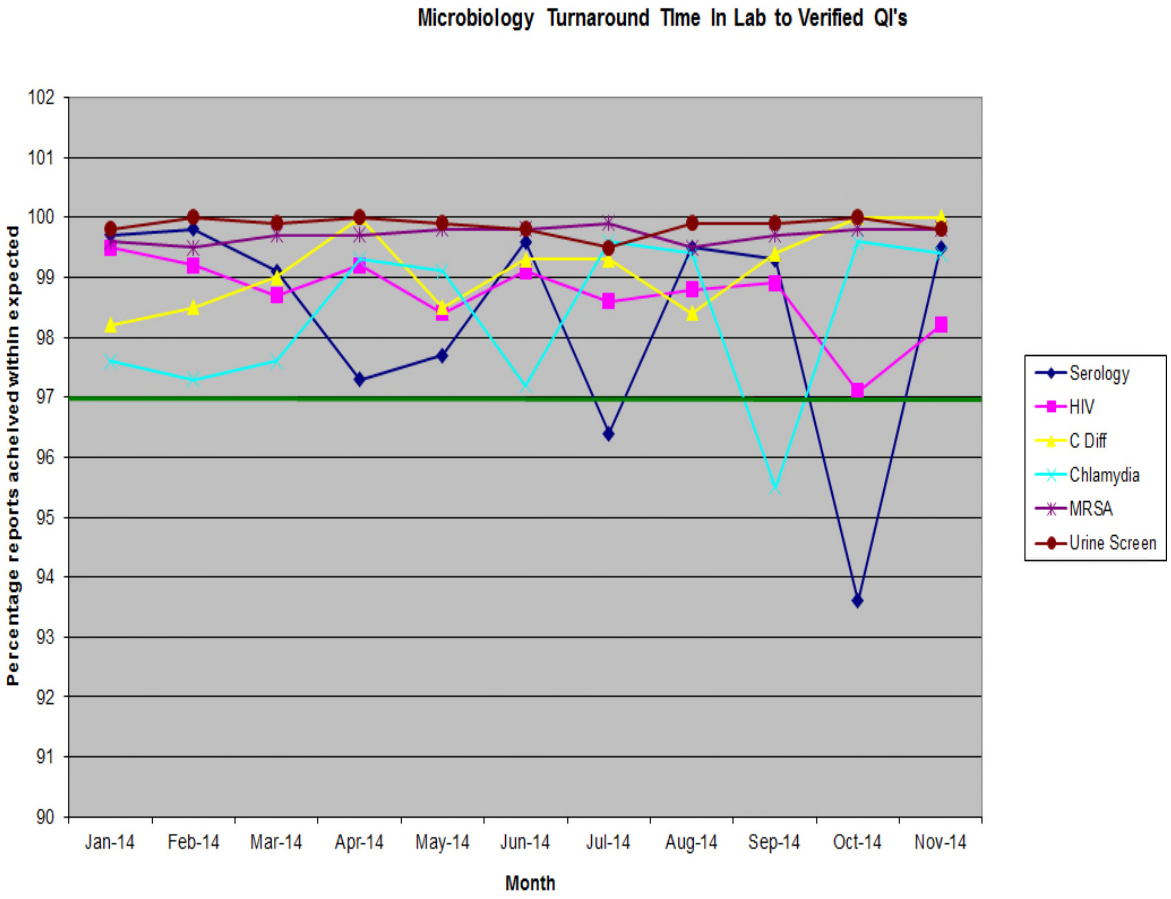
2015 Pathology Quality Objectives and Quality Indicators
Cumulative Report

	days to initial report				

Figure 1 Microbiology Annual Turnaround Time

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

2015 Pathology Quality Objectives and Quality Indicators Cumulative Report



No major quality issues occurred most performance was above 97% for In-laboratory to validation. The introduction of a Saturday ANC clinic did lead to some issues regarding weekend routine sample analysis. This shows as a reduced performance for Serology samples in October.

