Report of the External Review of Children's Congenital Cardiac Surgery Service at Leeds Teaching Hospitals NHS Trust

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Dr Damian Riley
Medical Director, West Yorkshire, NHS England
on behalf of the Review Team

9 April 2013

Executive Summary

Background

On 28th March 2013 Leeds Teaching Hospitals NHS Trust (LTHT) Chair, Chief Executive and Interim Medical Director were presented with new mortality data from the Congenital Cardiac Audit Database (CCAD) by Sir Bruce Keogh (NHS England Medical Director). This data indicated that LTHT's Children's Cardiac Surgery Unit had higher mortality rates for 2010-11 and 2011-12 compared to other children's cardiac units in England. Those present at the meeting were also informed that two senior clinicians had independently raised concerns, one over medical staffing of the unit the other on the quality delivered within it. In addition, at the meeting, a representative of the Care Quality Commission (CQC) informed LTHT that the CQC had information from patient complaints, which raised the concern that patients were being refused timely referrals to other Units for either a second opinion or for further treatment such as transplant.

LTHT confirmed that one of its surgeons was presently not operating pending a separate internal investigation.

At the meeting, LTHT decided to pause children's cardiac surgery pending further investigation. This decision was supported by NHS England and the CQC.

Following an urgent Quality Surveillance Group (QSG) convened by NHS England on 2nd April 2013 and the subsequent Risk Summit held on 4th April 2013, it was agreed by NHS England, CQC, the NHS Trust Development Authority and LTHT that a review would be carried out.

This review would have distinct phases.

The first phase would be an urgent review of LTHT Children's Cardiac Unit to ascertain if there were significant and readily identifiable safety concerns. The review would focus on clinical governance processes, staffing capacity and capability, and the patient experience which included referral management and patient pathways in and out of the Unit. This review will report its findings and conclusion back to the Chair of The Risk Summit for sign-off.

Subsequent phases of the review work will involve:

- A case note review of the deaths that have occurred and the complaints brought by a third Party.
- Understanding data handling, the application of data relevant to Unit mortality and inter-Unit comparison at a national level

This report presents the finding of Phase One of the review process, and the findings and recommendations should be interpreted together with any other evidence which subsequently becomes available.

Methodology

A multidisciplinary Review Team was convened with expert medical and nursing advisers from outside LTHT joining NHS England Area Team Medical Director and the LTHT Deputy Medical Director (Quality). The Review Team undertook a document review, direct interviewing of relevant staff groups and individuals, and direct observation of the Children's Unit. The Review did not observe surgery or out-patient clinics being undertaken. Case records were selected for those cases where specific concerns were known to have been raised.

Summary of Findings:

Within the context and remit of this review no evidence was found of immediate significant safety concerns in terms of clinical governance, staffing or in the management of the patient pathway for surgical care in the Unit, or for referral to other Units in the examples of the specific case files examined.

A number of very positive aspects of practice are present in the service provided by this Unit. The teamwork is strong, inter-professional working appears effective, surgical staffing levels are comparable to other Units, clinical supervision is in place and internal monitoring of morbidity and mortality is functional internally through audit and regular feedback systems.

The nursing workforce presented themselves as a highly committed and professional team with a strong child and family focus. Whilst some recommendations are made to support continuous improvement, no serious concerns were evident during the review regarding the nursing workforce or standard of nursing care, though it must be acknowledged that assurance is limited by the process of the review.

The report makes recommendations in a number of areas, which in the body of the report are identified as high, medium or low priority. The identification of a recommendation as high, medium or low priority should be considered by LTHT. It is noted that a number refer to overall policy and process in the hospital, whilst other refer to changes that may be specific to the Unit.

Each recommendation has been assessed as to its impact upon the decision to restart surgery, indicating the immediate risk posed to the safe recommencement of surgery by the Unit if the *status quo* was maintained. The matrix in Table 1 below summarises the impact assessment of these.

Conclusion

Data Management internally in the Unit and by LTHT for internal audit, routine care, routine morbidity and mortality audit processes was found to be adequate, but there were lapses in data uploading and export to national reporting databases, in particular to CCAD. The team has identified this as an area for improvement, in addition to recommending improvements in complaint handling, the format of multidisciplinary case discussions and the information conveyed in some clinic letters to patients. Whilst the issues identified represented low risk to the safe recommencement of surgery, members of the review team suggest that the amendments to complaints handling, and other methods of assessing patient feedback, should be attended to with some priority in order that the Unit may assure itself of delivering a good patient experience.

However the Review found no evidence that the Unit should not commence surgery again, and therefore recommends to the Risk Summit that this should be considered in a safe and structured way.

Dr Damian Riley
Medical Director, West Yorkshire, NHS England
on behalf of the Review Team

9 April 2013

Table 1: Impact Assessment of Recommendations

	High Impact/Risk	Medium Impact/Risk	Low Impact /Risk
Governance	No issues	No issues	• Pathologist attendance at MDT when relevant histology discussed is recommended • To modify gatekeeper role of Cardiologist in case selection and presentation to MDT • Complaint policy and response process to be modified. • Assessment of patient/family experience to be enhanced
Staffing	No issues	No issues	• External Mentor for more new consultant surgeons to be considered • Succession planning to be considered • Increasing PICU establishment to meet PICS standards
Patient Pathway and Referral Arrangements	No issues	No issues	• To introduce real-time monitoring and evaluation of referrals to other units for use as audit tool • Patient advice letter templates to be modified to reflect higher mortality of certain cardiac conditions
Data Management	No issues	No issues	• Coding accuracy and data management Resource to be clarified for data being assimilated for external validation and use in national programmes

Appendix 1.

Children's Heart Surgery Review (Phase One)

Terms of Reference

April 2013

This is a jointly agreed and commissioned review on behalf of NHS England and Leeds Teaching Hospitals NHS Trust which will report to the next NHS England Risk Summit on Sunday 7th April 2013.

