UNIVERSITY HOSPITALS BIRMINGHAM NHS FOUNDATION TRUST
BOARD OF DIRECTORS
THURSDAY 27 APRIL 2017

Title:	**QUARTER 4 COMPLIANCE AND ASSURANCE REPORT**
Responsible Director:	David Burbridge, Director of Corporate Affairs
Contact:	Louisa Sorrell, Head of Clinical Risk and Compliance Stacey Goodwin, Senior Manager Clinical Compliance

Purpose:	To provide the Board of Directors with information regarding internal and external compliance as of 31 March 2017.	
Confidentiality Level & Reason:	None	
Annual Plan Ref:	Affects all strategic aims.	
Key Issues Summary:	• There were 3 queries raised by the CQC in Q4 • The Trust either meets all NICE recommendations, or is working towards meeting all the recommendations, in 79% of cases (77% in Q3) • There were 4 external visits in Q4 • Compliance for quarterly review of risk registers is 100% • Internal Audit carried out an audit on the Trusts Board Assurance Framework and Risk Management process and provided 'significant assurance with minor improvement opportunities'.	
Recommendations:	The Board of Directors is asked to accept the report.	
Approved by:	D Burbridge	Date: April 2017

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BOARD OF DIRECTORS

THURSDAY 27 APRIL 2017

QUARTER 4 COMPLIANCE AND ASSURANCE REPORT

PRESENTED BY DIRECTOR OF CORPORATE AFFAIRS

1. Purpose

1.1 The purpose of this paper is to provide the Board of Directors with information regarding internal and external compliance as of 31 March 2017.

2. Trust Compliance with Regulatory Requirements

2.1 Care Quality Commission (CQC)

2.1.1 The Trust is governed by several regulatory requirements and the Risk and Compliance Unit currently has specific oversight of the CQC requirements.

2.1.2 Announced Inspection

The CQC carried out an announced inspection of the Trust in January 2015 and published its findings in May 2015. The Trust was assessed as being fully compliant with the CQC essential standards. However, the CQC did highlight some areas of weakness and these have formed part of an action plan which is monitored by the Director of Corporate Affairs Governance Group. There is 1 action which has not been fully implemented; details of the action plan are contained within Appendix A.

2.1.3 Focused Inspection

a) The CQC carried out a focused inspection relating to cardiac surgery on 21 and 22 December 2015. The visit was triggered by the release of data in September 2015 by the National Institute for Cardiovascular Outcomes Research, suggesting that the Trust was an outlier in terms of mortality. During September 2015, the Trust had established, before any notification from the CQC, a Cardiac Surgical Quality Improvement Program (CSQIP).

(b) Following the inspection, the CQC placed 2 conditions on the Trust's registration with the CQC, which were subsequently removed on 25 May 2016.

(c) NHS England has now taken over the oversight of this from the CQC and the Trust is currently in discussions with them to determine how they will be monitoring progress going forward.

2.1.4 CQC Correspondence

The table below provides a summary of data or queries raised by the CQC during Q4.

Date of request or contact	Division	Request or contact description	Findings of investigation & CQC response
31/01/2017	D	ENQ1-3290245029 ; SFR1-3295932470 Complaint received from a patient's relative regarding poor care on ward 625. The complainant raised the following concerns: 1) worsening patient conditions 2) lack of staff training 3) unpleasant environment 4) patients being neglected and left in wet beds 5) poor staff attitude and slow responses to buzzer 6) poor infection control	A range of evidence was reviewed in line with the issues outlined in the complaint. Areas of good practise were highlighted during this review along with areas for improvement. The Nutrition and Hydration audit flagged the need to remind staff to prepare for mealtimes and specifically to offer support to patients to sit out of bed where appropriate and check they are ready for meals before delivering trays of food and to tidy bed table before meals. These areas of improvement have been populated into an action plan and are being monitored by the Matron. There was no evidence to corroborate the concerns raised by complainant.
08/03/2017	D	ENQ1-3518585894 Complaint received regarding staffing on ward 409. The complainant claimed that the ward "only had 2 registered staff nurse throughout the night shift" on 16/2/17.	Although there were 3 Registered Nurses instead of 4 for the whole of the night shift, based on the information there was no evidence to suggest that the care provided was below standard.
	D	ENQ1-3539797976 Complaint received regarding staffing on ward 625. The complainant claimed that there were "insufficient qualified staff especially at night when patients IV alarms were regularly ringing and the HCA's on duty unable to adjust them because they are not qualified, disturbed patient's sleep."	There was no evidence to corroborate the concern raised and sufficiently trained staff were present on the ward. Training figures showed that 84% (21/25) of registered nurses were intravenous (IV) competent. The professional development nurses and clinical educators continue to provide support to the ward. Actions are already being implemented to improve staffing levels.

