Supplementary information for Joint Health Overview and Scrutiny Committee (Yorkshire and the Humber) held on 10 April 2014

Pages 3-6: Agenda item 7 – NHS England response dated 3 April 2014 - Legal Advice

Pages 7-60: Agenda item 8 – Further correspondence / additional information from NHS England

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NHS England Response dated 3 April - Legal Advice

1. **Breadth of request**

As I understand it the "relevant function" from which the JHOSC request for information under Regulation 26(1) derived, was the review and scrutiny of the temporary closure of the Children's Congenital Cardiac Surgery Service at LTHT in March/April 2013, and specifically Sir Bruce Keogh's role in that closure. This should have been obvious to NHS England from the e-mail exchanges and from discussions at the JHOSC, that this was the subject matter.

2. **"Reasonably" required**

It appears NHS England have not raised any issue about whether, once the relevant function has been identified, it can also be said that the information is "reasonably" required. However, I think to be on the safe side, and given that NHS England's lawyers may take the point later on, this should still be covered at the JHOSC meeting. This can be done by Cllr Illingworth explaining briefly why having the full details of the key redactions is important to understanding the reasons for the closure, its timing etc. and Members of the JHOSC confirming that they require this information.

3. **Redactions**

In relation to NHS England redacting the information requested, I think their response misstates or misunderstands the legal position in a number of ways. To help guide Members I have set out my understanding of the position below.

3.1 There is indeed the exemption for "confidential information which relates to and identifies a living individual" in Regulation 26(3)(a), except where one of the conditions in (4) applies. However, in deciding whether this exemption applies, the key issue is whether the information is "confidential" in the first place, and as I've said before I think it must be the case that "confidential" in this context means that the legal test of confidentiality must be satisfied. The reference in Regulation 26(3)(a) simply to "confidential" information is perhaps less specific than the equivalent FOIA exemption which provides that the exemption applies where disclosure would constitute a "breach of confidence" which is "actionable". However, given that 26(3)(b) provides an exemption for information where disclosure is prohibited by statute, I think it must be the case that 26(3)(a) is intended to cover those other circumstances where disclosure can be prohibited by common law rules, in other words where a common law duty of confidentiality applies.

3.2 To satisfy the legal test, information must have the necessary quality of confidence, and must be given in circumstances imposing a duty of confidence. In this context, it is difficult to see how any of the requested information could be regarded as intrinsically confidential. For example, in what way could Sir Bruce Keogh's e-mail messages about these matters to other colleagues in NHS England (or its predecessors), be construed as

creating a duty of confidence either on the recipients of the messages or by extension, on the "responsible person"?

3.3 In any event though, I think the courts would take the view that the burden of proving that information was legally confidential must be on the "responsible person". So it would be up to NHS England to explain how and why they considered specific redactions to be confidential.

3.4 There's also a well-established principle that a duty of confidence which might arise, can also be overridden by a countervailing public interest. In this context, given the significance of the decision to close the Service, and the powers and duties to scrutinise health bodies conferred on local authorities under the Health and Social Care Act and the Regulations, there will plainly be a very strong public interest in disclosure.

3.5 As mentioned above, Regulation 26(3)(b) provides an exemption in relation to "any other information the disclosure of which is prohibited by or under any enactment", unless 26(5) applies. Although the response from NHS England says very little about this, they may take the point that this would exempt "personal data". However, I think it's clear that this exemption will only apply to the extent that the Data Protection Act itself would prohibit disclosure.

3.6 This in turn will require an examination of whether the information is "personal data" in whole or in part, and if so whether disclosure could be made without breaching the data protection principles, or in accordance with one or other of the exemptions from the "non-disclosure" rule in the DPA itself.

3.7 The first data protection principle provides that personal data shall be processed fairly and lawfully, and in particular shall not be processed unless at least one of the conditions in Schedule 2 is met. Condition 6(1) of Schedule 2 permits processing where this is "necessary for the purposes of legitimate interests pursued by the data controller or by the third party or parties to whom the data are disclosed, except where the processing is unwarranted in any particular case by reason of prejudice to the rights and freedoms or legitimate interests of the data subject". If processing would involve an interference with the data subject's right to respect for his private life, then the requirements of Article 8.2 of the ECHR must be fulfilled. The result achieved by the balancing exercise required by Condition 6(1), must be compliant with Article 8.2 – South Lanarkshire Council v The Scottish Information Commissioner. This balancing exercise is also required to assess the general fairness of processing.

3.8 Generally, "the guiding principle is the protection of fundamental rights and freedoms of persons, and in particular their right to privacy and respect to the processing of personal data" - Commons Services Agency v Scottish Information Commissioner. However, the position is different where public officials are concerned and where the purpose for which the data are processed arise through the performance of a public function. In Corporate

Office of the House of Commons v IC and Norman Baker MP, the Tribunal decided "….where data subjects carry out public functions, hold elective office or spend public funds they must have the expectation that their public actions will be subject to greater scrutiny than would be the case in respect of their private lives".

3.9 Again, I think the onus would be on the "responsible person" to show why this information was personal data, and why disclosure would be prohibited by the DPA. However, it's difficult to see how Sir Bruce Keogh's e-mails about the closure of the Service could be regarded by their nature as being personal or private, or that he could have any reasonable expectation that these e-mails were beyond public scrutiny in some way. In carrying out the balancing exercise referred to above, there would of course be the "rights and freedoms" of the JHOSC, and by extension the wider public to weigh against what (little) weight could reasonably be given to those individuals whose personal data was incorporated in the information requested. It would seem however, that the "legitimate interests" or "rights and freedoms" to be taken into account are if anything, more significant and weighty than would be the case if this information were requested under the FOIA. Under the FOIA, a requester might point to the general interest in the transparency and accountability of public authorities, but under Regulation 26 there is the additional public interest in the proper and effective working of the scrutiny function entrusted to local authorities by the 2012 Act and the Regulations. There is also the public interest in the proper planning, provision and operation of the health service which should in turn be enhanced by the proper exercise of the scrutiny function.

4. Next Steps

In view of the response from NHS England, it seems the next steps should be as follows. Firstly, confirm formally that the subject matter of the e-mails, correspondence, and associated letters and reports requested, was the temporary closure of the Service, and specifically Sir Bruce Keogh's role in that process. At the same time, I would suggest it is confirmed to NHS England that if they are proposing to make any redactions, our understanding is they need to explain how these redactions can be justified under Regulation 26(3)(a) or (b). Second, it might assist if we had a dialogue with NHS England's lawyers about these matters, in the hope that a common understanding could be reached on at least some of the points mentioned above. Third, if it appears no progress can be made with NHS England, then I would recommend that we get confirmatory advice from Counsel on the matters mentioned above. Again, this may help to achieve a common understanding both on this request, and on future requests under Regulation 26.

Mark Turnbull
Head of Property, Finance & Technology
Legal Services
Leeds City Council
9 April 2014

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Children's Cardiac Surgery in Leeds – timeline/ additional information

Date	Information	Notes	Pages
28 March 2013	Sir Bruce Keogh attends LTHT.	Graph produced from mortality data presented. Children's Heart Surgery subsequently suspended by the Trust.	
30 March 2013	Conference call notes: Key issues, decisions and actions	Call No. 1	3-4
1 April 2013	Conference call notes: Key issues, decisions and actions	Call No. 2	5-6
1 April 2013	Conference call notes: Key issues, decisions and actions	Call No. 3	7-8
1 April 2013	Letter to LTHT from Chief Operating Officer (Ian Dalton)	Letter to Chair and CEx of Trust	9-10
2 April 2013	Quality Surveillance Group (QSG)	No notes provided, but referred to in minutes of QSG held on 4 April 2013	
3 April 2013	Actions from 9:00 hrs conference call	Email, timed at 10:05 hrs	11
3 April 2013	Actions from 13:30 hrs conference call	Email, timed at 18:58 hrs	13
4 April 2013	Minutes from Quality Surveillance Group		15-20
4 April 2013	Minutes from Risk Summit		21-33
5 April 2013	Letter to LTHT from Chief Operating Officer (Ian Dalton)	Letter to Chair and CEx of Trust	35-37
5 April 2013	Key points from conference call held at 17:30 hrs		39-40
5 April 2013	Note of agreed review process	Email, timed at 17:53 hrs	41
6 April 2013	Key points from conference call held at 17:30 hrs		43-44
8 April 2013	Minutes from Risk Summit	Noted that a further QSG meeting to take place a month later and a further Risk Summit may also be confirmed.	45-49

Children's Cardiac Surgery in Leeds – timeline/ additional information

Date	Information	Notes	Pages
8 April 2013	Letter to LTHT from Chief Operating Officer (Ian Dalton)	Letter to Chair and CEx of Trust	51-52
	LTHT – principles for restarting Paediatric Cardiac Surgery/ Intervention	Not dated. Assumed this formed part of the Risk Summit on 8 April 2013.	53-54

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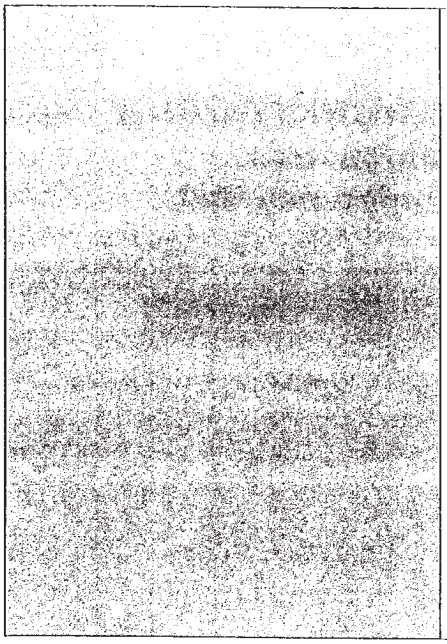
Key Issues, Decisions and Actions from NHS CB Leeds Heart Surgery - Conference Call.