Remit:

- With regard to the safety of surgery performed in Leeds on children up to and including 16 years of age for congenital cardiac conditions to review and advise upon
    - the clinical governance systems and processes in place to deliver safe and effective care
    - the ability of the Unit to undertake proposed surgical procedures
    - the existing service and comment on overall safety, with reference to current best practice

Review team

- **Professor John Wallwork:** Former Cardiothoracic Surgeon, Papworth Hospital
- **Professor David Anderson:** Consultant paediatric cardiac surgeon, Guys and St Thomas' NHS Foundation Trust
- **Dr Jo De-Giovanni:** Consultant Cardiologist, Birmingham Children's Hospital
- **Sue Ward** Director of Nursing (Children) Central Manchester Foundation Trust
- **Dr Damian Riley:** Medical Director, West Yorkshire Area Team, NHS England
- **Dr A Bryan Gill:** Deputy Medical Director (Quality and Governance), Leeds Teaching Hospitals NHS Trust

Objectives:

With regard to Governance Process

- To investigate the management arrangements for the Unit to ensure they are robust and fit for purpose
- To investigate incident levels and reporting, and complaint handling
- To determine data handling record keeping and clinical audit process
- To determine effectiveness of policies for devices and therapies
- To determine the Clinical prioritisation processes
- To determine the MDT approach used in patient management and reviews
- To determine the risk management process including maintenance of the risk register
- To understand safeguarding arrangements
- To determine infection control governance arrangements

With regard to Staffing and Unit Capability

- To explore recruitment, professional development, and appraisal/revalidation systems
- To determine the staffing levels, both quantitatively and qualitatively, for all relevant disciplines of staff (surgical, nursing, anaesthetic and Intensivist and ancillary) for the service being provided

- To determine the range of surgical procedures undertaken including analysis of individual consultant contribution and comment on the appropriateness of such for the Unit relative to the population served and patient demand

With regard to patient management and patient experience

- To ensure appropriate patient care pathways are operational
- To determine patient flows and patient management through the service including referral patterns to other Children's Congenital Cardiac Surgery Units

Principles:

- The review is jointly commissioned by NHS England and Leeds Teaching Hospitals NHS Trust
- Patient identifiable information shall not be released
- Serious concerns and risks to patient safety are to be notified without delay to the Medical Director of NHS England & Leeds Teaching Hospitals NHS Trust
- Media relations and communications with stakeholders is conducted through the commissioners of this review

Appendix 2

Review Methodology*:*

The Review took place on 5th, 6th and 7th April 2013.

The Review Methodology included:

Document Review:

Review of Trust Documents including Organisation Policies and Protocols
Review of specified Audit data and outcomes
Review of details from case records
Review of (redacted) complaint responses for last 2 years
Review of Incident data for last 2 years
Review of Terms of Reference of Clinical Governance Groups
Review of SOP for scheduling of operations
Review of Waiting List and activity data
Review of Workforce and staffing data

Structured interviews of all relevant staff groups including

Surgeons (3)
Consultant Cardiologists including Interventional Cardiologists (10)
Junior doctors (training grade cardiology staff) (2)
Anaesthetists (1),
Theatre staff (1),
Nursing staff (17),
Intensivists (2)
Liaison nurses (2),
Counsellor (1),
Psychologist (1),
Matron (1),

Direct inspection of

Ward 12
ICU environments
Trust HQ and Divisional HQ facilities

Staff were offered individual or group interview.
Surgeons were interviewed individually and as a group.
"Open interview slots" were allocated for any staff who wished to be seen individually.

Staff were asked if they considered any feature of the Unit to be unsafe, or if they knew of any reason why the Unit should not recommence surgery. Staff were asked all relevant questions pertaining to the Terms of Reference of the review (see above)

A total of 17 nursing staff were involved and interviewed

Direct observation of surgery or out-patient consultations was not part of this review.

Appendix 3

Grading of Evidence:

Evidence was interpreted with the following weighting:

Grade A evidence

Evidence of Implementation of Organisational Policies and Protocols
Patient Records
4D / Oscar database and PAS system
Professional assertions and Statements and corroborated answers
Minutes of Meetings
Facilities and Operation of Unit: Inspection by Review Team
Non-redacted complaint responses
Externally validated Audit data
Internal audit data from wards and dashboard.

Grade B evidence

Existence of Organisational Policies and Protocols
Opinions of staff groups without any other corroboration
Redacted complaints responses

Grade C evidence

Anecdote

Appendix 4

Review of Children's Congenital Cardiac Surgery Service at Leeds Teaching Hospital Trust.

Outline of Review programme for the 5th, 6th and 7th April 2013.

Friday 5th April 2013

Activity	Time	Staff Group/Individuals	Location	Comments
Review Team Assemble	09:00 - 10:30	N/A	LTHT Trust HQ	
Draft terms of reference	10:30- 12:00	Team (DR, BG, JW)	LTHT Trust HQ	
Meet Surgical Team	15:00	Team (DR, BG, JW) plus LTHT children's cardiac surgeons	Divisional HQ, LGI	
Meet Unit staff	16:00	Unit staff	Aire FM room, LTHT	
Inspection of Unit	17:00 …..		Unit	

Saturday 6th April 2013:

Operation Room – Radio Aire Seminar Room, E floor, Jubilee Wing, Leeds General Infirmary.

Activity	Time	Staff Group/Individuals	Location	Comments
Review Team Brief	10:00 - 10:30	N/A	Ops Room	
Staff Interviews	10:30- 12:00	Congenital Cardiologists	Ops Room	
Staff Interviews	12:00- 13:00	Theatre Team	Ops Room	
LUNCH	13:00 – 13:30			
Staff Interviews	13:30- 14:30	PICU Consultants	Ops Room	
Staff Interviews	14:30 – 15:30	Liaison Nurses	Ops Room	
Staff Interviews	15:30 – 16:30	Open Slot *	Ops Room	
Visit to Ward 12	16:30 – 17:30	Matron [redacted] [redacted] to support	Ward 12	
Visit to PICU	17:30 – 18:00	[redacted] to support	PICU	
Review Team	18:00 …..		Ops Room	

Sunday 7th April 2013:

Operation Room – Radio Aire Seminar Room, E floor, Jubilee Wing, Leeds General Infirmary.

