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Leeds
CITY COUNCIL

JOINT HEALTH OVERVIEW AND SCRUTINY COMMITTEE (YORKSHIRE & THE HUMBER)

Meeting to be held in Civic Hall, Leeds, LS1 1UR on
Tuesday, 25th November, 2014 at 1.30 pm

(A pre-meeting will take place for all Members of the Committee at 1.00 p.m.)

MEMBERSHIP

Councillors

J Bromby - North Lincolnshire Council
D Brown - Hull City Council
J Clark - North Yorkshire County Council
D Coupar (Chair) - Leeds City Council;
C Funnell - City of York Council
V Greenwood - Bradford MDC
B Hall - East Riding of Yorkshire Council
J Hyldon-King - North East Lincolnshire Council
M James - Calderdale Council
T Revill - Doncaster MBC
B Rhodes - Wakefield Council
M Rooney - Sheffield City Council
L Smaje - Kirklees Council
H Spence - Barnsley MBC
K Wyatt - Rotherham MBC

Please note: Certain or all items on this agenda may be recorded.

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A G E N D A

Item No	Ward/Equal Opportunities	Item Not Open		Page No
1			**APPEALS AGAINST REFUSAL OF INSPECTION OF DOCUMENTS** To consider any appeals in accordance with Procedure Rule 25* of the Access to Information Procedure Rules (in the event of an Appeal the press and public will be excluded). (*In accordance with Procedure Rule 25, notice of an appeal must be received in writing by the Chief Democratic Services Officer at least 24 hours before the meeting.)	
2			**EXEMPT INFORMATION - POSSIBLE EXCLUSION OF THE PRESS AND PUBLIC** 1 To highlight reports or appendices which officers have identified as containing exempt information, and where officers consider that the public interest in maintaining the exemption outweighs the public interest in disclosing the information, for the reasons outlined in the report. 2 To consider whether or not to accept the officers recommendation in respect of the above information. 3 If so, to formally pass the following resolution:- **RESOLVED –** That the press and public be excluded from the meeting during consideration of the following parts of the agenda designated as containing exempt information on the grounds that it is likely, in view of the nature of the business to be transacted or the nature of the proceedings, that if members of the press and public were present there would be disclosure to them of exempt information, as follows: **No exempt items have been identified on this agenda.**	

Item No	Ward/Equal Opportunities	Item Not Open		Page No
3			**LATE ITEMS** To identify items which have been admitted to the agenda by the Chair for consideration. (The special circumstances shall be specified in the minutes.)	
4			**DECLARATION OF DISCLOSABLE PECUNIARY INTERESTS** To disclose or draw attention to any disclosable pecuniary interests for the purposes of Section 31 of the Localism Act 2011 and paragraphs 13-18 of the Members’ Code of Conduct.	
5			**APOLOGIES FOR ABSENCE AND NOTIFICATION OF SUBSTITUTES** To receive any apologies for absence and notification of substitutes.	
6			**NHS ENGLAND'S REVIEW OF CHILDREN'S HEART SURGERY SERVICES AT LEEDS TEACHING HOSPITALS NHS TRUST** To receive a report from the Head of Scrutiny and Member Development introducing additional information associated with NHS England's Review of Children's Heart Surgery Services at Leeds Teaching Hospitals NHS Trust.	1 - 194
7			**NHS ENGLAND'S REVIEW OF CHILDREN'S HEART SURGERY SERVICES AT LEEDS TEACHING HOSPITALS NHS TRUST - NEXT STEPS** To receive a report from the Head of Scrutiny and Member Development to allow the Joint Committee to consider any next steps in relation to NHS England's Review of Children's Heart Surgery Services at Leeds Teaching Hospitals NHS Trust.	195 - 198

Item No	Ward/Equal Opportunities	Item Not Open		Page No

THIRD PARTY RECORDING

Recording of this meeting is allowed to enable those not present to see or hear the proceedings either as they take place (or later) and to enable the reporting of those proceedings. A copy of the recording protocol is available from the contacts named on the front of this agenda.