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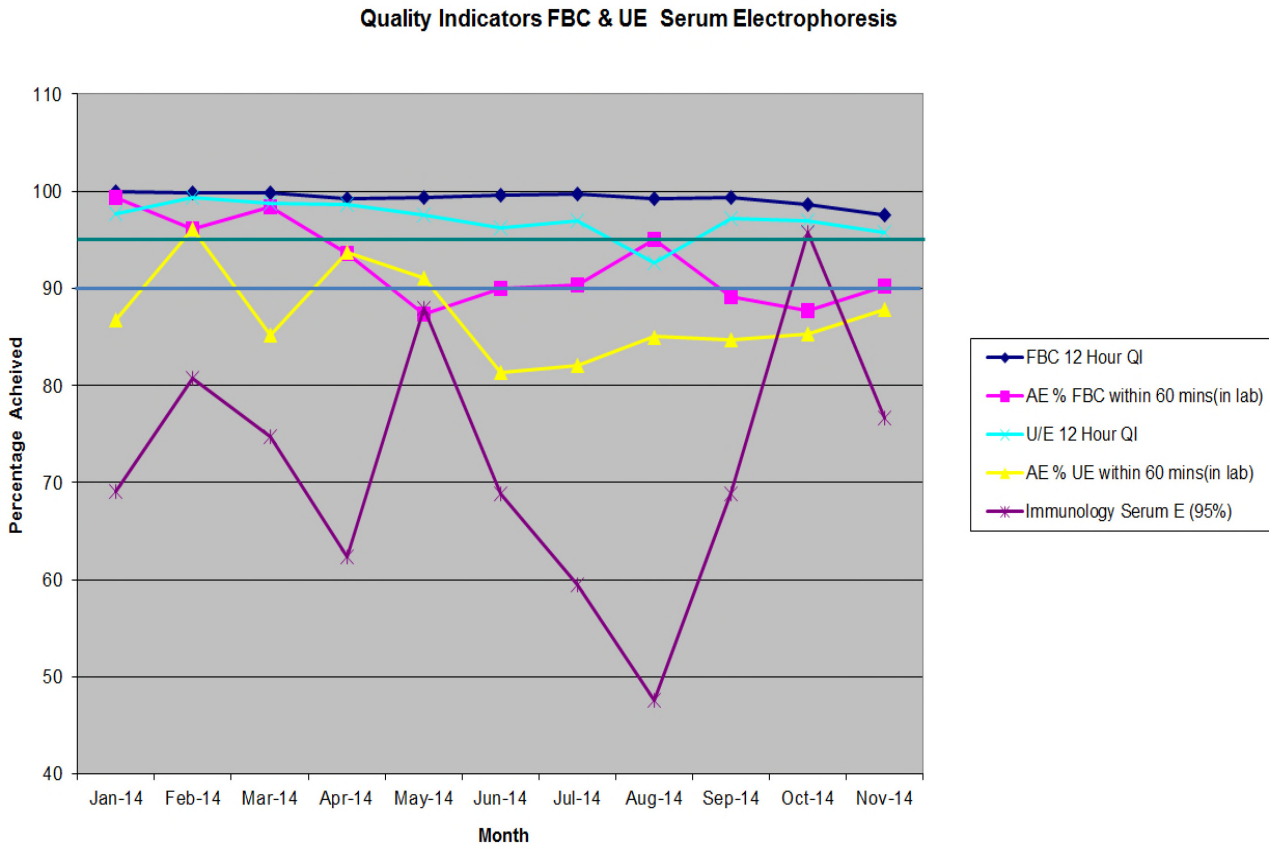
Figure 2 Haematology Biochemistry and Immunology annual Turnaround Times

2015 Pathology Quality Objectives and Quality Indicators Cumulative Report



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.

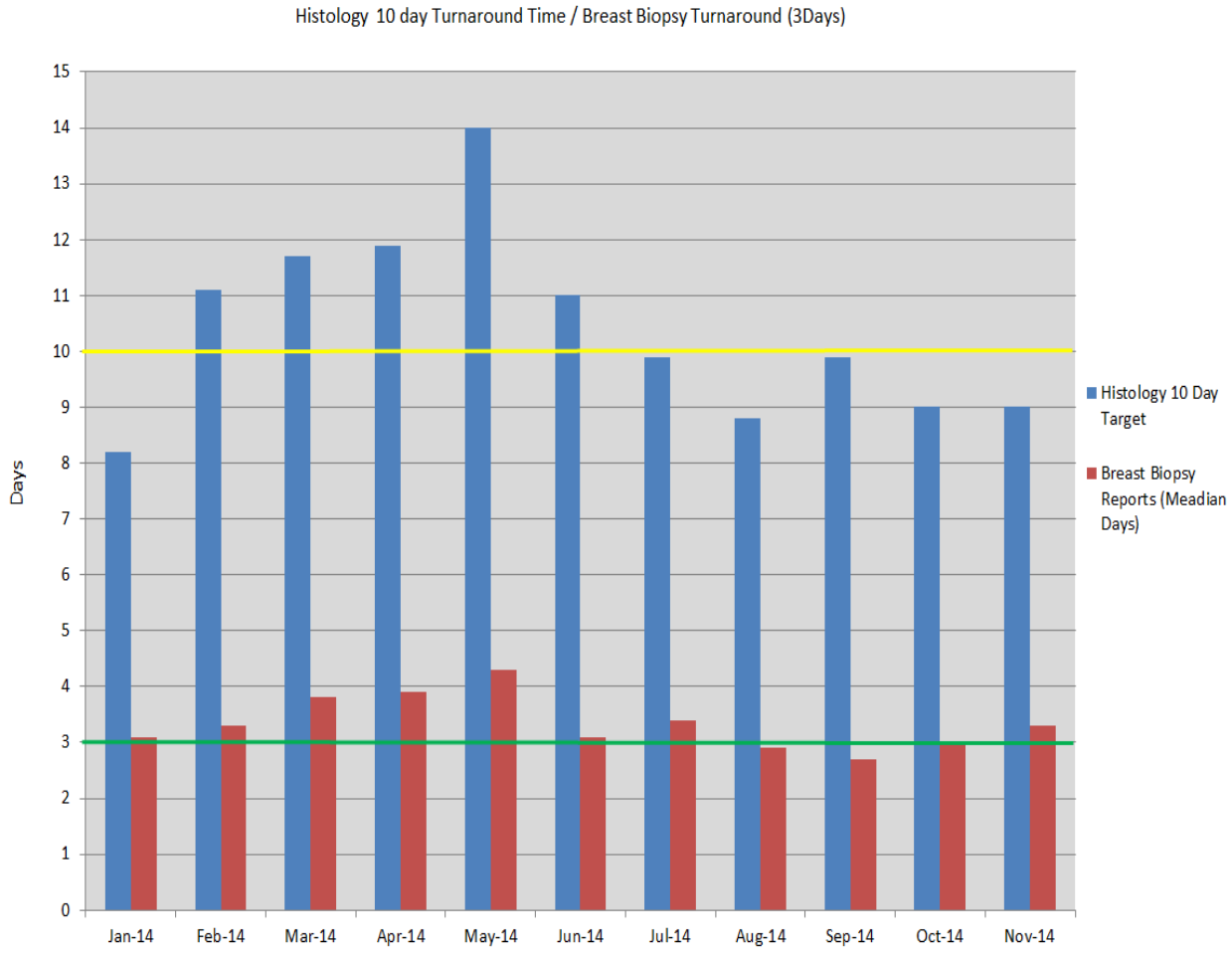
Haematology has maintained 95% of FBC's completed within 12 hours. Chemistry has maintained this target for U/E's in all but 1 month, August.