Activity	Time	Staff Group/Individuals	Location	Comments
Review Team Brief	09:00 – 09:30	Team Update (Mike Bewick)	Ops Room	
Report	10:00 – 12:30	Team	Ops Room	
Staff Interviews	12:30 – 13:00	Interventional Cardiologist	Ops Room	
LUNCH	13:00 – 13:30	Lunch		
Review Team	13:30 - 17:00	Surgeon Interview / Team discussion regarding scheduling in future Consolidation /Evaluation	Ops Room	

***Any member of staff who wishes to see the review team please feel free.**

Appendix 5

Review Findings:

Section 1: With regard to Governance Process

- To investigate the management arrangements for the Unit to ensure they are robust and fit for purpose
- To investigate incident levels and reporting, and complaint handling
- To determine data handling record keeping and clinical audit process
- To determine effectiveness of policies for devices and therapies
- To determine the Clinical prioritisation processes
- To determine the MDT approach used in patient management and reviews
- To determine the risk management process including maintenance of the risk register
- To understand safeguarding arrangements
- To determine infection control governance arrangements

General Management Arrangements

Issue	Evidence Seen / Reference Documents	grade	Findings / Opinion	Recommendations	priority	impact
capacity	LTHT Divisional organisation structure provided Staffing chart and clinically led reporting lines of management for new service design (April 2013) provided List of Consultant staff in all relevant disciplines provided	A	Board / Divisional / Service management arrangements demonstrated, with clinical leads and management reporting lines noted. This was in process of change to newer clinically led teams, from 1/4/13	LTHT to continue with planned changes	H	L
Systems	Electronic Clinical	A	Standardised clinical guidelines are in place.	No change recommended		

including Clinical Guidelines being followed	Guideline documents seen		Some minor differences in practice between consultants were noted by the nursing staff but practice was generally considered to be consistent across the clinicians.			

Incident management

Issue	**Evidence Seen / Reference Documents**	**grade**	**Findings / Opinion**	**Recommendations**	priority	impact
SI	SI policy seen	A	No SI in Unit in 2 years	No change recommended		
Incidents Process	Policy Multiple staff groups interviewed and congruous with their response about process,	A	(see also risk section) IR1 forms completed regularly by staff on Unit IR1s completed by ward staff → screened by Matron →Clinical Leads then score the risk using 5x5 matrix → Higher risk incidents reported to Trust Quality group Matron covers Ward 12 and Paediatric Critical care (Cardiac PICU and General PICU) Matrons reviews and logs on DATIX Monthly report to Ward Dashboard and report reviewed at Monthly Performance Review meeting which is attended by DGM, Divisional Nurse, and Divisional Medical Manager.	No change recommended		
Incident reporting	Paediatric cardiac services incidents and	A	94 incidents were reported during a 12 month period. None were serious untoward incidents, 1	No change recommended in reporting culture		

	complaints 2011-2013 Level 2 investigation report 174405 Discussion with staff. Syringe pump errors improvement work display.		required a “level 2” investigation (risk score 9). 41% were recorded as medication errors. All staff described that errors primarily fell into two themes – discrepancies in the documented amount of oramorph syrup and syringe pump errors. Action was underway to address both issues. Oramorph discrepancies had been identified as being due to displacement. The use of red aprons is being introduced to identify staff undertaking medication administration to reduce interruption. Staff who make drug errors were reported to receive a package of support but are not automatically removed from medication practice or re-trained. Staff reported a proactive, fair blame risk reporting culture. LTHT medicines management team was aware and had investigated	Nursing teams are introducing “do not disturb” process to medication rounding – to implement	H	L
Incident Review	Staff reported getting feedback via Specialty Governance group. Minutes of monthly governance meetings	A	Incidents are reviewed at monthly governance meetings and action plans are developed. Consultants, the Matron and band 7 staff are core members of this group, in addition the Matron advised that any staff member can attend. Staff reported receiving personal feedback from their line manager if they submitted an incident report and that learning is communicated via	No change recommended		

			communication boards, books and staff meetings. At a Trust level an e-Bulletin is used to share learning. The Matron reported that she undertakes spot checks to ascertain whether information has reached front line staff.			

Risk Management

Issue	Evidence Seen / Reference Documents		Findings / Opinion	Recommendations	P	I
Risk assessment	Interview with Staff Risk management documentation.	B	(see also above) Following IR1 completion, Matron and lead cardiologist decide risk score, classifying these as green amber or red Red if >15 Reported incidents reviewed at Monthly Performance Meeting. Red are escalated Reviewed at Divisional Clinical Governance Meeting (attendance as for performance meeting but also includes clinical directors) Through the Division, all RED risks are reported to Board. Board secretary seeks clarification as needed from DGM Specialty Governance Meetings held monthly and driven by clinicians. Process updated monthly.	No change recommended		

			Since January 2013 Trust reviewing Risk register process			
Proactive risk assessment	The Medical Director reported that a Trust review of risk management is underway.	B	No evidence was presented to demonstrate that individual wards undertake active risk assessments and maintain local risk registers. Staff reported attending an annual risk study day.	Establish local risk assessment processes at ward level	M	L

Complaints management

Issue	**Evidence Seen / Reference Documents**		**Findings / Opinion**	**Recommendations**	P	I
No of Complaints	10 complaints presented to Team for 2 years period Redacted email trail between Service and Corporate team reviewed	B	No complaints gone to PHSO One complaints relating to care given to child in 2005 not formally responded to, complainant informed it was out of time. In light of likely extensive grief and lasting effect on family, it would seem more appropriate for a meeting to be offered an some form of explanation and response to be offered	A flexible approach to time-limit for complaining to be adopted	H	L
Complaints Policy	Complaints Policy Being Open Policy	A	Guidance issued to staff at the Trust by the complaints team in the Policy document, including 'Tips and Sound bites', 'Checking and reviewing responses to complaints' and			

