

# **Pathology Department Calderdale and Huddersfield NHS Trust**

## **Annual Management Review of the Quality Management System**

**2016-17**

### **Executive Summary**

## Report Authors and Contributors

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### 1. Findings from previous review

Findings from 2015-16 review. Full records are available in Q-pulse

Number	Details	
QIN-870	Root cause analysis training for all to include Fishbone analysis methodologies or similar to train staff in understanding contributory factors in major incident fault categories	Status-Closed
QIN-869	Detailed trend analysis for departments to be fed into quality group meetings	Status-Closed

## 2. Review of 2016-17

### 2.1. Quality Policy

The quality policy (below) was formally reviewed updated and approved by Governance Board May 2016 No changes required. The next planned review date is 27/12/2018 and any change requests received in the interim will be escalated to board as appropriate

**The Pathology Directorate of Calderdale and Huddersfield NHS Trust provides an extensive range of services delivered by three main laboratory areas and Point of Care Testing, with the support of reference facilities. All areas are supported by comprehensive phlebotomy, reception and administration services.**

#### **Blood Sciences Department incorporates**

**Clinical Biochemistry Department** providing a diagnostic and clinical advisory service covering acute and general biochemistry, endocrinology, allergy, cardiac and tumour markers, toxicology and therapeutic drug monitoring.

**Haematology Department** providing a diagnostic and clinical advisory service for acute and general Haematology tests, and specialized haemoglobinopathy tests.

**Blood Transfusion** provides blood and blood products to support the clinical services within the Trust and local private hospitals.

**Immunology** provides a range of assays to aid the diagnosis and monitoring of various auto-immune diseases.

**Medical Microbiology Department** provides a diagnostic and clinical advisory service for all aspects of clinical microbiology and infection control. This includes bacteriology, mycology, parasitology, virology and serology.

**Cell Pathology Department** providing the majority of aspects of Cell Pathology including non-gynae cytology, histology and andrology. Mortuary facilities are provided at the Huddersfield Royal Infirmary and Calderdale Royal Hospital.

**Point of Care Testing (POCT)** provides multidisciplinary clinical and laboratory support to all clinical areas involved with near patient testing within the Trust.

**Anticoagulation Service** Providing testing and monitoring service for patients on oral anticoagulant therapy, with clinics in Outpatient departments at HRI, Phlebotomy suites HRI/CRH and a variety of community settings.

**The Directorate is committed to providing a high quality clinical laboratory service that makes a significant contribution to patient care, meets the needs of its and compliance with ISO 15189 and all relevant national and international standards..**

#### **To achieve these aims the Directorate will:**

- Operate a quality management system that integrates the organisation and its procedures, processes and resources
- Set quality objectives in order to implement this quality policy and to achieve continual quality improvement
- Ensure that all personnel are familiar with this quality policy and are committed to ensuring user satisfaction.  
Ensure all personnel are familiar with the contents of the quality manual, and all procedures relevant to their work
- Commit to the health, safety and welfare of its entire staff and comply with all relevant environmental legislation
- Ensure that visitors to the department are treated with respect and that due consideration is given to their safety while on site.
- Uphold professional values and demonstrate commitment to good professional practice and conduct

## **2.2. Review of requests, and suitability of procedures and sample requirements**

QMS audits are next scheduled for June 2018 for each laboratory section.

## **2.3. User satisfaction & assessment of user feedback- and staff suggestions**

### **2.3.1. Quality improvement notes**

128 records raised during the review period. Records raised by or on behalf of both staff and service users- please see appendix 4.1 of full report. Where appropriate improvement actions have been taken and recorded in the records prior to closure. Full details of all records are available for the Pathology Quality Manager upon request

### **2.3.2. Pathology-wide user Surveys**

The department participated in the annual standardised survey hosted by the Royal College of Pathologists.