Teleconference held: 30 March 2013

Attendees:		Call Number: 1
NHSCB Corporate		Lyn Simpson (Chair) Ann Sutton Steve Field Keith Willett Damian Riley Mike Bewick Andy Buck Colin Douglas Roger Davison Tom Easterling Stephen Groves Jonathan Sanderson
NHS TDA		Kathy McLean Yasmin Chaudhry Rob Checketts Ralph Coulbeck Greg Madden
		Andy Mitchell
CQC		Macolm Bower Brown

	Update
NHS CB	We were reassured that operational arrangements are in hand. Our local leads are Andy Buck and Damian Riley. Overview of the current position at Leeds provided by Andy with respect to current cohort of patients and pathway. Trust is producing a daily sit rep for CQC and are keen that multiple requests for submissions are kept to a minimum. Participants to consider what data is required above the CQC SitRep if any. A further telecon is scheduled for Monday morning – call details below.

	A meeting with the Trust is scheduled for Tuesday morning NHS CB, CQC and NTDA in attendance with Trust CEO and MD. Terms of reference for the Trust's review will be agreed with us, CQC and NTDA. A risk summit is scheduled for 16 April. It is anticipated that this may be a preliminary session, depending on progress of the trust's review. SofS was briefed yesterday and spoke to 3 local MPs.

Other issues arising
Next call: **Monday 1 April: 0800 917 1950; participant code 99441723# unless situation develops further when a further call may be called by any of the participants.**

Ref	*Action*	Who	When	
1	***Damian Riley and/or Andy Buck to arrange a meeting/discussion with Stuart Andrew***			
2	***Andy Buck to advise NHS CB (Corporate) or support/resources required in the management of incident.***			
3	***Review of divert arranagements with EMBRACE***	Andy Buck	ASAP	√

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Commissioning Board

Key Issues, Decisions and Actions from NHS CB Leeds Heart Surgery - Conference Call.

Teleconference held: 1st April 2013

Attendees:	Call Number: 2
NHSCB Corporate	Lyn Simpson (Chair) Ann Sutton Steve Field Damian Riley Mike Bewick Andy Buck Tom Easterling Stephen Groves Jonathan Sanderson Jill Harris
NHS TDA	Kathy McLean Yasmin Chaudhry Rob Checketts Greg Madden Peter Blythin Maureen Chung Ralph Coulbeck
CQC	Macolm Bower Brown

	Update
	The purpose of the teleconference was to undertake a review of any issues arising in the last forty eight hours with respect to emergency/elective or transfer/transport issues. Update provided by Damian Riley with respect to the current inpatient cohort at LGI (Ward 12). Confirmed that this was being managed as an incident, with Andy Buck and Damian Riley leading and with support from the NHSCB (Corporate Team). TDA report close contact with Brian Gill – Medical Director at Trust is being maintained.

[redacted]	Note that some clinicians at LGI are seeking legal review of the decision to suspend surgery. Daily reports being received by CQC from the General Manager, reports reflect update provided by Damian Riley. No proactive media reports to be issued.

Other issues arising
Teleconference at 10.30 – 1st April 2013 to agree the terms of reference the meeting of the incident management team and Trust on Tuesday.

Ref	Action	Who	When	
1	*Damian Riley and/or Andy Buck to arrange a meeting/discussion with Stuart Andrew*			
2	*Andy Buck to advise NHS CB (Corporate) or support/resources required in the management of incident.*			
3	***Review of divert arranagements with EMBRACE***	Andy Buck	ASAP	√
4	***Tom Easterling to contact NHSCB Communications to ensure that core team are sighted on any press release.***	Tom Easterling	Immediate	

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Key Issues, Decisions and Actions from NHS CB Leeds Heart Surgery - Conference Call.

Teleconference held: 1st April 2013

Attendees:		Call Number:	3
NHSCB Corporate		Lyn Simpson (Chair) Damian Riley Mike Bewick Andy Buck Stephen Groves Jonathan Sanderson Gill Harris	
NHS TDA		Kathy McLean Greg Madden Peter Blythin	
CQC		Macolm Bower Brown	

Update	
	Participants in this teleconference had attended the earlier teleconference and the purpose of the core group was to determine coordination of incident going forward. Lyn Simpson explained that because of the repurcissions external to the Trust, the significant media interest and potential impact on NHS reputation this was being managed as a incident but that following the meeting with the Trust tomorrow morning the intention would be that this would be handled using the Regional QSG. (Managing Quality in the health system) Important that the date of the risk summit is brought forward. Meeting with Trust on Tuesday at 08.00 hrs should be a small cast and should focus on operational safety issues Issues to be explored through Regional QSG include: assurance of data and any gaps,

	assurance around safe staffing, assurances around the concerns expressed by both clinicians and parents. The outcome of the initial Regional QSG should be shared with the Trust Gill Harris to agree with Peter Blythin and Malcolm Bower Brown attendance at the Regional QSG and confirm to Lyn Simpson

Other issues arising

Ref	Action	Who	When	
1	*Gill Harris to confirm membership of Regional QSG*			
2	*Damian Riley/Andy Buck to confirm* ***attendance at the 08.00 hrs meeting with Trust - ? to be limited to 2 representatives per organisation***			

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Our Ref: sg/ls20130401

Maggie Boyle
Chief Executive Officer

Linda Pollard
Chair

Leeds Teaching Hospitals NHS Trust
Leeds General Infirmary
Great George Street
LEEDS
LS1 3EX

1 April 2013

Dear Linda and Maggie,

I am writing to set out the process NHS England will lead this week in respect of the decision of Leeds Teaching Hospital to pause paediatric cardiac surgery.

Firstly, though, I wanted to thank you and your staff for working closely with colleagues from NHS England and the NHS Trust Development Authority over the weekend, and for the work of your staff to minimise the impact on patients over the bank holiday.

I am aware from your meeting with Sir Bruce Keogh and CQC colleagues on Thursday, that your decision to pause paediatric cardiac surgery services was as a consequence of a number of issues, including concerns raised by clinicians and the available information regarding mortality data.

You are due to meet with colleagues from NHS England, the NHS Trust Development Authority and CQC tomorrow morning to discuss next steps. In advance of that meeting, I would like to explain the process NHS England will follow to enable a timely decision to be made regarding the safe resumption of services. It is our intention as commissioner of these services to run the review under the auspices of the National Quality Board's quality guidance (Quality in the new health system - maintaining and improving quality from April 2013). This will allow a review to take place that will look at revised information available regarding mortality, the concerns raised by clinicians, the concerns raised by patients, and to seek assurance regarding staffing levels, consultant cover in the Unit, and internal governance processes.

Our intention is to hold a risk summit earlier than originally planned. In acting in the best interests of patients, it is anticipated that the initial risk summit will be scheduled for Thursday 4 April 2013. However, please be aware this initial risk summit may not be definitive and should this prove to be the case, NHS England will expect the pause in services to remain in place until a further risk summit could receive additional information before agreeing to the resumption of services.

NHS Commissioning Board
Quarry House, Quarry Hill, Leeds, LS2 7UE

iandalton@nhs.uk

To this end, the meeting tomorrow will be with a small cast and will focus on supporting the trust to manage safely the operational consequences for the delivery of services to patients during this time. It will also be an opportunity to summarise the next steps including the arrangements for a regional Quality Surveillance Group that will meet tomorrow afternoon.

In the meantime, my colleagues and I will continue to work with you to ensure that children requiring these services continued to be treated at alternative units.