	Electronic governance system.		'Guide to letter writing'; all recommend the use of accessible language appropriate to the complainant. Several of the examples viewed appeared not to comply with this, nor the wider advice within the guidance to staff, for example, the low level of empathy shown or an acknowledgement that the events surrounding the complaint have been stressful and traumatic for the complainant and family members. The policy document is lengthy and does not refer to the potential value of using complaints and concerns as valuable sources of organisational learning and patient care until page 8. The supplementary information on complaints management would appear to be one approach to improve this position; however, its lack of inclusion within the policy and framing the importance of using feedback to improve patient care challenges the strength of the overall organisational governance concerning complaints management.	Policy Review advised	H	L
Complaints handling: process	Interviews with DGM, Service manager and Clinicians interviews Complaint response-time internal audit	A	All logged onto Datix-Web Complaints received by Corporate HQ team Sent to Divisional Manager. Divisional manager decides who to send complaint to For clinical complaints, they are sent to Children's Service Manager who liaises with the relevant clinician who supplies factual response. This is formatted into a letter and sent for	To review process: recommend Board level designated accountable officer for complaints (Chief Nurse or Medical Director) sign off Continue to log using Datix-web Advise continue to improve response times	H	L

			checking to Divisional Manager, then to Divisional General Manager for sign-off. Then it is sent to Complainant, with copy to clinician and to DGM and to Corporate team Service manager said they "*match the clinical or technical complexity of the response to that used in the complainant's letter*." Subsequent Specialty Clinical Governance and Divisional Meeting discuss overall themes and essence of complaint. No clear examples could be given as to learning or changes as a result of any complaint. Trust wide review of complaint handling is already underway, prompted by recent Trust patient survey	More understandable style to be considered More emphasis needed on learning from complaints,	M H	L L
Style of Response	All Redacted complaint responses	B	The responses list events and actions without any real explanation of why they did or did not take place at certain stages. Not all concerns raised were acknowledged or responded to within the correspondence seen. Overall, the tone of the correspondence could be interpreted as patronising and defensive. The correspondence contained limited or no acknowledgement of any organisational learning or acceptance of unintended distress or anxiety for the complainants or the patients.	As above	M	L

Timing of responses	Trust data for monitoring of complaint response times	A	Showing steady improvement	To continue improving	M	L
Specific Complaints refuted by Unit	Partially redacted complaint responses to 2 patients who had been transferred to [redacted] 4D database entries on case	A	Not able to substantiate allegation [redacted] Style of responses: Very factual. Significant use of technical language Limited evidence of empathy In these two cases, little evidence of description of “why” things were done, only ”what” things were done. No evidence of reflection by the Unit / management or any acceptance that any learning could be derived. No evidence in the complaint response that meeting with complainants offered	No immediate action by Trust in relation to response formally indicated, but Trust to be prepared to offer opportunity to meet families Future Responses to complaints to indicate empathy and all possible learning	M H	L L
Allegation raised at Risk Summit that a patient was advised to self-fund for treatment outside England	4D database entries on case	B	Not able to substantiate allegation [redacted]	No further action needed		

						
Patterns of Patient management and referral that were causing concern	Interviews with Liaison Nurses, with ward and ICU nursing staff and cardiologist	A	Not able to substantiate concerns Staff specifically asked, and without exception they informed review team that there had not been a large number of complaints, no increase seen in recent weeks, that they had never witnessed any hesitation to refer to any particular Unit at any time if requested to do so for a second opinion. Example quoted of 27 referred cases which were operated on at Evelina Unit in past 3 years	Implement real-time patient/family feedback	M	L
Complaints prevention	Discussion with Matron	B	The Matron described a daily walk-round to speak to families with a view to addressing any concerns.	To Consider intentional rounding	L	L

Data Management

Issue	Evidence Seen / Reference Documents	Gr	Findings / Opinion	Recommendations	Pr	Imp
"missing data"	Statements from cardiologists and intensivists and surgeons CCAD February 2013 draft Data Quality Audit report Fosters Alerts reviewed monthly PICANET data	A A	CAD draft report identified Overall DQI for the Unit (surgery and catheter) was 93.5% compared to 95% for previous year. Draft Report concludes "*On the whole, the NICOR/CCAD data where submitted were accurate, well documented, good quality and were appropriately recorded in Theatre and Congenital Cath lab books that were seen*. " Comments made in report referring to database manager not ensuring records are available for visit. Draft Report states "*a less than adequate database management support has been available to the clinicians since the last validation visit"* Since then, LTHT and Unit have taken action and changed personnel, increasing the resource and staffing for uploading data to database. Surgeons state they personally enter an operation code. It is not clear to review if data completion or coding for some operations truly reflects the entire complexity of the operation particularly if the data manager did not	To continue implemented changes to data management and to address recommendations in the CCAD draft report.	H	L

			understand significance and some data fields not complete CCAD draft Report notes feedback monthly to clinicians of data and states *"Clinical Staff are therefore involved in the validation of diagnostic and procedure codes on a routine basis but the timeliness of this may have lapsed*" Review team considered Unit collected data adequately for day to day running, and for morbidity and mortality meetings. (see also Audit). Mortality data kept. PICANET (PICU) data reportedly more accurate. Dedicated data entry resource was adequate for this.			