The RCPath guidelines on urgent turnaround times from A/E (less than 60 minutes) have not been maintained by Chemistry whilst Haematology has managed in part to attain the standard. The root cause being the change in laboratory practice (MES) during 2014.

Immunology was out-with for maintaining 95% serum electrophoresis reported within 7 days for most of 2014. It continues to be challenged on this target whilst awaiting interfacing of analysers. Risk active on Trust Risk register.

Figure 3 Histology QI's for 2014

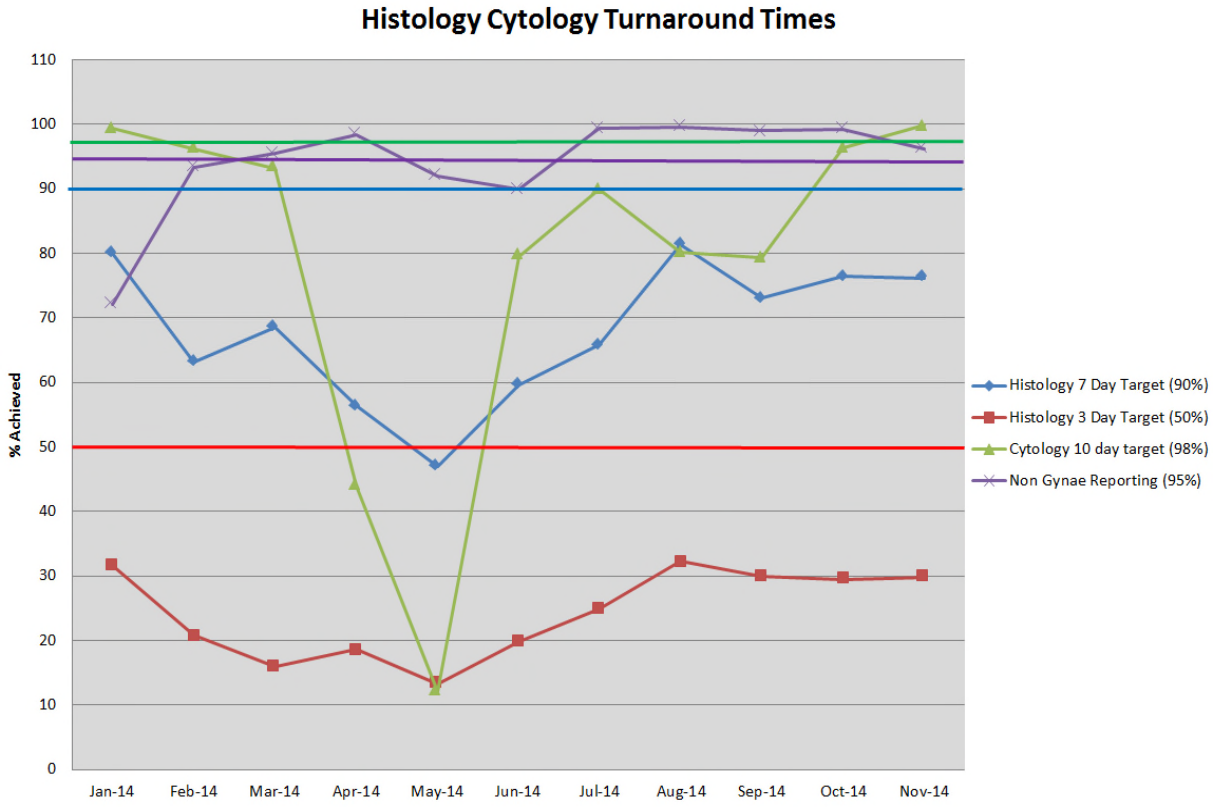
2015 Pathology Quality Objectives and Quality Indicators Cumulative Report