Use of Recordings by Third Parties– code of practice

a) Any published recording should be accompanied by a statement of when and where the recording was made, the context of the discussion that took place, and a clear identification of the main speakers and their role or title.

b) Those making recordings must not edit the recording in a way that could lead to misinterpretation or misrepresentation of the proceedings or comments made by attendees. In particular there should be no internal editing of published extracts; recordings may start at any point and end at any point but the material between those points must be complete.

Agenda Item 6

Leeds
CITY COUNCIL

Report author: Steven Courtney
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Report of the Head of Scrutiny and Member Development

Report to the Joint Health Overview and Scrutiny Committee (Yorkshire and the Humber)

Date: 25 November 2014

Subject: NHS England's Review of Children's Heart Surgery Services at Leeds Teaching Hospitals NHS Trust

Are specific electoral Wards affected? If relevant, name(s) of Ward(s):	☐ Yes	☒ No
Are there implications for equality and diversity and cohesion and integration?	☐ Yes	☒ No
Is the decision eligible for Call-In?	☐ Yes	☒ No
Does the report contain confidential or exempt information? If relevant, Access to Information Procedure Rule number: Not applicable Appendix number: Not applicable	☐ Yes	☒ No

Purpose

1. The purpose of this report is to present the Joint Health Overview and Scrutiny Committee (JHOSC) for Yorkshire and the Humber with further information associated with NHS England's ongoing review of quality of children's heart surgery services at Leeds Teaching Hospitals NHS Trust (LTHT).

Background

2. It has been reported that during 2013 a number of concerns were raised regarding the quality of Children's Heart Surgery Services provided at Leeds Teaching Hospitals NHS Trust (LTHT). These concerns led to the temporary closure of services on 28 March 2013, pending an investigation.

3. A Quality Surveillance Group (QSG) was convened by NHS England on 2 April 2013 to oversee the investigation process and at a subsequent Risk Summit meeting (held on 4 April 2013), it was agreed that a two-phase review would be carried out.

Phase 1

4. The first phase of investigation consisted of a 'rapid review', which found no significant or immediate safety concerns and surgery re-commenced on 10 April 2013, while the second phase of investigation took place.

5. It should be noted that, while no immediate safety concerns were identified, the rapid review highlighted a number of recommendations and areas for improvement. Some details of LTHT's actions and progress have previously been reported to the JHOSC.

Phase 2

6. It has previously been confirmed that the second phase of investigation would consist of three specific workstreams, namely:

    - A case note review of the child deaths that had occurred in the period from 2009 to 2012 which was the time period used in the collection of NICOR data (*Mortality Case Review*).
    - An investigation of the experiences, views and concerns of parents and families (*The Family Experience Review*).
    - An investigation of concerns raised by other clinicians in relation to inter-unit transfers and patient pathways *(The Independent Review of Concerns about Paediatric Cardiac Surgery at LTHT)*.

7. It was subsequently confirmed that an 'Overarching Report' would also be produced, drawing together the outcomes and key themes from each of the three specific workstreams.

8. The reports, findings and recommendations from the Mortality Case Review and the Family Experience Report were published by NHS England in March 2014 and were subsequently considered by the JHOSC in April 2010.

9. Both these reports highlighted a number of recommendations and areas for improvement. While the JHOSC received a verbal address on proposed actions against the recommendations, the joint committee has not considered a formal written response and/or progress report against the identified areas for improvement.

Main issues and considerations

10. The main purpose of this report is to present the Joint Health Overview and Scrutiny Committee (JHOSC) for Yorkshire and the Humber with the following information:

    - The Independent Review of Concerns about Paediatric Cardiac Surgery at LTHT (presented as Appendix 1); and,
    - Leeds Teaching Hospitals NHS Trust: Overarching Report about Paediatric Cardiac Surgery (presented at Appendix 2).

11. Both reports were published by NHS England in October 2014 following completion by Verita – an independent organisation commissioned by NHS England to undertake the review and produce its findings.

12. Senior representatives from NHS England, Verita and Leeds Teaching Hospitals NHS Trust have been invited to attend the joint committee to present both reports and help members consider and discuss the associated findings and recommendations.

13. To further assist the JHOSC consider the reports, representatives from other interested parties, including Children's Heart Surgery Fund (CHSF), have also been invited to attend the meeting and assist the joint committee in its consideration of both reports and subsequent deliberations.