Audit

Issue	**Evidence Seen / Reference Documents**		**Findings / Opinion**	**Recommendations**		
Unit clinical audit activities	MSSA audit presentation seen Feb 2012 Chylothorax audit presentation PAWS audit presentation Routine pre-op urinalysis	A	An audit programme is in place	No change recommended Audit programme to continue		

	audit Surgery to ICU Handover audit presentation Coronary anatomy in TOF / echo accuracy audit Surgical site infection surveillance programme					
Other	Hand hygiene audit	A	See infection control			
Mortality and morbidity	(see documents log in appendix) M+M meetings discuss relevant cases Dr Foster Alert Print Outs issued to Specialty Governance group	A	Trust uses Dr Foster alerts reactively All relevant staff groups attend M+M meetings with exception of pathologist	Consideration to be given to pathologist attending M+M meeting when relevant histology is discussed	M	L
ICU audit	PICANET data	A	PICANET shows Length of Stay in ICU in line with expected with other Units (this can be seen as one proxy measure for morbidity)	No Action		

Introduction of Device and therapies

Issue	**Evidence Seen / Reference Documents**	**Gr**	**Findings / Opinion**	**Recommendations**	P	I
Allegation that Staff may not follow	Policy seen Interviews with cardiology staff	A	No significant concern identified Relevant staff aware Policy present	Continue to follow existing processes		

protocol			Ethical approvals process for clinical and research			

Real-time monitoring of standards and clinical governance

Issue	Evidence	Gr	Findings	Recommendations	P	I
Safety Thermometer	Electronic ward dashboards	A	VTE, pressure ulcers and falls are reported on the monthly dashboard. No concerns were evident relating to these aspects of practice.	No change recommended		
Quality Assurance	Electronic ward dashboards	A	Ward Managers undertake a weekly quality assurance round, which includes review of hand hygiene, nutrition, documentation and cleanliness. Matrons undertake the same review on a monthly basis. Findings are fed-back to staff and displayed on communication boards. Staff reported that action plans were developed to address deficits. A range of improvement tools were being utilised to facilitate improvements.	Consider on-going refinement of systematic approach to quality improvement.	M	L
Infection prevention and control	MSSA audit Interview with Intensivists and Nursing staff on ward Hand hygiene audit results Electronic ward dashboards	A	No significant concern identified Relevant staff aware Policy present Except for January 2013, hand hygiene results satisfactory HCAIs are reported on the ward dashboard. There have been no MRSA bacteraemias in the past 12 months in the cardiology services.	No change recommended		

			Hand hygiene audits showed 100% compliance for ward L12. PICU had risen from 42% compliance to 90% in the past 3 months			
Ward rounds	Staff discussion	A	Nurses and consultants reported that the co-ordinating nurse always attends ward rounds. Releasing time to care work is being undertaken to improve ward round efficiency.	No change recommended		
Nursing handover	Staff discussion	A	Nursing hand over had been reviewed as part of the Releasing time to care programme. Staff reported a 15 minute reduction in handover time. SBAR has been introduced to improve communication. Board rounds are held twice daily to update staff on each patient's status.	No change recommended		
Documentation	Documentation review. Electronic ward dashboard	A	A risk-based nursing assessment is in place. Care plans were found to reflect the needs of the child and family. Documentation standards are audited by the Matron and Ward Managers. A patient held record has been introduced to support continuity.	No change recommended		
Access to medical/ surgical support	Discussion with staff	A	Staff reported improvements associated with implementation of a "Cardiologist of the week". All nursing staff reported feeling confident to escalate concerns about a patient to the relevant consultant. Nurses felt well supported by medical and	No change recommended		

			surgical staff 24/7.			
Team culture	Discussion with staff	A	Nursing and medical staff reported an excellent team culture in which professionals work effectively together. Communication and relationships between professionals were considered by all staff groups to be strong and effective. All staff cited a strong believe in the quality of the service. Nursing leadership is currently being reviewed. The substantive Ward Manager is currently acting up into the Matron role following retirement of the post holder. A band 6 sister is acting up into the Ward Manager role. Both staff appeared confident in their acting roles and staff from all professional groups describes strong and clear leadership.	No change recommended		
Patient feedback	Electronic ward dashboard Inpatient ward survey	A	Limited patient feedback is captured in a routine manner. Staff were aware of the Friends and Family Test but this did not appear to have been implemented. A standard Trust survey is given to 10 families per month but returns were reported to be poor and staff didn't appear to receive regular feedback on the findings. The Liaison Nurses reported that families are currently expressing support for the service with a small number requesting transfer to another service.	Consider reviewing the process to obtain family feedback. Develop a system to enable regular feedback that is reported to staff and acted upon. Consider developing a specific children's survey. Consider use of electronic patient feedback systems.	H	L

Section 2:
With regard to Staffing and Unit Capability

- To explore recruitment, professional development, and appraisal/revalidation systems
- To determine the staffing levels, both quantitatively and qualitatively, for all relevant disciplines of staff (surgical, nursing, anaesthetic and Intensivist and ancillary) for the service being provided
- To determine the range of surgical procedures undertaken including analysis of individual consultant contribution and comment on the appropriateness of such for the Unit relative to the population served and patient demand

Staffing

Issue	Evidence Seen / Reference Documents	Gr	Findings / Opinion	Recommendations	P	I
Surgical capacity and locum usage	Appointments process discussed w Trust and with locum consultant surgeons Discussion with Theatre,. Anaesthetist, cardiology and Surgical Team Staffing sheet from Trust	A	Locum consultants have considerable experience. Have trained initially in Europe. Have worked for many years in Leeds Unit in non-consultant Grade Appointed to Locum Consultant posts in 2012. External (College) representative on panel for locum consultant appointment – full AAC process followed Mentored and work allocated by senior surgeon. Close team-working arrangements described by surgeons and confirmed by theatre staff and anaesthetists. Anaesthetists were highly complementary about surgical competence of all surgeons. 3 WTE surgeons a present, 4th temporarily not operating	Staffing levels to continue		

			Surgical team augmented by 5th surgeon who comes once/month for 2 or 3 days operating This compares favourably to many other Units in England One has general Surgery CCT but does not have Cardiac specialty CCT, All surgeons when interviewed demonstrated insight into case complexity and the need to work within limits of competence. All gave evidence of referring to other colleagues or Units if they felt it was required. One surgeon, formerly a Consultant in England, comes once / month to do operations. Those cases are selected in advance by senior surgeon through scheduling meeting. All imaging and records are sent in advance to the surgeon for inspection. All surgeons (including the visiting surgeon) see the patient prior to operation – usually the day before. All surgeons personally take the consent from the family.	One surgeon is advised for future post applications to consider certification as cardiac surgeon CCT	L	L
Surgeon competence	Appoints process (RCS oversight-check) Discussion with surgeons about case allocation and log books	A B	External Surgeon (College) representative on panel No concerns found re surgical competence. All surgeons quoted significant numbers of relevant operations undertaken, maintained log books and had experience of complex cases.			