Staffing issues during 2014 has again created a larger slippage in turnaround time within Histology with the 10 day turnaround breached between the months of February to June. Breast biopsies were monitored from request to first report, the median days achieved has consistently fallen outside the national target of 3 days in 2014. Pathologists reporting time requires audit to improve overall performance.

Figure 4 Histology 7/3 day Turnaround & Cytology & Non Gynae Turnaround

2015 Pathology Quality Objectives and Quality Indicators Cumulative Report



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

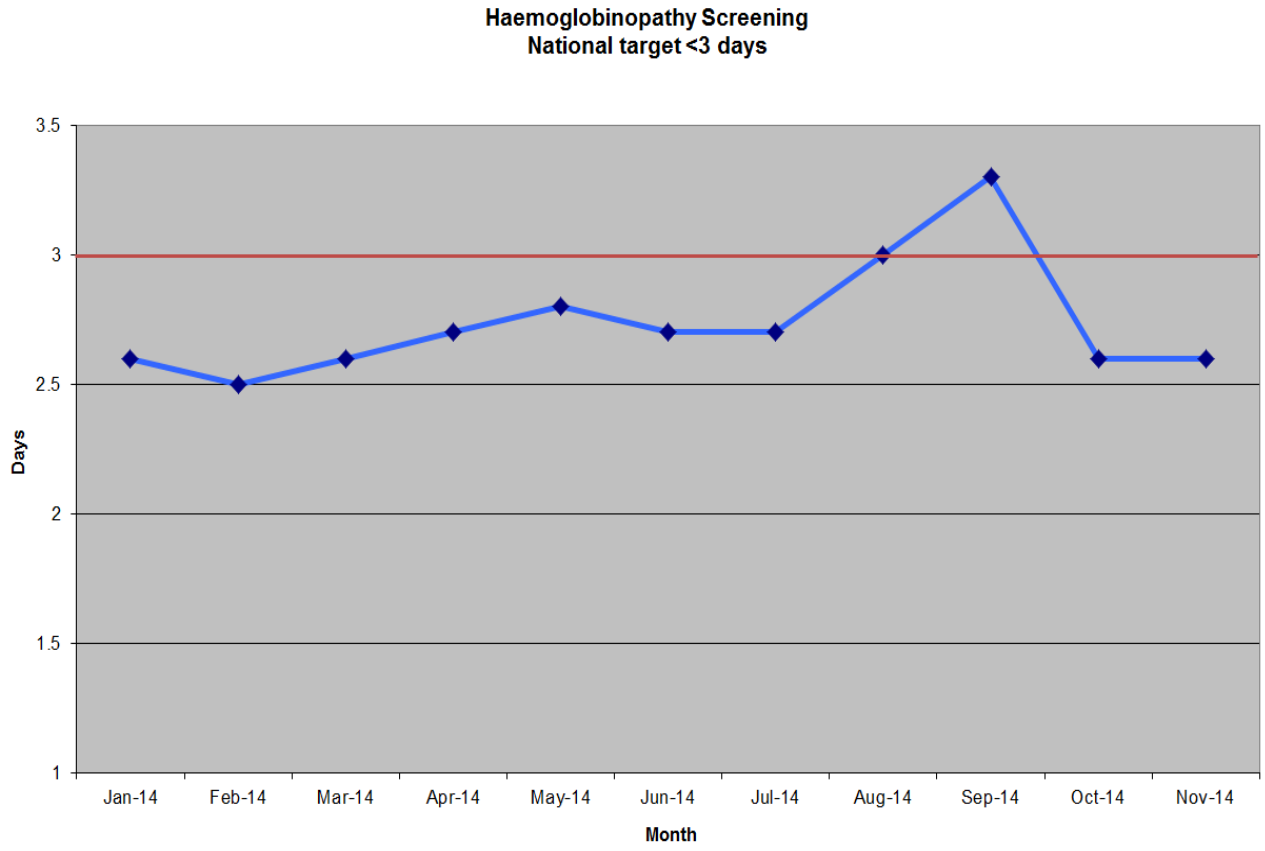
Histology has struggled to meet the national 3 and 7 day turnaround times in 2014 a recurrent theme. Intra laboratory processes have been audited to define hold up and “sample/specimen waits” time. Histology is tasked to improve target performance in 2015.