Yours sincerely,

Ian Dalton CBE
Chief Operating Officer/Deputy Chief Executive

Cc: Professor Sir Bruce Keogh, Medical Director, NHS England
Lyn Simpson, Director of Operations and Delivery, NHS England (Corporate)
Dr Mike Bewick, Medical Director (North), NHS England
Andy Buck, Area Director (West Yorkshire), NHS England
Dr Damian Riley, Medical Director (West Yorkshire), NHS England
Dr Kathy McLean, Medical Director, NHS Trust Development Authority

From: Sanderson Jonathan (NHS ENGLAND) <jonathan.sanderson@nhs.net>
Sent: 03 April 2013 10:05
To: Dalton Ian (NHS ENGLAND); dark Karen (NHS ENGLAND); Riley Damian (NHS ENGLAND); gill.harris@northwest.nhs.uk; Buck Andy (NHS ENGLAND); Bewick Mike (NHS ENGLAND); Davidson Roger (NHS ENGLAND); Douglas Colin (NHS ENGLAND); Bruce.Keogh@dh.gsi.gov.uk; Keogh Bruce (NHS ENGLAND)
Cc: Simpson Lyn (NHS TRUST DEVELOPMENT AUTHORITY)
Subject: RE: Call now at 9am RE: Call at 8.45 on 3 April

Follow Up Flag: Follow Up
Flag Status: Flagged

All

Actions from the 9am call:
i) Andy and Damian to confirm with Trust that the arrangements agreed on Thursday remain in place and Ian's letter describes the process NHS England will follow as a result of the Trust's pause;
ii) Lyn, Gill, Mike and Bruce to agree arrangements for the Risk Summit;
iii) any changes to the above require refresh of comms lines to be agreed with Colin and Roger before any announcement.

Jonathan

Jonathan Sanderson | Office of the Chief Operating Officer NHS England
Mobile: 07920 283517
Email: jonathan.sanderson@nhs.net

From: Sanderson Jonathan (NHS ENGLAND) <jonathan.sanderson@nhs.net>
Sent: 03 April 2013 18:58
To: Dalton Ian (NHS ENGLAND); dark Karen (NHS ENGLAND); Riley Damian (NHS ENGLAND); gill.harris@northwest.nhs.uk; Buck Andy (NHS ENGLAND); Bewick Mike (NHS ENGLAND); Davidson Roger (NHS ENGLAND); Douglas Colin (NHS ENGLAND); Bruce.Keogh@dh.gsi.gov.uk; Keogh Bruce (NHS ENGLAND); Simpson Lyn (NHS TRUST DEVELOPMENT AUTHORITY)
Subject: RE: Call now at 9am RE: Call at 8.45 on 3 April

Follow Up Flag: Follow Up
Flag Status: Flagged

Sorry for the delay - actions from the 1:30 call:

i) post risk-summit Ian to determine governance and managerial arrangements in discussion with colleagues;
ii) Lyn and Gill to discuss provision of national support for the region and area teams;
iii) in Bruce's absence, Mike to be lead spokesperson on behalf of NHS England;
iv) Lyn to coordinate daily SITREP reports and with Gill to ensure capacity and transfer protocols with other trusts are assured;
iii) Lyn will brief Ian after the risk summit and a decision will then be made whether to convene a conference call.

Jonathan Sanderson | Office of the Chief Operating Officer NHS England
Mobile: 07920 283517
Email: jonathan.sanderson@nhs.net

-----Original Message-----
From: Sanderson Jonathan (NHS ENGLAND)
Sent: 03 April 2013 10:05
To: Dalton Ian (NHS ENGLAND); dark Karen (NHS ENGLAND); Riley Damian (NHS LEEDS NORTH CCG); gill.harris@northwest.nhs.uk; Buck Andy (NHS ENGLAND); Bewick Mike (NHS ENGLAND); Davidson Roger (NHS ENGLAND); Douglas Colin (NHS ENGLAND); Bruce.Keogh@dh.gsi.gov.uk; Keogh Bruce (NHS ENGLAND)
Cc: Simpson Lyn (NHS ENGLAND)
Subject: RE: Call now at 9am RE: Call at 8.45 on 3 April

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Actions from the 9am call:
i) Andy and Damian to confirm with Trust that the arrangements agreed on Thursday remain in place and Ian's letter describes the process NHS England will follow as a result of the Trust's pause;
ii) Lyn, Gill, Mike and Bruce to agree arrangements for the Risk Summit;
iii) any changes to the above require refresh of comms lines to be agreed with Colin and Roger before any announcement.

Jonathan

Jonathan Sanderson | Office of the Chief Operating Officer NHS England
Mobile: 07920 283517
Email: jonathan.sanderson@nhs.net

Thursday 04 April 2013

Quality Surveillance Group – LGI

Attendance:

Name	Organisation	Contact
Gill Harris (Chair)	NHS England	gill.harris@northwest.nhs.uk
Teresa Fenech	NHS England	Teresa.fenech@northwest.nhs.uk
Mike Bewick	NHS England	mike.bewick@nhs.net
Andy Buck	NHS England	andy.buck@rotherham.nhs.uk
Damian Riley	NHS England	damian.riley@nhs.net
Lyn Simpson	NHS England	Lyn.simpson1@nhs.net
Elaine Darbyshire	NHS England	
Alison Dickinson (Notes)	WYAT	alisondickinson@nhs.net
Moreen Choong	NTDA	maureen.choong@nhs.net
Kathy McClean	NTDA	kathymcclean@nhs.net
Debbie Westhead	NTDA	Deborah.westhead@cqc.org.uk
Allan Goldman	GOSH	Allan.goldman@gosh.nhs.uk
Malcolm Bowser – Brow	CQC	malcolm.bowser-brow@cgc.org.uk
Danny Keenan	CQC	Danny.keenan@cqc.org.uk

Action notes:

	Action	Lead	Timescale
1	Apologies for absence None The purpose of this meeting is to follow up the QSG held on 2.4.13, and to ensure that people are sighted on the context and information prior to the risk summit later today. Children's congenital cardiac surgery is currently suspended due to data presented by Sir Bruce Keogh yesterday through voluntary action by LTHT, who have been cooperative.		
2	Action notes from meeting 2.4.13 Amendments & updates: o Item 6 – DR to arrange a meeting with LTHT again: will try to obtain and review any litigation held in the last 3 years o Item 18 – should read 'CQC is supportive of NHS England *request* to suspend services. It has been noted that CQC *is not likely to* take immediate ... With the above amendments, the previous notes were **AGREED** as a true and accurate record.		

3	**Further meetings updates** A meeting was held with LTHT at 8am this morning and formal notes will follow. The key pints discussed are: o Letter received form Ian Dalton o The capacity for the management of urgent cases due to suspension. This will be discussed in the risk summit planned for later today. Assurance is needed that the system can cope with capacity. o Operations: statement from Stacey Hunter that there are 300 – 350 cases per year. Item 8, Point 2 may be in dispute with information from receivers. o Item 14 considered CQC data o A site visit was carried out on 3.4.13. A draft report will be tabled. o Position statements will be made		
4	**Review of quality risk issues** 4.1 Data Issues Dr. Kevin Smith was asked to review the data. It was agreed that this report had limited value and would not be shared at the risk summit. Discussion point 1: case mix; Point 2 – Agree with the discussion; Point 3 – Cause of death unknown therefore intensive review of deaths needed. Denominators need validity so it is unclear what the Leeds argument is. It is unclear what the outcomes on the completion of cases will be. There are 33 interventions data missing which could change the statistical analysis. The quality of data is questionable; why have Leeds omitted to send data on 33 interventions? NICOR usually send audit personnel to sites to randomly audit data quality. **ACTION:** to ask NICOR about the quality of data and what it will look like with the additional data It is reported that other organisations are more systematic at submitting data than Leeds. Suggesting poor Information Governance in Leeds. **ACTION**: to enquire if NICOR have had full sets of data from other organisations **ACTION**: Ask LTHT to improve data collection **ACTION:** Ask LTHT how they use their data	**Mike Bewick** **Mike Bewick** **Damian Riley** **Damian Riley**	7th April 7th April 7th April 7th April

	There are several sources of data available for SMR, and it would be helpful to identify what level of authority is put on each. It is important that in the risk summit that new data should not be introduced, but the refined NICOR data should be revisited. It was noted that the Dr Foster data records death and could be used to cross-reference the 9 reported deaths from Leeds. It is important that a close down on data is agreed. **ACTION:** Additional national work should be carried out to agree what data sets should be agreed in future to prevent recurrence. It was **AGREED** by al present that there was no evidence to suggest that Sir Bruce lacked integrity, and that the actions taken were appropriate. It was also **AGREED** that whatever actions were taken in the risk summit should not increase the risk of death by more than 2 per year. <u>4.2 Professional Concerns</u> 2 separate professionals raised concerns about the Leeds unit. One of the professionals is out of the country, but MB visited another unit to meet the other surgeon who had raised professional concerns to Sir Bruce Keogh. A paper has not been produced for this meeting and consent is still outstanding from the patients referred to. MB interviewed a cardiologist; Paediatric consultant; and chief executive. MB was supplied with 14 cases collected over 12 months where they have concerns. Some of the cases are known to the CQC. The main themes include: o Concern about the treatment of children including treatment reported to have been carried out, was supported by the documentation and inaccurate treatment plans o Communications poor when patients have asked for a 2nd opinion o Legitimacy of figures was questioned (this is an opinion and not for sharing) o Cardiologist to cardiologist requests are limited from Leeds o Operations occasionally carried out for short term gain The group also questioned about the surgeon who recently left Leeds and moved to Alder Hey; and the question of the surgeon who is voluntarily not practicing in Leeds. <u>4.3 Public concerns</u>	**Mike Bewick**	5th April