	Comments from other staff including nurses, anaesthetists	B	Surgeons will now be under scrutiny since this issue arose in March 2013. It may cause some level of stress.	External Mentor for surgeons to be considered	L	L
Induction of new nursing staff and skills development	Ward 12 orientation pack Interviews with staff	A	New staff are allocated to a preceptor and undergo an internal education programme supported by the Clinical Educators. Competency is assessed by the preceptor. Staff reported having good access to continuing education and those interviewed were able to offer examples of education programmes that they had undertaken. These included clinical training as well as leadership and management. A programme of rotation between the ward and PICU is in place. Staff described that this was a positive experience, which developed skills and provided insight into the patient journey.	Consider placing all new starters on an accredited critical care programme.	M	L
Junior doctors and training grades	Interview	B	Consultant cardiologist and surgeon access 24/7 Well supported Good training opportunities Very positive culture evident Positive comments from many staff regarding Teamwork which appears highly valued	No change recommended		
Establishments	Papers prepared by Divisional Nurse Manager: LTHT Paediatric Cardiology Ward L12- Nurse Staffing (April 2013) and LTHT	A	The current PICU establishment provides 5.6wte/bed compared to the Paediatric Intensive Care Society (PICS) Standard (2010) of 7.01wte/bed. A business case is reported to have been approved to increase the PICU establishment by19.8wte band 5 nurses to enable compliance	Recruitment to additional posts New Unit opening in April 2013 Consider a review of	M L	L L

	Intensive Care (PIC) Staffing Benchmarked against PIC Standards November 2010 – update December 2012 Discussion with Matron and Ward Staff		with current standards. Ward staffing is stated to be based on Defining Staffing Levels for Children and Young People's Services, RCN (2003) rather than the updated guidance published in April 2011. Ward managers were reported to be 40% supervisory and 60% clinical. Establishments contain a 20% uplift to cover annual leave, sickness and education and training. This is below that recommended by the RCN but compares fairly with other paediatric services in the North of England. Skill mix within Ward L12 is appropriate, with a high proportion of experienced band 5 staff nurses. 6 Cardiology Specialist (Liaison) Nurses are in post, which is slightly below the Safe & Sustainable recommended level of 7. One specialist nurse is designated as the Transition Nurse, which accords with Safe & Sustainable standards. 3 Clinical Educators support training and education across PICU and Ward L12. This complies with PICS standards.	establishments against the standards set out in Health care service standards in caring for neonates, children and young people. RCN (2011). Consider making Ward Managers 100% supervisory		
H.R Datasets	Divisional Performance Review Report January 2013	A	Turnover of nursing staff was reported to be low though no data was reviewed. However all staff involved in the discussions had been in post over 5 years and a summary of staff experience provided by the Divisional Nurse Manager demonstrated that the majority of cardiology ward nursing staff	No change recommended		

			had over 5 years' experience in cardiology nursing with 10 staff had over 10 years' experience. The PICU was considered to have a higher number of less experienced nurses. Sickness absence was reported as 4.41%, which compares with national averages. Sickness action plans are monitored via the divisional performance review. An electronic system is used to monitor sickness and highlight trigger points. The Matron and Ward Managers described a culture of proactive sickness management. Staff reported having an appraisal in the last 12 months and having PDPs in place. Compliance with mandatory training is monitored via Divisional performance reviews.			
Shift system	Discussion with nursing staff	A	An 11.5 hour shift system is worked by all staff.	Consider reviewing the impact of long shifts on incidents and sickness absence rates.	L	L

Professional Development

Issue	Evidence Seen / Reference Documents	gr	Findings / Opinion	Recommendations	p	I
Appraisal and revalidation systems and implementation	ORSA submission Consultant appraisal	A B	No concerns All Consultants and locum consultants have had			

			annual appraisals by a different consultant outside Unit Surgeon 1: march 2012: date confirmed for 2013 Surgeon 2: Date confirmed for 2013 Surgeon 3: Date TBC Surgeon 4: Date TBC	Expedite Appraisals for 2013	M	L
Nursing Induction and Supervision	Ward 12 orientation pack	A	New staff are allocated to a preceptor and undergo an internal education programme supported by the Clinical Educators. Competency is assessed by the preceptor. Staff reported having good access to continuing education and those interviewed were able to offer examples of education programmes that they had undertaken. These included clinical training as well as leadership and management. A programme of rotation between the ward and PICU is in place. Staff described that this was a positive experience, which developed skills and provided insight into the patient journey.	Consider placing all new starters on an accredited critical care programme.		

Section 3:
With regard to patient management and patient experience

- To ensure appropriate patient care pathways are operational
- To determine patient flows and patient management through the service including referral patterns to other Children's Congenital Cardiac Surgery Units

Procedures undertaken and Patient Pathways

Issue	Evidence Seen / Reference Documents		Findings / Opinion	Recommendations	P	I
Referrals in to Unit	Description of process from Cardiologists, Service manager, Theatre staff and anaesthetists	A	Satisfactory Process in MDT meetings Network consists of LTHT based paediatric cardiologists who visit DGH's in Region. They support local Paediatricians with specialist interest Referrals come via DGH paediatricians, to LTHT cardiologists. LTHT cardiologists manage patients in out-patient clinic, and as required at their judgement bring case for discussion (by alerting the MDT coordinator) at the weekly surgical case conference meeting. Output of this goes to weekly surgical scheduling meeting Planning meeting weekly, Appropriate attendance including theatre lead nurse.	Consider joint medical/surgical review of all cases This will avoid situation of cardiologist becoming "gatekeeper" to surgery.	M	L