Other considerations

14. Following the areas for improvement and recommendations identified from the 'rapid review', the JHOSC has sought assurance regarding the implementation of those

recommendations and associated reporting arrangements. The meeting provides a further opportunity to seek further assurance in this area.

15. Actions against the findings and recommendations from the Mortality Case Review and the Family Experience Report have not been formally reported (i.e. by way of a written report) to the JHOSC. The JHOSC may wish to seek further verbal assurance against the identified areas for improvement and recommendations.

16. Nonetheless, members will consider any further actions/ activity in this area elsewhere on the agenda.

Recommendations

17. To note and comment on the details presented in this report, appendices and matters discussed at the meeting.

Background documents[1]

18. None used

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[1] The background documents listed in this section are available to download from the Council's website, unless they contain confidential or exempt information. The list of background documents does not include published works.

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VERITA

IMPROVEMENT THROUGH INVESTIGATION

Independent review into concerns about paediatric cardiac surgery (the 14 cases) at Leeds Teaching Hospitals NHS Trust

A report for
NHS England

October 2014

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Verita is a management consultancy that works with regulated organisations to improve their effectiveness and levels of service. It specialises in conducting independent investigations, reviews and inquiries.

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Contents

1. Introduction 4
2. Terms of reference 8
3. Executive summary 10
4. Approach and methodology 13

Details of the investigation

5. The concerns raised 17
6. Risk assessment 18
7. Second opinions and referrals 43
8. Delay 54
9. Communication 62

Appendices

Appendix A Report abbreviations 71
Appendix B Letters from Sir Leonard Fenwick to Dr Mike Bewick 72
Appendix C Team biographies 80
Appendix D Terms of reference 83
Appendix E Template document to record views and findings 86
Appendix F List of interviewees 89
Appendix G Documents reviewed 91
Appendix H Glossary of terms 93
Appendix I LTHT’s referral policy 97
Appendix J LTHT’s second opinion policy 98

1. Introduction

1.1 In November 2013 NHS England commissioned Verita to undertake a governance review into concerns about paediatric cardiac surgery at Leeds Teaching Hospitals NHS Trust (LTHT) on behalf of the responsible Quality Surveillance Group (for a full list of abbreviations used see appendix A).

1.2 This review was commissioned against a complex set of circumstances that had culminated on 28 March 2013 with the paediatric cardiology unit at Leeds General Infirmary (LGI), part of LTHT, agreeing to a temporary cessation of surgery as a result of concerns from three sources:

- Mortality data released by staff from the National Institute for Cardiovascular Outcomes Research ("NICOR") in March 2013. The data gave a partially risk-adjusted analysis of patients who died in the 30 days after a surgical procedure and who were operated on in the years 2009 to 2012.
- Complaints and concerns of families of children treated in the Unit and reported to the Care Quality Commission, Sir Bruce Keogh medical director at the Department of Health[1], Children's Heart Federation and Little Heart Matters.
- Concerns relating to patient care expressed to Sir Bruce Keogh by other NHS professionals.

1.3 NHS England convened a risk summit on 4 April 2013 and agreed that investigation of the concerns about the LTHT Unit would be undertaken in two phases.

1.4 Phase 1 would be a rapid review of the LTHT Unit clinical standards, patient pathway management, and clinical governance. This was undertaken by an externally-led team of investigators.

1.5 Phase 2 would have the following components:

(a) a detailed examination of mortality case review of the deaths identified by NICOR by an externally-led team of specialist clinicians
(b) detailed interviews and investigations of parental concerns
(c) an investigation of the concerns raised by other professionals.

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[1] On 1 April 2013 NHS England came into being and Sir Bruce Keogh became the medical director.

1.6 The phase 1 review was undertaken on 5 - 7 April 2013. The review found no major concerns although it highlighted a number of areas in which processes could be improved, and concluded that the unit could resume surgery from 10 April 2013.

1.7 The Mortality Review was undertaken and a report of the findings published in March 2014.

1.8 The parental concerns were investigated by Professor Pat Cantrill and her report, *Family Experience Report – A thematic analysis of the experience, views and concerns of some of the parents whose children received care from Leeds Teaching Hospitals NHS Trust Children's Cardiac Services between 2009 and 2013* (the Family Experience Report) was published in March 2014.