	A high level summary is that the CQC are aware of 10 families who have complained, and an additional 1 that NHS England is aware of. The themes include: o Getting consultant appointments o Difference in opinion about treatment options o Pressure to terminate pregnancy o Cleanliness and Hygiene issues o Delays in surgery o Difficulties in transfer Within this group there are also concerns on the quality of LTHT responses to complaints reviewed during the walk around visit on 3.4.13. Copies of the redacted complaints responses have been requested but have not so far been forthcoming as LTHT have requested an ISA. No new complaints have been received since the suspension of the service. Trend analysis of complaints has been requested as part of the dossier from LTHT. <u>4.4 Staffing concerns</u> There are 3 FTE consultants in place, but 2 are locums. **ACTION**: to investigate why they are still locums. It has been reported that an additional consultant flies in from Europe monthly to carry out surgery. It is unclear how this surgeon can maintain their patients on this basis. **ACTION**: of the 3 surgeons it needs to be identified how many see neo-natals and what procedures they carry out.	**Mike Bewick** **Mike Bewick**	**5th April** **5th April**
5	**<u>Feedback from site visits</u>** A site visit was carried out on 3.4.13 by members of NHS England and NHS TDA. Issues identified: o Management of support for patients seeking a second opinion – a conflicting response was given by members of staff when questioned o Risk register only contained reference to 'safe & Sustainable' and nothing else. The surgery who is voluntarily not operating was not on the risk register o Transfers: 1 x 14 year old has been waiting for transfer for 9 weeks to GOSH. AG will look into this when he returns to GOSH	**Allan Goldman**	
6	**<u>Terms of reference</u>**		

	Item deferred		
7	**Risk Summit** Themes to be discussed include: o Data collection and real time use o Concerns around managing complaints and how they are shared o High level professional concerns o NICOR data valuator set to be used for completeness (Clarity to be sought from NICOR) o Questions around staffing (volumes; locums; continuity of care) o Continued or new risks from last week and ongoing concerns o Capacity available – process needs to be streamlined Some concerns have been raised with LTHT prior to this meeting. The aim is to get an understanding. It is anticipated that a further QSG is held next week.		
8	**Incident management & Impact assessment** Item Deferred		
9	**Agreed actions** **ACTION:** to ask NICOR about the quality of data and what it will look like with the additional data **ACTION**: to enquire if NICOR have had full sets of data from other organisations **ACTION**: Ask LTHT to improve data collection **ACTION:** Ask LTHT how they use their data **ACTION:** Additional national work should be carried out to agree what data sets should be agreed in future to prevent recurrence. **ACTION**: to investigate why they are still locums **ACTION:** of the 3 surgeons it needs to be identified how many see neo-nates and what procedures they carry out.		
10	**AOB time and date of next meeting** No AOB.		

	Date of next meeting to be determined.		

Children's Congenital Cardiac Surgery Risk Summit

Thursday 4th April 2013

Attendance:

Name	Title	Organisation
Mike Bewick (MBe)(Chair)	Deputy Medical Director	NHS England
Maggie Boyle (MBo)	CEO	LTHT
Bryan Gill (BG)	Interim Medical Director	LTHT
John Thompson (JT)	Consultant Paediatric Cardiologist	LTHT
Stacey Hunter (SH)	Divisional Manager	LTHT
Gill Harris (GH)	Director Of Nursing	NHS England
Teresa Fenech (TF)	Deputy Director of Nursing	NHS England
Lynn Simpson (LS)	Director of Operations and delivery	NHS England
Julie Higgins (JH)	Director of commissioning	NHS England
Andy Buck (AB)	Director	NHS England
Damian Riley (DR)	Medical Director	NHS England
Rhona Collins (RC)		NHS England
Elaine Darbyshire (ED)	Communications lead	NHS England
Maureen Choong (MC)	Director of quality	NHS TDA
Kathy McClean (KM)		NHS TDA
Malcolm Bowser – Brow (MBB)	Deputy Director of operations	CQC
Debbie Westhead (DW)	Compliance officer	CQC
Danny Keenan (DK)		CQC
Allan Goldman (AG)	Consultant Paediatric cardiologist	Great Ormond Street Hospital
Councillor Judith Blake (JB)		LCC
Nigel Nicholson (NN)		LCC
Alison Dickinson (AD)(Minutes)	Programme manager quality and Strategy	WYAT

No.	Item	Action
1.	**Welcome and Introductions** Attendees were invited to introduce themselves around the table.	
2	**Professional clinical advisors: introductions.** Children's services representatives from Leeds City Council were welcomed and invited to introduce themselves. Their attendance required as expert advice on safeguarding issues and as lay members to the group.	
3	**Background and Scene setting / Feedback from QSG** The scene was set citing the Francis report and the aims of the group: o To reach a settlement and agreement about children's	

	cardiac surgery o To present a united public front o A responsibility to develop excellent care o To restore public confidence in, and the reputation of LTHT A draft terms of reference have been prepared and are available to consideration, however it was agreed that the business of the group was such that it was better to proceed with that as a priority. A risk summit is usually called earlier in the process but was deemed to be beneficial to be held at this time. Sir Bruce Keogh is currently out of the country but has been working with MBe closely and advising. On 28.3.13, data was presented to Sir Bruce suggesting adverse mortality statistics from the Childrens Cardiac Surgery unit at LTHT. At the same time, Sir Bruce also received information of concerns from other professionals about the service. The decision was taken to suspend the service. It is not proposed to revisit that information but to consider any new information received. It was noted that it is the duty of this group to be constructive and to make the best decision for patients. MBo corrected that a graph was received by Sir Bruce and not data.	
4	**Incident Update / Impact Analysis** Since 28.3.13 surgery has stopped and alternative arrangements have been made to treat patients. A review of those arrangements suggests that Trusts across England have been very willing and helpful and transfers well serviced by EMBRACE. There is confidence that there is capacity in the system with no issues being reported from other providers. However it was noted that the process should be robust with a review of current protocols and transfer arrangements. LTHT reported that they have concerns that infants need additional intervention for transfer of ventilation and intubation which if staying at Leeds they may not need. A concern was raised by LTHT that a communications release has been sent out by NHS England prior to this meeting which they believe is pre-emptive of the outcome. This was strenuously denied by members around the table. LTHT expressed a hope that surgery could be restarted at Leeds as soon as possible. Reassurance was given that no pre-emptive decisions had been reached ad that this would be an honest and open meeting where additional information would be heard and if possible a decision reached.	

	AGREED: will make sure this is addressed with Ms at the meeting scheduled later today. LTHT were then happy to proceed with the meeting.	
5	**Overview from each stakeholder.** **5.1. Data** The original graph that was used by Sir Bruce Keogh was shown to the group with the provisional analysis. It was agreed that this was produced by NICOR which is a research based subset of CCAD. The data was subsequently refined by David Cunningham and this information was also shown to the group. It was agreed that there are 4 potential databases used: Dr Foster / LTHT Trust Mortality data / CCAD routine data / NICOR. The CCAD data is not currently available due to issues accessing their website so 3 of the above have been considered by the group and their merits debated. o Dr Foster: Believed to be quite crude data that does not allow for complexity. Doesn't risk adjust but is quite useful o NICOR: data is preliminary based on a newly developed algorithm. Will be useful when refined and embedded. Allows for complexity. Not freely available to organisations as yet. o CCAD: risk adjustments made for complexity of cases. Data collection supported by site visits where data is validated. The CCAD team are currently routinely visiting LTHT to validate their data o LTHT data: VLAD chart of data reviewed over the bank holiday weekend was shared with the group demonstrating that LTHT are not an outlier on this data for 2011 -2012. **Q** - LTHT were asked how they assure themselves that surgery is safe: **A** - This is through identifying all deaths; every case has undergone an MDT review; no 2 patients had been suffering from the same condition; all information produces a unit score. It was noted that methodology is not available that would give 100% assurance for any unit. LTHT operate a 'bottom up' approach, with all deaths reviewed by the team and then reviewed by the medical director. **Q** – Governance processes at LTHT and how 33 cases are apparently missing from 20 11 – 2012 NICOR data sets: **A** – The model on the system requires all data fields to be completed in order to record. It was not possible to fill all data fields for all of the patients. The data relates to procedures and not patients. Minimum data was supplied on all patients but the	

	data was still used pre-emptively. The CCAD is a tested procedure and the quality assurance visits give an update and validates data submitted. The LTHT score for this is 90%. **Q** – would it be appropriate to ask questions on the data that has been revealed: **A** – The information presented is not fit for purpose and should be allowed to run its course. The system is good but the premature use of data cannot be agreed with. This data is fundamentally flawed as LTHT is not an outlier on validated data. Both CCAD and the professional opinion is that the data should not have been used in this way. The VLAD plot will also not be used for the purpose of this meeting either. **ACTION:** NHS England would like time to consider the new information. <u>5.2. Professional Concerns</u> Sir Bruce Keogh received 2 sources of professional concerns, and these have been followed up by MBe. 1 of the individuals are currently out of the country, and this lead will be followed up on their return. The other lead is from an individual on behalf of a unit in another Trust. MBe met with the consultant surgeon, CEO and paediatric consultant on 3.4.13 to discuss the concerns raised. He was presented with 14 cases – which cannot be shared at the moment for reasons of confidentiality –but is able to share themes from the cases. The Other Trust raised the point that there may be suspicion shed on them due to the recent safe and sustainable review which put the 2 units in direct competition. They also raised the pint that they believe that the relationship between Leeds and their Trust is also poor. This allegation is based on the fact that there are few consultant to consultant discussions or referrals between the units and that this is not the case with any other unit. The key allegations levied by the Other Trust are: o There are often delays in onward referrals or operations carried out in LTHT that are not appropriate o Operations are sometimes carried out that are palliative when a curative operation is available. Occasionally the operation carried out for palliative reasons causes additional difficulty in carrying out the curative procedure. o Erroneous advice to terminate pregnancy has been given o Parents have been advised that certain treatments are not available or are only available elsewhere at great cost. This leads to patients being put on a palliative pathway. (A particular cases was cited).	**NHS England**