Cytology screening programme has consistently failed to attain national targets due to exceptionally low staffing levels. Short to medium term staffing levels must be monitored to negate this happening in 2015. Improvements are noted towards year end.

Non Gynae 95% reported in 7 days fell outside the acceptable limits in May and June 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

2015 Pathology Quality Objectives and Quality Indicators Cumulative Report



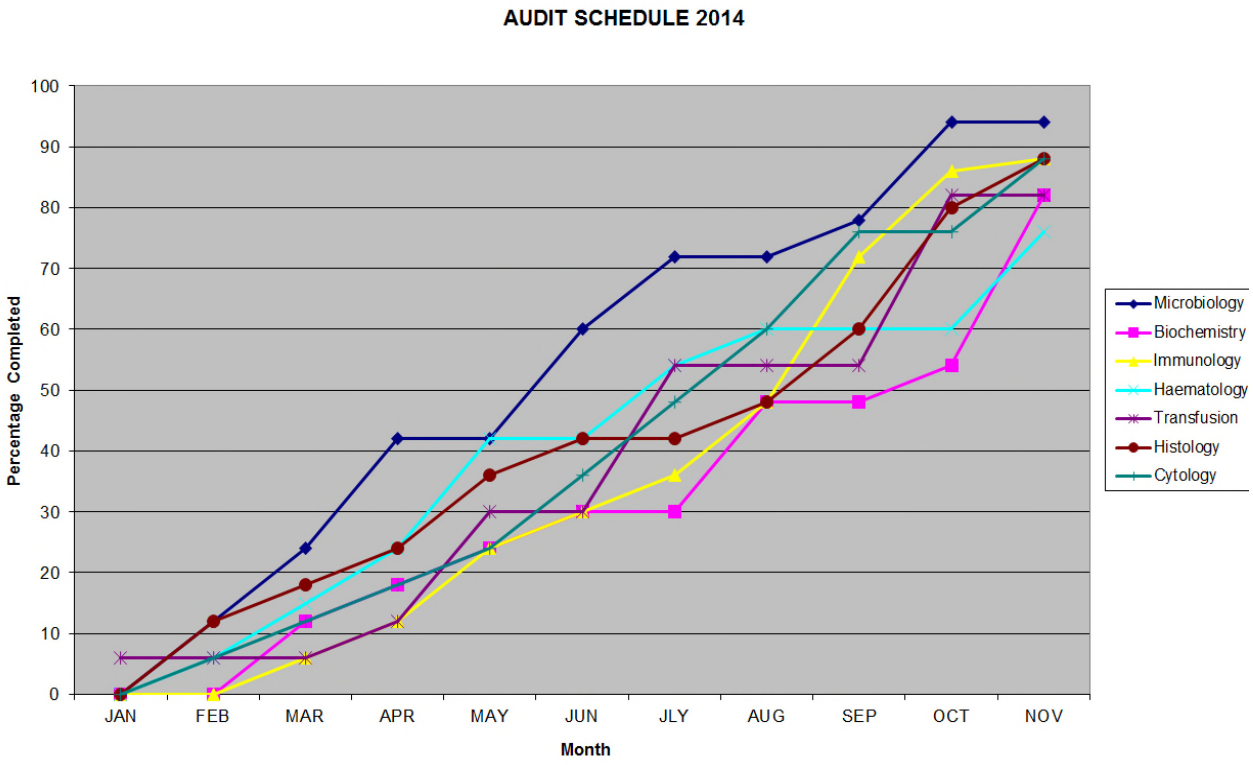
The national target of Haemoglobinopathy screening has been attained for most of 2014 failing to attain only once.

Audit Schedules

2015 Pathology Quality Objectives and Quality Indicators Cumulative Report

It is a quality requirement that both Quality Management Systems and laboratory processes are audited to assess if the laboratory is compliant with ISO15189:2012 and CPA, London QA, HTA and MHRA. The annual audit schedule was introduced for 2014 and department's progress was monitored at the monthly quality review meetings. Figure 5 shows the cumulative progress of audit completion for 2014.