			Plans 3 weeks ahead. Space for emergencies left on schedule			
Referrals from Cardiologists or surgeons to other Units	Description from lead cardiologist Evidence of a patient record from case conference stating "if patient requests 2nd opinion we will support this" Evidence from patient complaint responses describing how at clinic appointments patients were offered referral to other Units for 2nd opinion. Liaison nurses interview	A	No concern identified about seeking second opinion from, or referral to, any other unit. Liaison nurses interview comment that no reticence to refer has ever been witnessed	Real-time recording of referrals made to other units, and why, useful for learning and governance	L	L
How patients / parents are guided to informed consent	Example templates for out-patient letters seen eg for LV hypoplastic Left heart.		Unit letter template quotes "up to 50% mortality" for complex high risk HLH [redacted] The mortality Is up to 70% in the opinion of the review team, in the subgroup with small/restrictive atrial septal defect	Revise family information sheets to reflect current national/centre results	M	L
Waiting List Delay in appointments and access to surgery	Waiting List data for interventional cardiology and cardiac Surgery		Activity increase in 2012 compared to 2011. Numbers on in-patient waiting list remaining stable.	No change recommended		

Procedures	Description from Lead cardiologist and liaison nurse and surgeons 2 patients 4D records	B A	Highly specialised work eg transplant and hypoplast surgery are transferred to other units, Effective and timely referral appears to be undertaken In-line with accepted practice In cases of Hypoplastic LV parents generally recommended to consider Evelina or Birmingham Unit since the Dr Foster Database shows these Units undertake the most. Transplant – preference unit is Newcastle unless family request for GOSH	No change recommended		
Transfer of Patients	Transfer of patients policy Staff discussion		Paediatric intensive care unit retrieval is included in the Trust-wide transfer policy. This policy doesn't appear to include other paediatric transfer scenarios. PICU staff described use of a specific safe transfer tool but this does not appear to be included in the transfer policy.	Consider developing a separate Paediatric Transfer Policy.		

MDT processes and activities

Issue	**Evidence Seen / Reference Documents**		**Findings / Opinion**	**Recommendations**	**p**	**l**
Liaison between cardiologists and	"4D" Oscar database system demonstrated.	A	Satisfactory process	Continue current practice See also comments above re all		

Surgeons Decision making process to list for surgery			Evidence seen of how it records out-patient attendances and DNA's, in-patient admissions, links to clinical record notes, and lists those clinicians present at case conference . Decision making process and discussions at Case Conference meetings recorded in these notes. Evidence seen of process for adding patients to Surgical List, and that the urgency or listing is decided at that point.	cases being presented See also comments regarding pathologist attendance		
Nursing input to MDT	Discussion with staff	A	Nursing and medical staff reported that a senior nurse from the cardiology ward and a Liaison Nurse always attend the weekly MDT meeting and actively participate in decision-making.	No change recommended		
Psychosocial meetings and input	Discussion with staff	A	The Liaison Nurses work closely with the psychologist, counsellors, play specialist, social worker and physiotherapist to address the holistic needs of the child and family. A weekly multi-professional meeting takes place to discuss cases, identify needs and plan support. Ward nurses attend this meeting if the patient being discussed is an inpatient. Consultants do not attend but are invited. Counsellor and/or psychologist generally present in Fetal diagnosis clinic and would be involved in counselling re termination and survival options.	No change recommended		

Unit Facilities and Capacity

Issue	Evidence Seen / Reference Documents	Gr	Findings / Opinion	Recommendations	P	I
Surgical scheduling and allocating waiting lists and priorities	Discussion w surgeons SOP	A	No concerns. Multidisciplinary input. SOP in place	No change recommended		
Clinical Environment (TBA- new PICU/ward and theatre)	Direct Inspection		"State of the art" purpose-built PICU due for occupation in 1 week	To undertake move without delay	H	L
Cleanliness	Electronic ward dashboards		The ward and PICU appeared clean. A new PICU has just been completed, which will amalgamate the existing PICU and PHDU. The service is expecting to move into the new facility in the next few weeks.	No change recommended other than To move as planned		
Child and family friendly	Observation		The clinical areas have family rooms, play facilities and appropriate family-friendly décor.	No change recommended		

Appendix 6

Evidence Log

Ref	Title	Summary of document content	Weighting
Miscellaneous – Independent review process			
M1.1	Terms of reference of review	Terms of reference for the review group	
M1.2	Information sharing agreement		
M1.3	Signature and disclosure of conflict of interest		
M1.4	Agenda		
M1.5	Notes of meeting 6.4.13		
M1.6	Notes of meeting 7.4.13		
XX	Data Report to risk summit 4.4.13 seen by Review Team		
Incidents & Complaints			
IC 1.1.1	Complaints	10 complaints from 2011 to date	
IC 1.1.2	Data demonstrating all fetal cases and outcome (Aug 2012 – April 2014	Outlines TOP; IUD; live birth outcomes	
IC 1.1.3	Example standard letter HLH restrictive Interarterial communication	Standard fetal counselling letter template	
IC 1.1.4	Selection of patient information leaflets	Also include support groups and unit information folder	
IC 1.1.5	Incidents and Complaints	Document showing volume and nature of complaints and incidents 2011 - 2013 (Including Level 2 Investigation Report 16.09.12)	
IC 1.2	Examples of Children's Directorate Performance Review	July 2012 - March 2013	
IC 1.2.1	July 2012	Children's performance Improvement plan – timeliness of IR1 inputting; Children's performance improvement plan – Admissions, discharges and transfers transacted on PAS within 30 minutes	