1.9 Our review addresses the concerns raised by other professionals, which is the third strand of the phase two work outlined in 1.5.

1.10 After commissioning this review NHS England asked Verita to also produce an over-arching report identifying any themes from the three pieces of completed work, to identify any lessons to be learnt and make recommendations.

This review/context

1.11 The authors suggest that this report is read in conjunction with the over-arching report. A number of factors make up the relevant background and context and appear only in the over-arching report in order to avoid repetition.

1.12 This report has two versions. There is an unpublished version, which provides detail and analysis of the concerns about 14 cases set out in letters from Sir Leonard Fenwick, chief executive of The Newcastle upon Tyne Hospitals Foundation NHS Trust, to Dr Mike Bewick, deputy medical director NHS England North, on 12 and 18 April 2013 (appendix B), and the dossier included with the letter of 18 April. It includes confidential medical and other information about the 14 patients and includes quotations from our interviews with some parents. This version has the same framework as the unpublished version, much of the same content and the same findings, but does not contain the confidential information.

1.13 Removing all identifying information and not quoting from confidential records limits the extent that readers can follow the case of any particular patient. However, we do not feel that this diminishes the value the report provides or the robustness of its findings, for two reasons:

- the report is about policies and practices at Leeds, and the patient's cases have allowed us to illuminate these policies and practices
- Leeds and Newcastle commented on the factual accuracy of the full, unpublished report, when it was in final draft form, and had material to allow them to identify the patients.

1.14 We looked only at the 14 cases and draw no general conclusions from them about the standards at the unit or the hospital. To set this number in context, 3,849 appointments for children took place at the cardiac centre at LGI in 2013-14 and clinicians from LGI attended 5,672 appointments at clinics elsewhere in Yorkshire. During the same period 397 operations were carried out and 1,104 foetal echoes were recorded. In addition, 203 pacemaker and catheter procedures were carried out. These numbers show a significant increase from 10 years earlier. In 2003-4, 282 operations and 131 catheter procedures took place. The period covered by Newcastle's concerns is about 10 years, so these 14 patients are a small proportion of all those treated during this period.

1.15 However Leeds, as with the other cardiac centres in the NHS, aspires to provide a world-class service, so it is important to try to discover what led to concerns about the 14 cases so that lessons can be learnt to minimise the likelihood of recurrence.

1.16 In some cases we only had medical notes and information from healthcare professionals as evidence, but in others we also had statements provided by the families of child patients, and in six cases we also spoke to families. We were struck by the strength of feeling and sincerity of those families with whom we spoke, and, where relevant, by the consistency between what they told us and what they had written in earlier statements. Some of our findings do not support some of the recollections and beliefs of these families, but this should not be seen as casting any doubt on the sincerity of the families concerned.

Yorkshire paediatric services

1.17 Paediatric cardiac care in Yorkshire is carried out on the hub-and-spoke model, with many patients receiving some of their care at their local district general hospital. Some families are offered ‘open access’ to the children’s ward at their local hospital; i.e. they can take their child to the ward without a referral from their GP or having to go through A&E.

Review team

1.18 Verita is a management consultancy that works with regulated organisations to improve their effectiveness and levels of service. It specialises in conducting independent investigations, reviews and inquiries.

1.19 The review team was led by Lucy Scott-Moncrieff, supported by Barry Morris, Jess Martin and administrative staff from Verita. They were assisted by a clinical advisory panel consisting of Katrina Cooney, Kenneth MacArthur, Anthony Salmon, and Jelena Stojanovic. Their biographies can be found at appendix C.

2. Terms of reference

2.1 The full terms of reference is attached at appendix D. The key points are summarised below.

Overview

2.2 Sir Bruce Keogh has asked deputy medical director Dr Mike Bewick to undertake a review into concerns about paediatric cardiac surgery at LTHT. The external consultancy Verita has now been appointed to investigate the governance processes around the care of children at Leeds, and the specific cases detailed in the letter from Sir Leonard Fenwick.