Figure 6 Audit progress for 2014



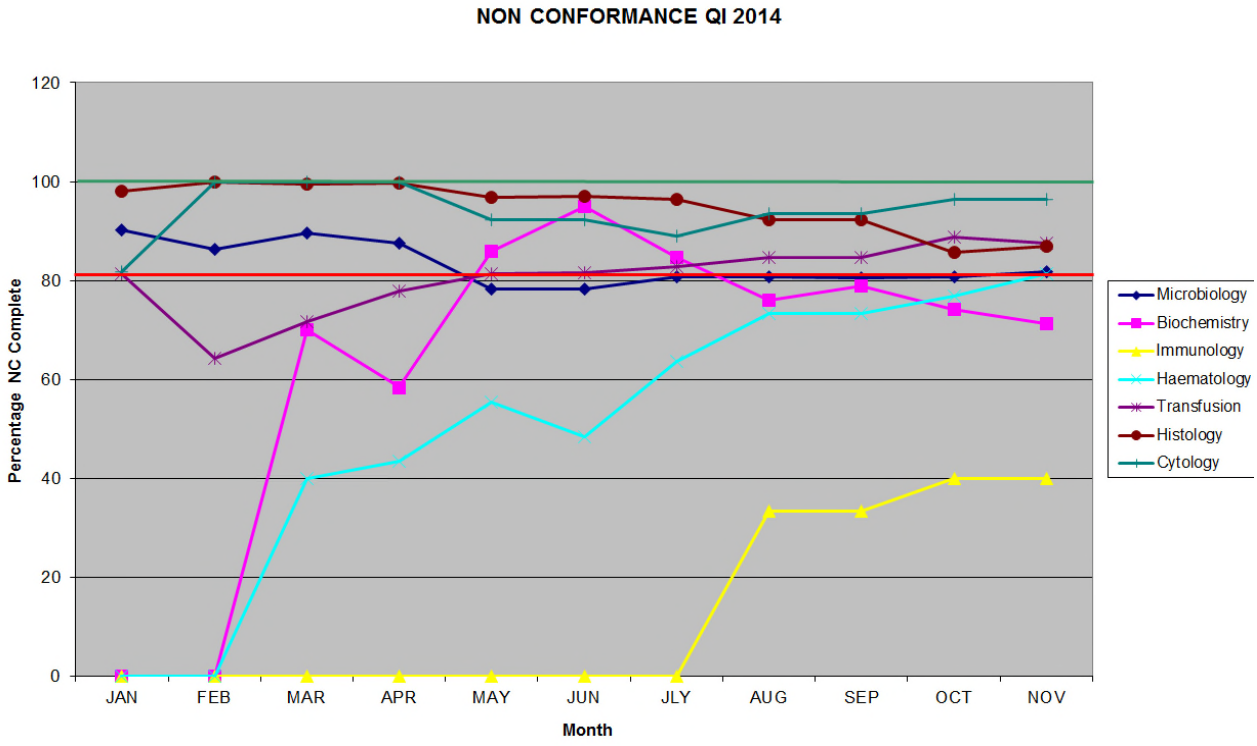
There has been a systematic approach to audit in 2014, with audits occurring regularly throughout the calendar year and scheduled in the audit module of Q Pulse. From Figure 6 evidence points to a steady progress of audit completion during 2014. Haematology must ensure year end audits are completed.

Non Conformance

2015 Pathology Quality Objectives and Quality Indicators Cumulative Report

Non conformance was used as a quality indicator in 2014. 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 ISO 15189:2012, 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



Red Line = average pathology non-conformance clearance time
A quality indicator of non conformance cleared within 8 weeks was set at the beginning of 2014. For some EQA non conformances such as those in Biochemistry, the NC is not cleared until the next correct EQA is assessed.

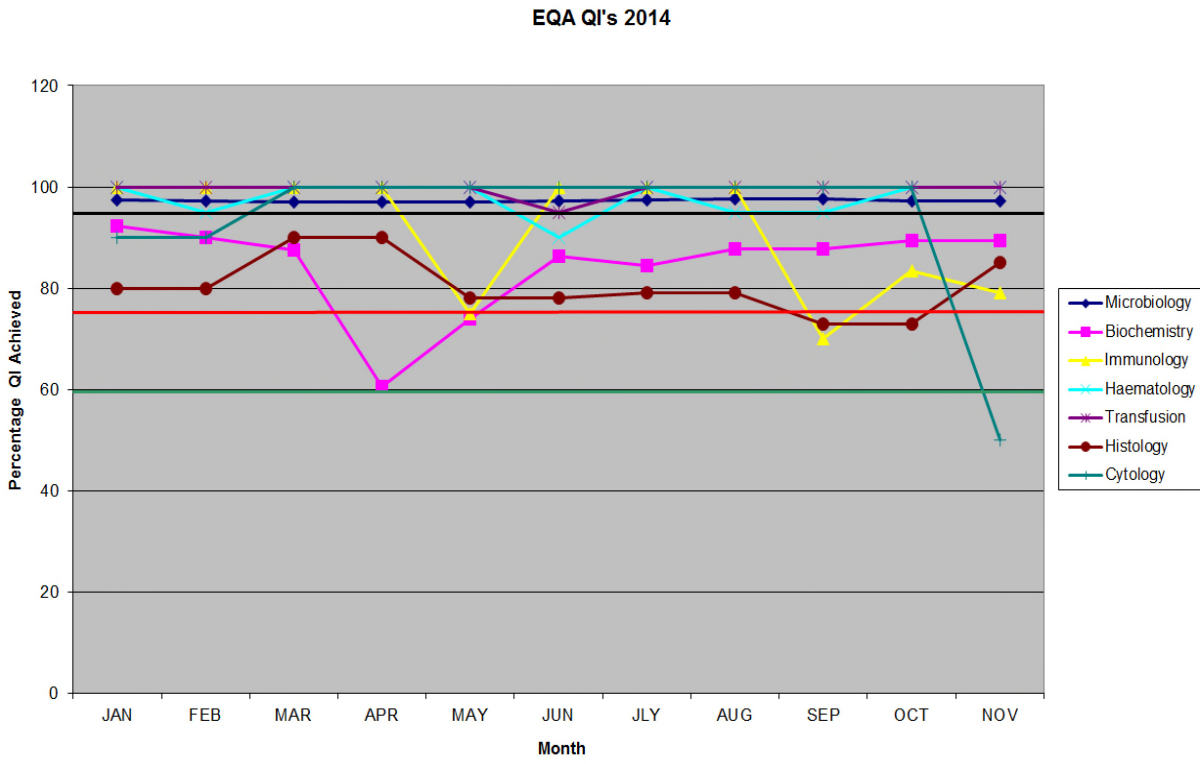
2015 Pathology Quality Objectives and Quality Indicators Cumulative Report