2.2 Clinical Compliance Framework

2.2.1 As advised in the quarter 1 2016 report, the existing compliance framework was reviewed in light of the recent CQC inspection into cardiac surgery and was amended to include speciality focused measures.

2.2.2 The quarter 2 2016 report provided a summary of the new framework and the outcome of the pilot. During quarter 3 and 4 the compliance framework was rolled out across all agreed specialities within the Trust. These are currently being scored by the Clinical Compliance team and will be reported at specialty meetings during quarter 1 2017/18.

2.3 NICE

2.3.1 The Trust either meets all recommendations, or is working towards meeting all recommendations, in 79% of cases (77% in the previous quarter). In 9% of cases, the guidance is under review by a senior clinician. In 10% of cases the Risk and Compliance Unit are awaiting a response from the Guidance Lead. In 2% of cases there is a divergence against NICE recommendations.

2.3.2 Overdue responses are highlighted at Specialty meetings and the Divisional Clinical Quality Group (DCQG) meetings. The Divisional follow- up follow up all overdue responses with the individuals.

Figure 1: Breakdown of non- compliance with NICE guidance by Division

Non-Compliant	**Partially Compliant**	**Overdue Response**	**Under Review/Working towards compliance**
Division A			
0	**1**	**1**	**18**
Division B			
2 non-compliant - Divergence Approved by CQMG **1** Awaiting decision from the Divisional Director	**0**	**8**	**11**
Division C			
1 – Divergence Approved by CQMG	**1**	**11**	**31**
Division D			
0	**0**	**7**	**31**

2.4 Trust Compliance with External Visits/Peer Reviews

2.4.1 The Trust has a process in place to ensure the appropriate coordination and

evaluations of external recommendations arising from external agency visits, inspections, accreditations and peer review/assessment.

2.4.2 There were **4** external visits during Q4. There were **8** visits from previous quarters where the outcomes were unknown at the time of reporting. The current status of the visits are as follows:

a) Positive assurance (no concerns/risks were found or all actions have been completed and evidenced) – **2** visits
b) Neutral assurance (concerns/risks were found and an action plan has been received by Risk and Compliance to address all shortfalls) – **4** visits
c) Negative assurance (major failings were found during the visit or identified actions are overdue) – **1** visit
d) Reports have not been received for **5** visits and details of these visits will be included in the quarter 1 2017/18 report.

Inspecting Organisation	Area being inspected	Division	Date of Visit	Outcome of Visit	Assurance Level	Assurance / outstanding actions
DGSA (Dangerous Good Safety Audit)	Medical Physics	A	6th Jan 2017	The DGSA were happy that we were operating within the requirements prescribed in current statutory and guidance documents for the carriage of dangerous goods and the safe handling of radioactive substances. 2 recommendations were made: to monitor our vehicle more regularly (monthly) and the second related to training of RRPPS staff who are handling over packages to couriers.	Positive	Training completed. Monthly vehicle monitoring is in place.
UKAS (United Kingdom Accreditation Service)	Biochemistry	A	15th – 16th March 2017	Awaiting action plan – TBC in Q1 2017/18 report.	TBC	Awaiting action plan – TBC in Q1 2017/18 report.