	If this allegation is supported, this may lead to regulatory involvement. 14 is a significant number and worthy of consideration. If proven, this would be a high level of seriousness. It is noted however, the potential conflict of interest and the fact that the Other Trust were co-defendants on the 'Save Our Surgery' litigation. Any evidence would need to be validated through an independent review process. LTHT categorically refute the allegation. It is not clear if the other Trust attempted to raise these issues with Leeds as they arose as the Medical Director at the other Trust is new in post, but it is believed that they had a duty to do so. Leeds dispute having ever received any prior information from the other Trust about these alleged issues and believe that the timing of this is critical following on from recent events related to the review. It was stressed that no judgement was being made by NHS England at this time and that the facts were merely being relayed. **AGREED**: that the normal process for raising professional and inter- unit complaints is that evidence is shared across the organisations and to the medical director. It is the medical director who will contact the other organisations medical director to raise the concern and discuss. **ACTION:** the concerns raised must be investigated and may have a high level of seriousness; additionally there may be a level of seriousness for the other Trust if concerns were not raised earlier in the process LTHT have investigated 3 of the allegations thoroughly and believe they have evidence to absolutely refute. The response was circulated to the CQC 3 weeks ago and have had no notice of additional actions required. **Q:** Did MBe inform th other Trust of the due process that should have been taken? **A**: he did. **Q:** MBo was surprised that this information was tabled in this meeting and not given prior to this. **A**: MBe takes this criticism, however notes that he did contact BG at 1am, and also mentioned to MBo in a telephone call this morning. As the information has not yet been validated, it should be given low weighting in the final assessment. It should be noted that this information is not validated whistleblowing and needs to be investigated. The 4 patients concerned have put themselves into the public domain.	**NHS England**

	5.3. Public Concerns The CQC stated a confidentiality caveat prior to starting this section and that only high level theme would be outlined to prevent identification of families. There have been 10 individual complaints of which some had more than 1 issue, and other highlighted similar issues. The main themes are: o Difficulties in getting consultant appointments o Difficulty and delay of referral to the unit o Diagnostic differences between Leeds and other units o Differing intervention advice between Leeds and other units o Undue pressure to terminate pregnancy o Cleanliness and hygiene o Delays in surgery 4 of the above complainants have directly complained to Leeds, who have responded to 3 and sent their response to CQC for comment. No comment has yet been received, however the CQC are continuing to review and will respond in the near future. The remaining complaint has only been received recently and is still under investigation by Leeds. It is believed that Specialist commissioners have not received copies of the complaints as this is not the routine process. LTHT are concerned that their first knowledge of the complaints was through the press and took specialist legal advice at the time. As part of the walk-round visit carried out on 3.4.13, TF reviewed complaints responses which 'categorically refuted' the complaint. Redacted copies requested but not yet received. CQC reported that there is a possible 11th complaint that they have received but this needs further clarity prior to sharing. It was also noted that no cases have been referred to the ombudsman. 5.4 Staff concerns DR was asked to review the surgeons and non-surgical staff. There are 4 FTE surgeons – 1 is subject to voluntary exclusion. They are also supplemented by an additional surgeon who flies in from Europe. The surgeon who flies in has previously been a consultant at LTHT and is known to them. The consultant is based in Denmark, but works in Denmark, Egypt and Uk doing similar work. She takes part in some MDT functions although does not take part in the on-call rota. Patients are allocated through MDT, most of whom this surgeon has prior knowledge through previous surgery. This surgeon usually flies in Thursday, operates Friday and Saturday	

	and returns home Sunday. Post operative care and planning is covered by the rest of the surgeons. 6 month data is available. The 3 FTE surgeons all undertake all specialties offered by the unit – including neonates - and are registered as specialists. 2 are locum consultant surgeons who appear to have been locums for some time and were upgraded to locum consultants Autumn 2012. The delay in upgrade was due to existing capacity in the system which was only released last year and appointments were also delayed due to the Safe & Sustainable review process. It was reported that it is common practice for units to function with locums. The surgeon under voluntary exclusion does not see patients less than 1 year. There is no reported evidence that surgeons are putting patients at risk and BG is happy to give additional assurance outside of this meeting There was concern expressed by the group that due to leave and holidays there were only 2 locums covering the unit. LTHT responded that they are qualified to carry out the full range of procedures and are accountable for that and the unit is not unsafe. The cardiology consultants have the full confidence of the LTHT senior team, there is improved team working including good relationships with nursing staff. There are pre-determined acceptable staffing levels for these types of units, which LTHT reach. <u>5.5 Site visit</u> A site visit was conducted on 3.4.13 by senior staff from NTDA; WYAT; NHS North Of England. A supporting report is under development The approach taken was the 15 steps challenge (NHS Institute) around the key 4 domains. Discussions also took place with staff and relatives around the key themes of: o Patient pathway o Transfer of care o Concerns o Satisfaction o Skills levels o Commitment A lot of positive information came from the 15 steps investigation. o Environments – No cleanliness issues identified o Nursing skill mix – was good. Opportunities for development reported; lots of support; and excellent teamworking o The team asked to see copies of the complaints received which are still to be seen.	

	○ Management of requests for a second opinion – a conflicting view point was given by people questioned ○ MDT arrangement – noted, and decision making process outlined but it is often left to the surgeon to relay information. The review team suggested the implementation of a written summary similar to that used by the cancer MDT. ○ Departmental risk register – the only risk outlined relates to Safe & Sustainable It was reported that few patients request a second opinion from the the Other Trust's unit. ***JT left the meeting at this point (5pm).**	
6	**Organisational Overview** **6.1 LTHT Position** MBo reported that it feels like it has been a 'long week' since 28.3.13. LTHT have tried to engage and to get to the route of the concerns. The predominant issue was related to the use of the graph sent to Sir Bruce, which was challenged at the time that the decision was taken to suspend the service. Staffing allegations have been addressed earlier in this meeting. The CQC have indicated some residual concerns but these are not believed to be significant. A suggestion had been made that statutory powers may be invoked, but it is not believed that this is possible in these circumstances. MBo has discussed with her team if they believe there is anything that would give them concern about this service, and gave assurance to this meeting that there is not. As a contingency plan for patients when the service was suspended, capacity in the system was reviewed. There were difficulties experienced by LTHT in securing a place for patients and examples used to illustrate issues arising. Most patients transferred to Liverpool and Leicester, with another Trust proving to be more reticent about accepting patients. Concern was expressed that there was now a greater risk posed by the service being suspended than there had been prior to suspension. It was reported that at least 2 patients had undergone interventions that would not have been necessary had the service not been suspended. LTHT believe that there is no evidence of herm to warrant the action taken and the consultants believe they have taken any actions necessary to remedy the situation. They have written to LTHT chairman, CEO and board stating that the surgical risk is now greater. This is supported by MBo. Capacity has been difficult to manage in real terms but there is no lack of will in the system. It may become an increasing challenge.	