However, Immunology failed to complete reporting of non-conformance over the first half of the year, and only attaining 40% clearance within 8 weeks. (Pathology average (82%). Chemistry and Haematology also struggled earlier in 2014 but improved performance as the year progressed.

External Quality Assessment

External quality assessment was also used in 2014 as a quality indicator. Each department setting expected compliance for EQA and measured against actual compliance. Figure 6 shows the EQA quality indicators for 2014.

Figure 8 EQA Quality Indicators.



Above Green Line = acceptable for Histology
Above Red Line = acceptable for Biochemistry
Above Black Line = acceptable for Haematology & Cytology & Microbiology

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

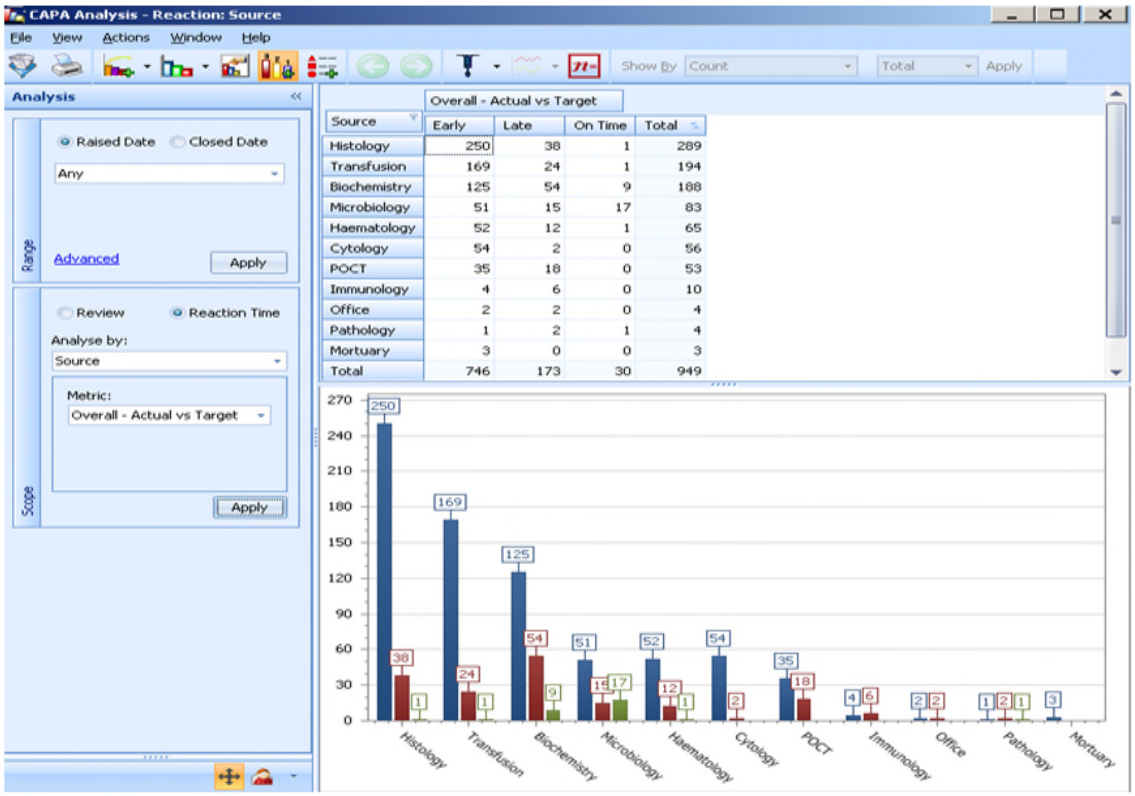
2015 Pathology Quality Objectives and Quality Indicators Cumulative Report

EQA systems require compliance of above 75% (red line). Biochemistry had one blip in April 2014, and struggle with non returns. This is being addressed my management. Immunology had a one point EQA failure in September which has not reoccurred. Cytology's poor performance in November reflects introduction of new Non gynae EQA.