UKAS (United Kingdom Accreditation Service)	Haematology	A	16th March 2017	Awaiting action plan – TBC in Q1 2017/18 report.	TBC	Awaiting action plan – TBC in Q1 2017/18 report.
UKAS (United Kingdom Accreditation Service)	Cellular Pathology	A	11th Oct 2016	This visit took place as not all evidence had been satisfactory to close out all findings from their previous visit in the given timeframe. The inspectors also found new shortfalls in the QMS not present at their previous visit. The management team were informed that they must correct all shortfalls within four weeks or there would be an imposed withdrawal of accredited status. Due to the unlikelihood of this, voluntary withdrawal was recommended by UKAS with re-application of the department after the installation of the new equipment (summer 2017)	Negative	Re-application for accreditation will be done once equipment is in place. Validation/ Verification & training will also be required for successful application. Actions to rectify all shortfalls are being monitored through monthly Quality Management Meetings and weekly meetings with the quality lead and management team.
MHRA - Medicines and Healthcare Products Regulatory Agency	Radiopharmacy	A	30th Nov-1st Dec 2016	3 major deficiencies and 12 others were identified. The 3 major deficiencies found were: 1. The risk of product mix up and microbial contamination is not minimised by the design of the current manufacturing process	Neutral	MHRA have requested ongoing progress and compliance reports on a monthly basis. The Radiopharmacy, Nuclear Medicine and Pharmacy management teams who are meeting regularly to assess progress and compile the reports for submission. These reports are

				2. Process simulation for sterile radiopharmaceutical manufacture is deficient 3. There is inadequate control of the manufacturing environment for the manufacture of sterile products.		also sent to Risk and Compliance for assurance.
MHRA - Medicines and Healthcare Products Regulatory Agency	Pharmacy	A	14th Sept 2016	1 major deficiency and 5 minors were identified. The major deficiency found was: 1. Premises and equipment (including fridge temperatures not being checked, thermometer not calibrated, temperatures excursions not reported appropriately/no CAPA, no pest control QA arrangements)	Neutral	Action plan received and progress is underway.
MHRA - Medicines and Healthcare Products Regulatory Agency	Pharmacy - Melchett Road Aseptic Production Unit - compliance with GMP	A	11th Oct – 13th Oct 2016	3 major deficiencies and 5 others were identified. The 3 major deficiencies found were: 1. The Quality Management System was deficient (including issues around deviation management, complaints, investigation, root cause analysis, CAPA systems, SOPs) 2. Aseptic processing and monitoring was deficient	Neutral	Action plan received and progress underway.

				3. Housekeeping /facility maintenance (including insect trap not working, several large cobwebs found, ineffective cleaning, no soap holder in change room).		
HTA - Human Tissue Authority	Tissue Services	A	7th-8th Dec 2016	The draft report has been received - The HTA has assessed the establishment as suitable to be licensed for the activities specified subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection. There were no major deficiencies. Only 7 minor shortfalls were found within consent standards, governance and quality systems and disposal standards.	Positive	A corrective and preventative action plan must be returned to the HTA within 14 days of the issue of the final report. At the time of writing this report the Trust has only received the draft HTA report
NHS England Quality Surveillance Team (QST) - Peer Review Programme	Heart and Lung Transplant	B	1st June 2016	2 serious concerns were identified (definition of a "serious concern" is an issue that, whilst not presenting an immediate risk to patient or staff safety, is likely to seriously compromise the quality of patient care, and therefore requires urgent action to resolve): 1. A second	Neutral	Consultant respiratory physician – currently locum with appointment to substantive position likely be late Summer / Autumn 2017. Clinical psychologist Proposal for a joint post to cover transplantation and Adult Congenital Heart. Appointment would likely be late Summer / Autumn

				consultant respiratory physician is needed. 2. A clinical psychologist as a core member of the cardiothoracic transplant team is needed.		2017.
CCG - Clinical Commissioning Group	Renal Medicine	B	13th July 2016	Unannounced visit to ward 303. Overall the verbal feedback was very positive.	TBC	Awaiting report – TBC in Q1 2017/18 report.
CCG - Clinical Commissioning Group	Liver, Upper GI and Colorectal	B	21st July 2016	Unannounced visit to wards 727 & 728.	TBC	Awaiting report – TBC in Q1 2017/18 report.
B.S.I. - British Standards Institution	Oncology	D	14th – 15th March 2017	Awaiting report – TBC in Q1 2017/18 report.	TBC	Awaiting report – TBC in Q1 2017/18 report.

2.5 Quality Surveillance Programme

2.5.1 The National Quality Surveillance Programme (formerly National Peer Review Programme) lead an Integrated Quality Assurance Programme for NHS England. This programme requires specialised services and all of cancer services to complete a self-declaration on their Quality Surveillance Information System (QSIS). This year it is required to be submitted from 1st April 2017 - 1st June 2017.