	Management has been creative ie patient swaps. Patients are safe but this has not been without impact The additional allegation introduced in this meeting raised about professional concerns that MBo had no prior knowledge of. MBo has suggested that she may need to consider the position of LTHT and whether to re-open unilaterally. This has re-opened old wounds for some people who previously had closure. The timing of this has also been unfortunate following on from the Safe & Sustainable review. LTHT are struggling to see how this can be justified as a reasonable response. <u>6.2 NHS England Position</u> Issues raised have tried to be divorced for the Safe & Sustainable review. Gratitude was expressed to MBo for her responsible actions and attitude. Capacity arrangements have worked well to date additional assurance required for the coming days if services are not restarted. <u>6.3 CQC position</u> Concerns are related to capacity in the system. <u>6.4 Local Authority Position</u> A formal safeguarding process would not be commenced on the evidence available. Concerns expressed are strategic and should be explored outside of this meeting. The follow on process is to log this with safeguarding board. DR outlined that the number of child deaths in 2012 / 2013 has been 6 / 350 cases. <u>6.5 NTDA</u> The new information received needs to be reviewed. It is worthy of reiterating that LTHT made a voluntary suspension of the service. The discussion and conclusion about next steps will influence the next step by the NTDA. <u>6.6 Proposal by NHS England</u> A 3 phase plan should be implemented covering short terms and longer term actions to assure the safety of the service. o Phase 1: This will be a rapid review of governance and safety whereby a team of independent experts will spend this coming weekend at LGI reviewing the service. MBe will start to draw up a terms of reference and an independent team will be tasked with starting work tomorrow (5.4.13). it is anticipated that this may lead to a phased re-introduction of services early next week following another risk summit.	

	○ Phase 2: A review will be undertaken of the 9 deaths that have occurred and the complaints brought by a 3rd Party. ○ Phase 3: will involve working with Dr Foster and NICOR to discuss the data used nationally and identify the best way forward to prevent recurrence of these issues elsewhere in future. Tomorrow (5.4.13) MBe / DR / AB will meet with MBo to inform staff and to reach a common agreement on the way forward. Meantime LTHT were asked to continue with the voluntary agreement of continuation of suspension of service. LTHT expressed concern that continued delays to re-open will lead to actual harm and that LTHT will be culpable as they don't believe that there is any evidence to continue with the suspension. **LTHT withdrew from meeting temporarily to consider their position.**	
	Discussion in interim. NTDA If we say no to re-starting service, LTHT will carry all of the risks . Need to ask the CQC if they would take regulatory action in this circumstance; any death will be put down to this; and would commissioners continue to commission the service? NTDA will hold the service to account and will have powers to direct action which were only received on 1st April 2013 so have not been tested to date. CQC CQC will need to consider if further action is required if LTHT re-start services unilaterally. It is unlikely to use emergency powers, so any actions taken will be longer term using statutory powers. *Confidential -- not for inclusion in general minutes to providers – CQC were planning to visit the unit routinely in the next round of assurance visits. In light of the concerns today consideration of any safeguarding issues should be included.* Data To be included in the review for 2 -3 days only. Allan Goldman He has received some assurance from GOSH colleagues about the data. The staffing at GOSH is 3 surgeons. The logistics to cover in the event that unit reopening is delayed needs to be smoothed: ie need daily sitreps and need to know where the next bed is.	
	Post reflection discussion	

	LTHT MBo believes that: o Data: the data that was used original should not have been used in the way that it was., and that mortality is no greater than expected o Staffing: there is nothing in the staffing concerns that would be sufficient to close the unit o Professional concerns: These are potentially significant over the weeks and months but again would not be sufficient evidence to close the unit o CQC: LTHT are familiar with 4 out of the 10 complaints but they are not of sufficient gravity that the CQC would suspend the service. o Safeguarding: the lay view is that there is now more risk in the system. Some issues need some process but this is not possible to instigate until the service resumes. On review, it would be difficult to explain to stakeholders a continuation of suspension of services. It should be noted the MBo believes that the service is safe and assured. CQC Can't respond on position, however, information received so far has not led to the conclusion that emergency powers should be invoked. The CQC needs to reflect on the new information brought today and if any regulatory action is required. NHS England **Q:** If the unit reopened, how would this be undertaken? **A:** There is no evidence to suggest a pause is indicated. There are no electives scheduled for tomorrow. Now and Monday would concentrate on emergency and urgent surgery first, and within 48 /72 hours to consider rebooking elective surgery to commence next week. **Q:** How many patients are there in the 48 / 72 category? **A:** 2 patients are in the current bed base as at 9am this morning. There is 1 antenatal mum who refuses to go anywhere but Leeds.	
7	Summing up, agree actions and timescales and confirm whether any participant thinks further actions are required to protect patients Without external verification to validate the safety of opeing, the group would not be able to advise re-opening the unit. If voluntary suspension is agreed, NHS England will share the risk with LTHT. The group would also be unhappy with the phasing in plan as emergency patients carry the most risk. Would advise LTHT to take external advice re: phasing process.	

	Mortality data: o Independent verification of other data will be accepted o Other people are no looking at the data **Q:** What has not been addressed that is causing the service to still be paused? **A:** Assurance needed around softer governance issues and whistleblower claims. A rapid governance review is now needed. Colleagues who were part of Safe & Sustainable should not be included in the review. A definition of an operating procedure for referrals would also be helpful to ensure all pathways are in place. <u>Proposition</u> An independent review will be carried out over the weekend to gain governance assurance The terms of reference will outline the process which is expected to be through but at speed. The terms of reference will be developed and agreed by MBe / DR and an external expert John Wallwork. These will be sent to MBo. There will need to be an emergency operations process in place to ensure the contingency system is managed effectively over the next few days. 24/7 availability is needed from tomorrow. It is not clear what the consultants response will be to this. **AGREED:** Agreement reached on the proviso of a specific joint communication release	
8	**<u>Communications plan</u>** A joint statement has been drafted between NHS England and LTHT. This is the only statement to be made.	
9	**<u>Further Risk Summit</u>** A smaller risk summit will be reconvened early next week to discuss the findings of the independent review. This will be necessary to prevent the service re-opening prematurely. <u>9.1 Next steps.</u> o A joint statement will be drafted and agreed. o MBe will arrange for external reviews to be in Leeds by tomorrow (5.4.13) o Terms of reference will be developed, reviewed and agreed o MBe / DR to meet consultants tomorrow o Operations model to be developed by LS o Daily sitreps to be set up by LS o The review is not to include new evidence but this will be	**NHS England / LTHT** **MBe** **MBe** **MBe /DR** **LS** **LS**

	the mechanism to answer existing concerns. o Teleconference to be held Sunday evening Contacts over weekend: NHS England – GH LTHT - SH	

NHS England

Our Ref: sg/ls20130405

Maggie Boyle
Chief Executive Officer

Linda Pollard
Chair

Leeds Teaching Hospitals NHS Trust
Leeds General Infirmary

5th April 2013

Dear Linda and Maggie,

I am writing further to yesterday's Risk Summit, chaired by Dr Mike Bewick, to set out the position of NHS England and the process we intend to follow in order to be able to reach a decision to a restart of paediatric cardiac surgery at Leeds Teaching Hospital NHS Trust.

At the meeting between Sir Professor Bruce Keogh and yourselves, at which the CQC was also represented, on Thursday 28th March, four issues were raised that led to the agreement on your part to a pause in the provision of surgical services. These issues related to the new data and analysis about mortality, staffing, patient concerns and complaints, alongside concerns raised by other professionals.

The initial mortality data from NICOR (the National Institute for Cardiovascular Outcomes Research) appeared to indicate that the Trust was an outlier, which gave considerable cause for concern.

The patient concerns and complaints, about which the CQC was also aware, relate to ten patients, of which we understand three have been formal complaints and a further one of which has subsequently become a formal complaint. The issues raised include difficulty in getting appointments, referrals to other units, concerns about diagnosis and choice of interventions, undue pressure to terminate pregnancy and delays in surgery.

The issues raised by other professionals include concerns about referrals, choice of interventions, the advice given to pregnant women and the advice about the availability of specialist procedures.

The staffing issues include the absence of the lead surgeon on leave, the voluntary exclusion from surgical practice of one surgeon (about which the Trust had therefore already taken appropriate action), the reliance on two locum surgeons and the use of a surgeon who undertakes surgery at the Trust on two days each month.

Whilst these concerns were referred to at the meeting on Thursday 28th March, the detail became clear during the ensuing week, leading to a full presentation of the

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concerns at the risk summit on Thursday 4th April, at which all the issues were considered.

The risk summit concluded that NHS England and the Trust will work together today and over the weekend to secure further assurance about key outstanding issues concerning governance and risk. This will include the issues arising from the concerns raised by other professionals and parents, and the remaining concerns about staffing levels.

This immediate process will involve:

a) the validation by NICOR of the data provided yesterday by the Trust, and its review by independent clinical experts in this narrow field; and,

b) a review of the clinical governance in the unit. The independent clinical review team will aim to assess that the services available for paediatric cardiac surgery are of a standard consistent with other units in the country with a similar case mix. The evaluation will look in detail at current working practices, across paediatric cardiac surgery and intensive care. It will involve looking at details of the current protocols and policies within the unit and a review of any recent incidents or complaints; and will interview staff involved in the care of these children. This work will be led by Professor John Wallwork and other independent clinicians.

The detailed arrangements for the above are being made and enacted immediately. Damian Riley, Medical Director (West Yorkshire) will support the process.

This information will be considered on either Sunday 7th or Monday 8th April to be agreed in collaboration with Trust in order that a decision can be agreed on a phased approach to restarting surgery at the hospital.

A second phase, which was agreed at yesterday's risk summit , will review the case notes; this will commence shortly, and the details will be agreed with the Trust.