The results of the 2016 survey can be found in Appendix 4.2 of full report

There were 50 comments extracted from the survey covering all the disciplines. Of the 50:

- 17 positive comments
- 3 Negative comments
- 30 positive with suggestions for further improvement

### **2.3.3. Other User Surveys/engagement initiatives**

Appendix 4.3 of full report illustrates the variety of user surveys undertaken within the review period.

All surveys were recorded within the audit module of Q-pulse and audit findings raised, where applicable to investigate issues or improve the service. Records of all audit findings are available from the Pathology Quality Manager upon request.

## **2.4. Internal Audit and Risk Management**

### **2.4.1. Internal Audit**

Internal audit of the quality management system as well as departmental repertoires have been undertaken in 2016-17. Summaries of audits can be found in appendix 4.4 of the full report (items 4.4.1 - 4.4.8)

The management of the schedule and close out of audit findings has been monitored as part of the Pathology Quality Group and Governance board agendas with the aid of the KPI dashboard with non-conformances raised to investigate issues to root cause.

### **2.4.2. Risk Management**

The department has followed trust procedures for reporting departmental risk register. Risks have been monitored through the governance board agenda. Appendix 4.5 of full report illustrates the risks entered to the register for 2016-17 period

In addition to the trust systems each department has undertaken or is in the process of undertaking full process and health and safety risk assessments. The process risk assessments have been undertaken to ensure that all risks to processes-including pre-analytical, analytical and post analytical phases have been considered and assessed.

Where relevant significant risks and those not readily mitigated have been escalated to the risk register

## **2.5. Reviews by External Organisations**

During the review period a variety of external audits have been undertaken:

- Cellular Pathology- UKAS 15189 Surveillance 1
- BioSafe Inspection CL3
- ISO 15189. Blood Sciences Jan 2017 UKAS
- Microbiology-ISO 15189 Surveillance 2017- Surveillance 1
- Pennine Breast Screening QA Visit 2016

Details can be seen in Appendix 4.4- see item 4.4.8 of full report

As with audits above- the management of audit findings has been monitored through the quality group and governance board agendas.

## **2.6. EQA / Inter-Lab Comparisons**

Performance in EQA for each department is considered satisfactory for the review period. Where applicable investigations into failure have been completed or are still in progress. Please see Appendix 4.6 of the full report for full details and links to failure investigation records

*4.6.1- Microbiology*

*4.6.2- Cellular Pathology*

*4.6.3-Biochemistry*

*4.6.4-Haematology and Coagulation*

*4.6.5- Transfusion*

## **2.7. Quality Objectives and Indicators**

Quality objectives were set at the beginning of the review period and were mapped to trust objectives. Objectives have been drawn up as records within Q-pulse allowing for the setting of timescales and responsibilities in SMART format. Appendix 4.7 of the full report illustrates the objectives and current status.

The current performance indicators are listed in the Pathology KPI dashboard and now include the indicators suggested in the National Pathology Quality Assurance Dashboard (PQAD). Turnaround time monitoring is undertaken in all disciplines with investigation into issues recorded in Q-pulse.

Throughout the review period there has been an increase in the number of persisting red indicators and a decision made to establish a risk assessment process for these made by the Pathology Board. The risk assessment will cover impact on patient safety/results and the service as a whole. Robust plans to resolve red indicators to be drawn up and monitored through the governance meeting framework.

## **2.8. Monitoring and Resolution of Complaints**

Complaints, along-with concerns compliments and user feedback from patients or their representatives are recorded and reported in line with trust policy through the DATIX system. Turn round times and duty of candour requirements for complaints are monitored by Trust risk management department. Appendix 4.8 in the full report illustrates summary of complaints for the review period along with concerns, compliments and general feedback entries to the DATIX register for the same period.