2.5.2 The Quality Surveillance Team (QST) will also complete comprehensive peer review visits to select services each year - we have been informed that the following services will be reviewed within the next 18 months:

a) Pulmonary Hypertension
b) Renal Dialysis
c) Hepatitis C
d) Congenital Heart Disease

2.5.3 Services are required to upload evidence to the QSIS to demonstrate compliance with quality clinical indicators in the form of three documents:

a) Operational Policy
b) Annual Report

c) Work Programme

2.5.4. The Clinical Compliance Team will be liaising with the relevant leads of all specialised services to guide them through the annual self-declaration process as well as supporting the services listed in 2.5.2. with their peer review documentation. Outcomes of the self-declarations will be reported in Q1 2017/18.

3. Outcome of Audits

3.1. National Audits:

3.1.1. The Trust is currently either participating in, or scheduled to participate in, 32/34 National Audits listed on the HQIP Quality Accounts. There are two audits currently not participated in by the Trust:

a) The National Cardiac Arrest Audit – long standing agreement to not participate from Medical Director due to concerns over the methodology of the audit.

b) National Diabetes Audit – Currently not possible to fully participate due to extensive resource requirement to do so. This is under review as part of ongoing work on national audit.

3.2. Local Audits:

3.2.1. Figure 1 below provides an overview of the number of local audits registered on the Trust's Clinical Audit Registration & Management System (CARMS) within Q4. Figure 2 shows these figures compared to the previous quarters.

Figure 1: Q4 16/17 Audit Activity

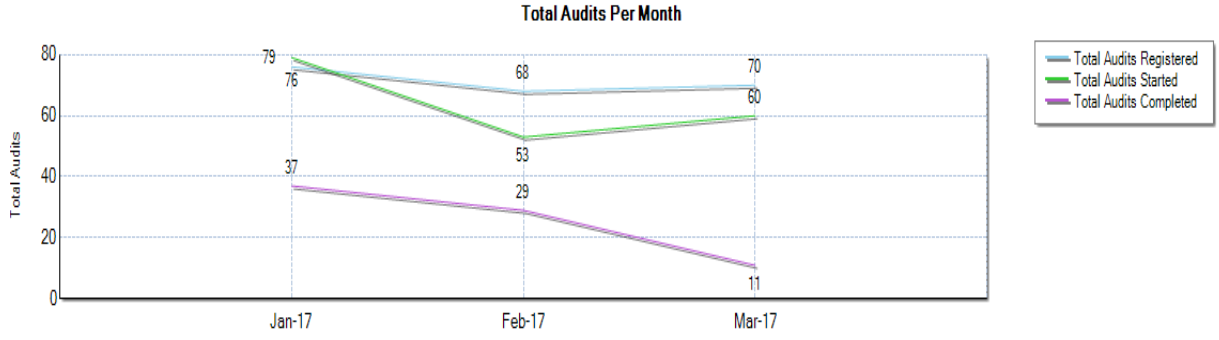

Figure 2: Comparison of audit activity with previous quarters

Quarter	Month	Total Audits Registered		Total Audits Started		Total Audits Completed	
1	April	48	**180**	55	**166**	18	**60**
	May	61		46		22	
	June	71		65		20	
2	July	56	**191**	46	**163**	15	**56**
	August	54		45		26	
	September	81		72		15	
3	October	86	**224**	95	**213**	10	**62**
	November	83		73		28	
	December	55		45		24	
4	January	76	**214**	79	**192**	37	**77**
	February	68		53		29	
	March	70		60		11	

4. Risk Register Audit

4.1. Internal Audit carried out an audit on the Trusts Board Assurance Framework and Risk Management process and provided 'significant assurance with minor improvement opportunities'.

4.2. Compliance for quarterly review of risk registers is as follows:

Target	Q1	Q2	Q3	Q4
95%	95.6%	96.8%	100%	100%

4.3. Where there is no evidence that high and significant risks have been reviewed, the Risk and Compliance Unit will liaise with the relevant management teams to ensure a quarterly review.

4.4. The audit will be repeated for Quarter 1 2017/18 to ensure continued monitoring of compliance with the risk register process.

5. Recommendation

The Board of Directors is asked to accept this report.

David Burbridge **April 2017**
Director of Corporate Affairs