IC 1.2.2	August 2012	Patient safety report; patient experience; effectiveness of care; Productivity and efficiency; Information Governance; workforce; finance; Other directorate issues	
IC 1.2.3	November 2012	Patient Safety; Patient experience; Productivity and Efficiency; Finance; other directorate issue	
IC 1.2.4	December 2012	Patient safety; patient experience; productivity & efficiency; Finance; other directorate issues	
IC 1.2.5	January 2013	Patient safety; patient experience; effectiveness of care; information governance; productivity and efficiency; workforce; finance; other directorate issues	
IC 1.2.6	April 2013	Handover agenda; Bank, agency & overtime reductions; indicators dashboard	
IC 1.3	Examples of Divisional Clinical Governance Oct-12		
IC 1.3.1	Agenda		
IC 1.3.2	Minutes of meeting		
IC 1.3.3	Completion of mandatory audits table		
IC 1.3.4	Level 2 investigation report		
IC 1.3.5	Case 1 HC investigation		
IC 1.3.6	SI report 2012 /21438		
IC 1.3.7	NICE non-compliance statement		
IC 1.3.8	NICE guidance implementation plan		
IC 1.3.9	Divisional clinical governance arrangements		
IC 1.3.10	Oxford delivery plan – summary of residual risks and delivery plan		
IC 1.3.11	Risk profile		
IC 1.3.12	NHSLA maternity clinical risk management standards 2012 – 13. Sept 2012		
IC 1.3.13	CEMACH 2007 – 2009 – perinatal mortality review	Local plan December 2012	
IC 1.3.14	Failsafe task list for Antenatal & Newborn Screening Programmes		
IC 1.4	Examples of Divisional Clinical Governance Jan-13		

IC 1.4.1	Agenda		
IC 1.4.2	Minutes of meeting 15.10.12		
IC 1.4.3	Exceptional Agenda		
IC 1.4.4	Learning points to avoid harm from misplaced Nasogastric tube that are inserted for the purpose of feeding		
IC 1.4.5	Action plan Ward 36 – December 2012		
IC 1.4.6	Maternal Obesity action plan		
IC 1.4.7	Oxford Delivery plan – summary of residual risks and delivery plan (updated August 2012)		
IC 1.4.8	Women's directorate clinical governance report Q2	Report date Oct 2012. includes complaint response times; incidents themes; investigations; mandatory audits; NICE guidance implementation	
IC 1.4.9	Leeds children's Hospital clinical governance report Q2	Report date Oct 2012. includes complaint response times; incidents themes; investigations; mandatory audits; NICE guidance implementation	
IC 1.4.10	SI report 2012 / 9344		
IC 1.5	Quality assurance guidance - Current Version		
IC 2.1	E-Bulletin Apr-13	Demonstrating 1 process used for communicating results of incidents and sharing learning with staff	
IC.3.1	HCAI		
IC 3.1.1	WCHND HCAI Action Plan 2012 - 2013		
IC 3.1.2	Infection Prevention and Control Policy No. 14	Expiry date Oct 2013	
IC 3.1.3	Managing the Risks associated with infection Prevention and control policy	**was noted to be due review 3.9.12**	
IC 4.1	Safeguarding Children's Policy	Current Version. Review date June 2013	
IC 4.2	Policy for the implementation of new interventional procedures Apr-12		
IC 4.3	Policy for the reporting and management of Serious incidents Oct-12	Review date October 2015	
IC 4.4	Policy for the reporting and management of incidents Nov 2011	Review date November 2013	
IC 4.5	Complaints and concerns policy Oct-11	Review date October 2013	

IC 4.6	Risk Management Policy – Oct 2011	Review date October 2013	
IC 4.7	Risk management group papers		
IC 4.7.1	Risk Management - Terms of Reference - Current Version		
IC 4.7.2	Trust Board paper Feb 2013		
IC 4.7.3	Corporate risk register Feb 2013		
IC 4.8	Being open policy Oct 2011- Oct 2013	Review due Oct 2013	
IC 5.1	Audit presentations	Examples of audits undertaken	
IC 5.1.1	Safe Airway bundle audit presentation		
IC 5.1.2	Annual report of the Paediatric Intensive Care Audit Network (PICANET) Jan 2009 – Dec 2011		
IC 6.1	Specialty Clinical Governance Forum - Terms of Reference	Terms of Reference	
IC 7.1	Waiting Lists and Access	Inpatient waiting list and run rates for paediatric cardiac surgery and paediatric interventional cardiology	
organisational			
O 1.1	Operational structure LTHT	Organogram	
O1.2	Divisional operational structure	Organogram	
O 1.3	Children's Heart Surgery Designation30th August 2012	Risk profile for Children's Heart Surgery Designation	
O 2.1	Yorkshire Heart Centre Congenital & Structural Intervention process Jan 2013	Process draft author J Bentham & J Thompson	
O 2.2	Duct dependent Heart disease guidelines		
O 2.3.1	Pre-operative proforma		
O 2.3.2	Clinical psychology / Counselling referral form		
O 3.1	Workforce	Medical and nursing workforce data	
O 3.2	Workforce	MDT Co-ordinator job description for Congenital Cardiac Services	
mortality			

MO 1.1	Clinical Governance steering group paper 8.10.12	Paper on Dr Foster's relative risk mortality – speciality level reporting – Sept 2012	
MO 1.2	Performance summary Feb 12 – Jan 13	Demonstrates mortality, LOS, readmission rates, peer group comparison data.	
MO 1.3	LOS 2009 - 2011	Including readmission rates	
MO 2.1	Standards for completing the certificate of the cause of death. Dec 2009.		
MO 2.2	Process for the reporting and investigation of mortality outlier alerts. January 2012		
MO 2.3	Cause of death proforma & Mortality case review proforma		
MO 3.1	Examples of coding audits	Interventional radiotherapy coding audits sept 2012 Thoracic surgery clinical coding audit aug 2012	
MO 4.1	Article heart journal March 2013.	Real time monitoring of risk-adjusted paediatric cardiac surgery outcomes using variable life-adjusted display (VLAD)	
MO 5.1	PAWS scoring chart (Example)		
MO 6.1	CCAD - Data Quality Audit 28th February 2013	Full report from CCAD procedures for congenital heart disease	
professional			
P 1.1	ORSA revalidation questionnaire Sept 2012		
P 2.1	Leave procedure Sept 2009	**LTHT to consider if review due**	
P 3.1	Staffing FTE rates 2.4.13		
P 4.1	NHS (appointment of consultants) regulations. Good practice guide Jan 2005		
P 5.1	National & International meeting 2011 - 2013 local courses attended (incomplete)	Also includes papers published	