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 2014



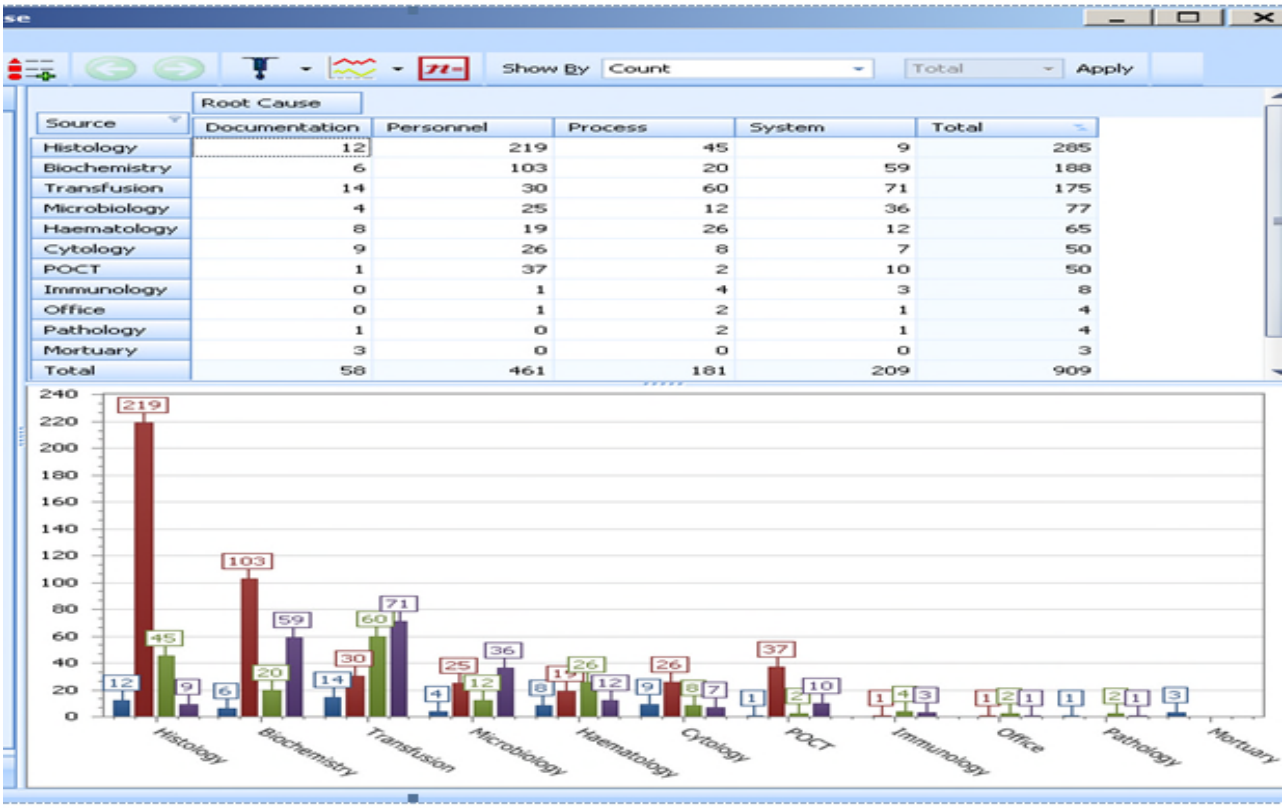
2014 Pathology overall clearance rate within 8 weeks 81.8%

Pathology overall non conformance closed within 8 weeks was 81.8% in 2014

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.

2015 Pathology Quality Objectives and Quality Indicators Cumulative Report

Figure 10 Root Causes of Non Conformances in Pathology 2014



Each department's non conformity can be analysed for the resolution to enable trends to be assessed by management.

Mortuary QI's were also monitored in 2014, measuring free body storage space monthly and mortuary audits.

2015 Pathology Quality Objectives and Quality Indicators Cumulative Report

Table 3 Mortuary QI's 2014

Department	Quality indicator	Measured by	Current Indicator
Mortuary BG/CFH	Free body storage capacity greater than 10% of total	Monthly audit	Capacity BGH attained
	Monitor Audit schedule at QRM	Monthly audit	12 out of 16 audits completed
	NC reporting	Expected 8 week closure monitored at QRM	100% closure of NC

Conclusion

The quality objectives for 2014 have been met as evidenced by the measurement of quality indicators which evidence that BCF Pathology has continued to provide a high quality customer focused, accurate, safe and cost effective service. Haematology, Biochemistry, Microbiology, Histology and Cytology remain CPA accredited and are focused on achieving ISO15189:2012 compliance, Transfusion remains MHRA complaint. 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.

(Pathology Quality Manager)
19/12/2014