In the interim, the arrangement as per my letter dated Monday 1st April remain in place and we expect the pause in surgery to continue. In the meantime, my colleagues and I will continue to work with you to ensure that children requiring these services continued to be treated at alternative units.

Yours sincerely,

Ian Dalton CBE
Chief Operating Officer/Deputy Chief Executive

Cc: Professor Sir Bruce Keogh, Medical Director, NHS England
Lyn Simpson, Director of Operations and Delivery, NHS England (Corporate)
Dr Mike Bewick, Medical Director (North), NHS England
Andy Buck, Area Director (West Yorkshire), NHS England
Dr Damian Riley, Medical Director (West Yorkshire), NHS England
Dr Kathy McLean, Medical Director, NHS Trust Development Authority
Malcolm Bower-Brown, CQC

PAEDIATRIC HEART SURGERY – LEEDS TEACHING HOSPITALS NHS TRUST

Key points from the conference call which took place on Friday 5 April 2013 at 17.30 with the following people present:

(Lyn Simpson, Julie Higgins, Jon Develing, Gill Harris, Tim Young, Jonathan Sanderson, Phil Storr, Andy Buck, Stephen Groves, Rhona Collins and Colin Douglas)

1. **Outline of the teleconference which took place with Ian Dalton at 17:00 on Friday 5 April 2013**

   - It was agreed that the QSG call on Sunday afternoon would go ahead.
   - Data from the mortality review would not be available until Monday.
   - A risk summit with participating organisations would take place on Monday afternoon and Mike Bewick would advise regarding the timetable.
   - Ian Dalton would be available to speak to the media and colleagues would start to consider a press release following the outcome of the review covering all eventualities.
   - Discussions took place regarding the on-call / virtual Ops room arrangements coordinated by Stephen Groves. A cover note would be circulated to colleagues that would include details for the forthcoming teleconference/briefings set out below.
   - A note will be cascaded to national directors to update them on progress late Saturday / early Sunday.
   - There were no reported issues on national capacity in terms of bed status.
   - Gill Harris would consider the presentation format for Ian Dalton to take to the QSG at 18:00 on Sunday.

2. **Key Actions Points:**

   - Tim Young/Karen Dark to finalise the letter to go out to Chief Executives.
   - Stephen Groves to finalise the on-call pack and covering letter in preparation for cascade today.
   - Tomorrows focus will be around the comms briefing and how we can assist with that along with looking at the information from Embrace/PICU. Stephen Groves and Julie Higgins to work together producing this.
   - Gill Harris updated the group that Alderhay had confirmed they were comfortable to accept as and when required and that Len Fenwick confirmed that the Freeman Hospital can accept if required.

3. **Future Calls/Meetings**

- Saturday 6 April, 11:00
- Saturday 6 April, 17:30
- Sunday 7 April, 11:00

From: Sanderson Jonathan (NHS ENGLAND) <jonathan.sanderson@nhs.net>
Sent: 05 April 2013 17:53
To: Simpson Lyn (NHS TRUST DEVELOPMENT AUTHORITY); Bewick Mike (NHS ENGLAND); Andrew.Buck@rotherham.nhs.uk; Buck Andy (NHS ENGLAND); gill.harris@northwest.nhs.uk; Douglas Colin (NHS ENGLAND); Davidson Roger (NHS ENGLAND); dark Karen (NHS ENGLAND); Riley Damian (NHS ENGLAND); Dalton Ian (NHS ENGLAND); Keogh Bruce (NHS ENGLAND)
Subject: Leeds - URGENT - telcon - NOW AT 5pm

Follow Up Flag: Follow Up
Flag Status: Flagged

Process for the review agreed:

1. Data and clinical governance review over weekend to review procedures and recent incidents, likely to conclude Sunday afternoon
2. QSG on Sunday evening, 6pm – chaired by Gill
3. Risk summit on Monday, noon – chaired by Mike
4. Risk summit to submit recommendation to Bruce and Ian on whether to restart surgery on a phased approach

Colin to prepare PN for different outcomes options in advance to consider and agree by close of play Sunday and to agree detailed plan of choreography from Monday morning onwards; Bruce to lead media on Monday if back into the country (if not possible then need an alternative plan).

Lyn to coordinate on-call rota and virtual support office (both in place); telcon and briefing process agreed (11am and 5pm Saturday and Sunday); capacity data will feed into meetings; review on-going issues (including media issues); enhanced transfer arrangements in place; PICU data to review bed availability. Lyn to update National Directors after each teclon.

Lyn confirmed no current capacity issues.

Jonathan Sanderson | Office of the Chief Operating Officer
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PAEDIATRIC CARDIAC SURGERY – LEEDS TEACHING HOSPITALS NHS TRUST

Key points from the conference call which took place on Saturday 6 April 2013 at 5.30pm with the following people present:

Lyn Simpson, Tim Young, Phil Storr, Gill Harris, Mike Bewick, Jonathan Sanderson, Andy Buck, Carl Jessop, Colin Douglas, Kate Caston, Stephen Groves and Karen Dark.

1) There were no reported Paediatric Intensive Care capacity issues.

2) There are no reports of children requiring transfer. This was confirmed via EMBRACE and Yorkshire Ambulance Service.

3) There were no commissioning issues or local issues to report.

4) There had been no media enquiries.

5) Mike Bewick provided feedback in relation to the review which was progressing within the Trust and thus far, no major areas of concern had been reported by the Clinicians undertaking the study. This feedback encompassed the nursing perspective.

6) Cardiac Surgeons were scheduled to be interviewed on an individual basis on 7 April 2013.

7) NHS TDA had reviewed several complaints and initial findings would suggest an emerging theme around the management of complaints within the Trust.

8) Mike Bewick would work on a straw man for possible outcomes / scenarios this evening.

9) Karen Dark agreed to confirm details of the calls taking place on Sunday 7 April 2013:

- Mike Bewick, Gill Harris and Lyn Simpson are scheduled to speak with Ian Dalton at 10.30am on Sunday to share reflections and provide a view on the way forward.

- The final weekend call of this group is scheduled for 11am. The dial in details are:

  Dial in: 0800 917 1950
  Participant's Passcode: 91821252#.
  (Lyn Simpson will dial in as Chair)

- A conference call has been scheduled to take place at 4pm in order for a verbal update to be provided in advance of the formal QSG call at 6pm. The

4pm call would replace the 5pm call and would involve the same cast list. The dial in details for the 4pm call are:

Dial in: 0800 917 1950
Participant's Passcode: 91821252#
(Gill Harris will dial in as Chair)

- The formal QSG call will take place at 6pm. The dial in details are:

Dial in: 0800 279 5946
Participant's Passcode: 7422901295#
(Gill Harris will dial in as Chair)

10) Andy Buck advised that the Risk summit would take place on Monday via telecom and he would request that a conversation is held in advance with the Trust Medical Director to obtain his views on the conduct of the investigation.

11) Lyn Simpson would send a briefing note to Ian Dalton and will request whether he is comfortable for this to be forwarded to the National Directors, the Chairman and the NEDs.

12) Colin Douglas noted that Ministers would need a brief tomorrow / Monday.

NHS England
North Region

"High quality care for all, now and for future generations"

Children's Congenital Cardiac Surgery Risk Summit

Monday 8th April 2013

Attendance:

Name	Title	Organisation
Mike Bewick (MBe)(Chair)	Deputy Medical Director	NHS England
Maggie Boyle (MBo)	CEO	LTHT
Bryan Gill (BG)	Interim Medical Director	LTHT
Stacey Hunter (SH)	Divisional Manager	LTHT
Gill Harris (GH)	Director Of Nursing	NHS England
Lynn Simpson (LS)	Director of Operations and delivery	NHS England
Andy Buck (AB)	Director	NHS England
Damian Riley (DR)	Medical Director	NHS England
Kathy McClean (KM)	Medical Director	NHS TDA
Debbie Westhead (DW)	Compliance officer	CQC
Jacquie Allan (Minutes)	Administration	NHS England

No	Item	Action
1.	**Welcome and Introductions** Attendees were invited to introduce themselves around the table.	
2	**Background and Scene setting** (MBe) thanked all of the organisations and complimented them on their assistance to date. It was agreed that everybody wanted to do the best for the children and that whatever the decision at the end of the meeting it will be consistent with the value of making it safer. A responsibility to develop excellent care, to restore public confidence in, and the reputation of LTHT The aims of the group: o To reach an agreement about children's cardiac surgery o To agree a written/verbal recommendation to Sir Bruce Keogh and Ian Dalton after the meeting	