Complaints from other service users tend to be recorded as clinical incidents (please see 2.10 of the report)

## **2.9. Supplier Performance**

Currently approved suppliers and reasons for their approval are listed within the supplier module of q-pulse. Non-conformances against individual suppliers are also recorded in Q-pulse. For the review period there were 9 supplier non-conformances records raised as follows:

- NC-1369 Siemens Diagnostics Biochemistry positive IQC shift (troponin) centaur h2 at HRI.
- NC-1330 Beckman Coulter Microbiology 2 episodes of the urine analyser IQ sprint being broken with loss of 4 and half days in microscopy lost
- NC-1357 NHSBT Transfusion NHSBT issued expired unit of platelets for patient, these were released from Leeds centre and delivered to CRH
- NC-1312 Leica Microsystems (U K) Ltd Cell Pathology Sensor errors in wax chambers
- NC-1307 Thermo Scientific Cell Pathology heat sensor in wax 3 reading low.
- NC-1345 Thermo Scientific Cell Pathology pipe blocked, failed to drain wax from retort. no tissue affected.
- NC-1448 Becton Dickinson Microbiology Lamina not delivered, despite 5 requested and charged for on order.
- NC-1337 Sakura Finetek Uk Ltd Cell Pathology "clunking noise" and erroring- not able to coverslip any slides
- NC-1414 Leica Microsystems (U K) Ltd Cell Pathology Sensor error stated lid was opened during processing.

See appendix 4.9 of the full report. No significant issues or trends highlighted Supplier performance considered to be adequate and appropriately monitored.

## **2.10. Identification and Control of Non-Conformities and Status of Corrective and Preventive Action**

The department has recorded non-conformances in the form of the following record types:

- Non-conformance
- Clinical incident

Clinical incidents are co-reported in both Q-pulse and the trust Datix system.

And the following records for preventive action

- Review of the operational procedures.- all SOP and lab instructions are subject to maximum 2 year review intervals. The overall departmental compliance with these timescales have been monitored as part of the quality group and governance board agendas using the Pathology KPI dashboard- (see appendix 4.10 for current version)
- Analysis of trend in corrective/preventive action records.
- External quality assessment – Refer to section 2.6 above
- Audit internal and external- Refer to 2.4 and 2.5 above.
- Staff training and competency assessment programmes
- Change management

The change management records for the review period are illustrated in appendix 4.12

- Quality improvement notes raised as part of the audit process and from staff /customer comments. Refer to section 2.3 and to appendix 4.1.
- User comments (Those not captured in the trust Datix system as summarised in section 2.8 and appendix 4.8)

The department collects informal user feedback comments both positive and negative in order to supplement the Trust system. A summary of this feedback can be found in appendix 4.13 of the full report.

## **2.11. Changes In The Volume and Scope of Work, Personnel, and Premises**

In line with Pathology change management policy and procedural documents – MP 200-032 and QP 100-128, all relevant changes have been recorded in Q-pulse as one of or a combination of the following record types:

- *Change management records*
- *Process control records*
- *Transfusion change management records*

These records record the management of the individual changes. A summary of records for the review period can be found in appendix 4.12 of the full report

Effective change control continues to evolve in the department and is considered fit for purpose.



### **3. Summary**

The board has objectively evaluated the following elements of the AMR as evidence of continued effective contribution to patient care.

#### **Performance indicators**

The current performance indicators are listed in the Pathology KPI dashboard and include the indicators defined in the National Pathology Quality Assurance Dashboard (PQAD). Turnaround time monitoring is undertaken in all disciplines.

Although throughout the review period there has been an increase in the number of persisting red indicators the level of complaints received remains low. Despite this, a decision has been made to establish a risk assessment process for these. The risk assessment will cover impact on patient safety/results and the service as a whole. Robust plans to resolve red indicators to be drawn up and monitored through the governance meeting framework. **(Meeting action MA-820)**

#### **Change control**

Change control is continually evolving in the department and is employed for all significant changes ensuring that risks to patient care are highlighted and mitigated prior to commencement of change wherever possible.

#### **User Complaints and Clinical Incidents**

Complaints and incident records remain at very low levels with no trends warranting further investigation.

#### **User Compliments**

Performance in the Annual Pathology User Survey was generally positive and the department continues to receive good levels of positive user feedback.