3	**Impact Analysis** We need to be clear about the recommendation and communications..	GH/LS
4	**Update** We have sort assurance that the management of transfers was safe and being managed effectively and there was capacity in the system . The assurance team saw no immediate concern. The system continues to cope well. Total of 10 infants needed to transfer: 1 x Birmingham (from Sheffield) 1 x Alderhey (from Leeds) 2 x Newcastle (from Bradford and Leeds) 6 x Leicester (from Leeds bed base) Operating as a virtual incident room which will stay in place until further notice. A letter was sent to the 9 organisations advising that we would be looking for support, a further letter will be sent when we are ready to stand the operation down. (BG) – Q / who would lead the conversations with the families re procedures, travel etc? (AB) – A/ This will be led at a local level in partnership with relevant trusts	
5	The Rapid Review in final draft format has been sent out – still awaiting one reply, but the rest of the Stakeholders happy with the content: The review was carried out over 3 days. Staff involved: 10 x Cardiology 3 x Surgeon 2 x Junior Doctor 1 x Anaesthetist 1 x Head of Theatre 17 x Nurses	DR

	Ward 12 ICU	
6	**Organisation Overview** **LTHT** (MBo) All of the staff at the Trust had responded positively to the review and agreed that the challenge was legitimate, no concerns were raised. (BG) Commented that on day 2 he was asked to step out of the room for part of a conversation, and this made him feel uncomfortable as if you are part of the review you should be included in all aspects – he wanted this noting **Review Findings – DR Feedback** Staffing levels – currently running on 4 doctors at Leeds, the average across these services is three. Reminded that mortality reporting is not unique to Leeds 11/12 data now change, was original in alert box, now revalidated moved out MBo – Believed that the Trust was safe to recommence surgery, within a planned schedule and to ensure that the current staff are supported appropriately MBe requested feedback from each agency on the level of assurance received in line with the issues raised in ID letter . **Regional** Considering the information presented, assurance now received that Nicor data had been validated and signed off. Data was confirmed at the meeting. This gave assurance that the unit was not a statistical outlier. • Staff levels comparable, further assurance required on the locum from Europe, regarding MDT input and case mix • Governance – required further assurance of information governance processes and complaints management but these did not reflect any immediate safety concerns • Professional concerns – unable to comment, info not	

	available • Staff Concerns – reported provided assurance, although do need audit person appointing • Public Concerns require further investigations **NTDA** To work with Trust on exported data Stressed that we should not underplay the knowledge of governance – this doesn't not mean the unit is unsafe but the Trust needs to be better at collecting and using information • Professional concerns – unable to comment • Staff Concerns – report provided assurance, although agreed need audit person appointing **CQC** Agreed with comments from other agencies and there are still some patient concerns which still need further explanation Internal Governance – Still some areas which need further exploration – but assured from the conversation that this is in hand No immediate safety concerns	
6	Summing up, agree actions and timescales and confirm whether any participant thinks further actions are required to protect patients Following on from the Rapid Review issues that need ongoing work, we need to decide the best agency to work with the Trust – one agency only needs to take the lead roles. These should be dealt through normal procedures and picked up at future QSG. At the first meeting it was agreed that a second phase would be introduced to report on the following: • Case review Children that have died within the time frame of the audit, but also to include 2012/13 • Case full review in complaints	

	• Referral patterns • Whistle blowing • Revisit other governance areas A virtual QSG will be called to discuss which agency will lead each action. Follow up 14th May 2013. MBe to speak with Sir Bruce re the Trust concern they may be treated differently going forward and scrutinised	
7	**Recommendation** MBe to recommend to Sir Bruce that the unit be reopened from Wednesday 10th April 2013. Verbal recommendation outlined Plan in place to open the unit in a measured and controlled way, with David Anderson continuing to monitor	
8	**Communications plan** A statement to be released through Sir Bruce Keogh if recommendations are agreed. No joint statement to be issued. MBe to contact MBo with the outcome. The decision then to be filtered to all agencies All agencies concurred – silence was requested until formally communicated Going forward it is critical that as partner agencies we communicate what each is doing	
9	**Further QSG** It was agreed that a further QSG would be held in one month's time, chaired by GH. If a further risk summit is confirmed it will be at this time.	GH

NHS England

Our Ref: sg/ls20130408

Maggie Boyle
Chief Executive Officer

Linda Pollard
Chair

Leeds Teaching Hospitals NHS Trust
Leeds General Infirmary

8 April 2013

Dear Linda and Maggie,

I am writing following today's risk summit, chaired by Dr Mike Bewick, that drew together the Trust, NHS England, the Care Quality Commission and the NHS Trust Development Authority, to set out the position of NHS England in respect to the phased recommencement of paediatric cardiac surgery at Leeds Teaching Hospital NHS Trust.

I wanted to begin by thanking you and your colleagues for their engagement with the multi-disciplinary independent team this weekend that has been working to establish the immediate safety of the unit.

Sir Professor Bruce Keogh and I have reviewed the recommendations of today's risk summit and we can confirm that NHS England has accepted the Trust's recommendation, supported by independent experts, that surgery should resume gradually over the next month, starting with lower-risk cases.

The review found that the Trust's data for monitoring surgical results was uniquely poor, triggering concerns about death rates and gaps in information. We expect to see significant improvements to the way the unit monitors the quality of care so that it can be compared with similar services.

We can confirm that the second stage of the review will now begin looking at other areas where improvement may be necessary. This will comprise:

- a review of the way complaints from patients are handled, including the issues raised by the Children's Heart Federation; and,
- completion of a review of patients' case notes over the last three years.

In addition, NHS England, in partnership with other agencies, will follow on issues that have been raised about referral practices to ensure they are clinically appropriate. The findings of this second stage of the review will be considered at a future meeting of the Quality Surveillance Group and this may lead to a further risk summit if required.

NHS England
Quarry House, Quarry Hill, Leeds, LS2 7UE

iandalton@nhs.uk

Yours sincerely,

Ian Dalton CBE
Chief Operating Officer/Deputy Chief Executive

Cc: Professor Sir Bruce Keogh, Medical Director, NHS England
Lyn Simpson, Director of Operations and Delivery, NHS England (Corporate)
Dr Mike Bewick, Medical Director (North), NHS England
Andy Buck, Area Director (West Yorkshire), NHS England
Dr Damian Riley, Medical Director (West Yorkshire), NHS England
Dr Kathy McLean, Medical Director, NHS Trust Development Authority
Malcolm Bower-Brown, CQC

Leeds Teaching Hospitals

Principles for restarting Paediatric Cardiac Surgery/Intervention

There will be a planned re-introduction of Paediatric Congenital Cardiac Surgery at Leeds Teaching Hospitals NHS Trust over a period of 3-4 weeks.

During the first 2 weeks the unit will undertake acute and elective work for those patients with less complex cardiac disease.

During the first 1-2 weeks we will ensure there are always 2 Consultants available to operate together.

In weeks 3 and 4 the complexity of surgery will be increased so that the unit has resumed its full workload.

This approach is to support the surgeons as the service resumes following a pause in surgery.

As per our standard practice, patients who require elective surgery will be discussed at the MDT and planned in the speciality scheduling meeting supported by the service manager. For those patients who need surgery in the next 3-4 weeks a clinical consensus will be reached about the appropriate approach: either operate in Leeds or refer to another centre.

Individual acute referrals will be discussed and a clinical consensus will be reached about the appropriate approach; either operate in Leeds or refer to another centre for the first 3-4 weeks.

As per current practice there will always be a surgeon not scheduled to operate who can provide assistance to colleagues in theatres as and when required. In addition to this we will continue to plan for consultants to operate together depending upon specific patient case mix.

Example of suggested theatre template for Weeks 1 – 4

Week One	**Monday**	**Tuesday**	**Wednesday**	**Thursday**	**Friday**
Theatre Six			STC VSD Closure (Child)	OMJ Sinus Venous ASD (Child) Sternal Wire Removal (Child)	OMJ Sinus Venous ASD (Adult)
Theatre Seven				STC ASD Closure (Adult)	

Week Two	Monday	Tuesday	Wednesday	Thursday	Friday
Theatre Six	OMJ VSD Closure (Child)	STC Resection Sub Aortic Stenosis (Child)	KGW Sinus Venous ASD (Child)	OMJ Partial AVSD Repair (Child)	STC Mitral Valve Replacement (Adult)

Theatre Seven				STC Aortic Valve Replacement (Adult)	

Week Three	Monday	Tuesday	Wednesday	Thursday	Friday
Theatre Six	OMJ AVSD Repair (Child)	STC Pulmonary Valve Replacement (Child) VSD Closure + Inspection of TV (Child)	KGW Mitral Valve Replacement (Child)	OMJ Tetralogy of Fallots Repair (Child)	OMJ Partial AVSD repair (Child) Secundum ASD (Child)
Theatre Seven				STC Mitral Valve Replacement (Adult)	

Week Four	Monday	Tuesday	Wednesday	Thursday	Friday
Theatre Six	OMJ Pulmonary Valve Replacement (Adult)	STC Tetralogy of Fallots Repair (Child)	KGW Tetralogy of Fallots Repair (Child)	OMJ Bi-directional Cavo-pulmonary Shunt disconnect PA (Child	STC Bi-directional Cavo-pulmonary Shunt (Child)
Theatre Seven				STC Pulmonary Valve Replacement (Adult)	