Aims of the review

2.3 The aims of the review are to:

1. Investigate the governance and communication processes around the care of children at the unit in Leeds, with particular reference to transfers to other trusts

2. Undertake specific clinical reviews of the 14 cases identified in Sir Leonard Fenwick's letter (unless the review team consider they have been adequately covered by previous phases)

3. Determine the actions necessary to secure and assure the safe and effective management of paediatric cardiac services at Leeds

4. Agree how the work of the review will be communicated to patients and public, including the conduct of any necessary patient recall exercises

2.4 In discussion with Dr Mike Bewick, after the start of the review, he agreed, on behalf of the responsible Quality Surveillance Group, that the report on the 14 cases identified by Newcastle should focus on systems and processes, and not on individual clinical decision-making, except insofar as such decisions provided evidence relating to systems and processes. It would also identify any examples of good practice.

2.5 In view of the fact that there is some overlap between our first and over-arching reports, we agreed that in the interests of clarity, any recommendations arising from our findings in this report would be contained in the over-arching report.

2.6 The over-arching report, published at the same time as this, identifies lessons to be learned, and makes recommendations, not only in relation to the 14 cases, but also arising from the Mortality Review and the Family Experience Report. This report will also look at the circumstances that led to the Leeds paediatric cardiac surgery being suspended in April 2013, and will consider any potential or actual wider implications for the NHS arising from any part of the Leeds review and the context and nature of the concerns raised by Newcastle.

3. Executive summary

3.1 Verita was commissioned by NHS England to undertake a governance review into concerns about paediatric cardiac surgery at Leeds Teaching Hospitals NHS Trust (LTHT).

3.2 The concerns arose from three sources:

1. Mortality data
2. Complaints and concerns expressed by families of children treated in the unit
3. Concerns relating to patient care expressed to NHS England from another NHS Trust

3.3 This review addresses the concerns at 3 above. The concerns were set out in letters from Sir Leonard Fenwick, chief executive of The Newcastle upon Tyne Hospitals Foundation NHS Trust, to Dr Mike Bewick, deputy medical director NHS England North. The letter detailed concerns about practices at Leeds, and referred to case summaries of 14 patients transferred from Leeds to Newcastle which were described by Sir Leonard as *"a distillation of our concerns relating to those cases"*.

3.4 At the very beginning of our review we met Sir Leonard and clinical colleagues at the Freeman Hospital, and they provided more details of their concerns.

3.5 The case studies, Sir Leonard's letter and our interview at the Freeman Hospital led us to identify four areas of concern:

- that Leeds assessed the risk of some surgical interventions too highly, and consequently failed to offer suitable treatment and/or failed to make a referral to another centre
- that Leeds delayed treatment or referral to the detriment of patients
- that Leeds was unwilling to make referrals to centres outside Yorkshire, particularly Newcastle
- that there were breakdowns in communication between Leeds and families at points where families needed to make crucial decisions, such that they were unsure of their options.

3.6 We (the authors of the report and the advisory panel) considered all the written and oral evidence provided to us, and concluded that there was evidence in two cases that the risk assessment process had not been satisfactory, that in two cases there had been unnecessary delay in seeking second opinions or making referrals and there had been failures in, problems with, or breakdowns in communication in five cases. These are set out in the body of the report, and findings on each case are collated in the table below.

3.7 The medical records, which contained notes made at the time, showed no evidence that Leeds was unwilling to make referrals to centres outside Yorkshire, nor that it was unwilling to refer to Newcastle in certain circumstances.

3.8 We also found that some of the situations described by families and by Newcastle were not supported by the balance of the evidence.

3.9 In other cases the situations were unusual and did not accord with good practice, but Leeds had no control over the circumstances.

3.10 Our analysis is set out in chapters 6 to 9.

3.11 We fully agreed with the accuracy of the Newcastle case summaries in two cases. In the other cases we considered that the summary did not present the full picture, or we disagreed with some of the assertions in the summary.

3.12 As explained below, we analysed the concerns raised by Newcastle, and allocated them to four categories.

- risk assessment
- delay
- second opinion/referral
- communication

3.13 At the end of our investigation we reached a conclusion on each case in each category, which we set out in the table below. Where we refer to ‘no cause for concern’ we have not made a finding because neither the notes nor our preliminary discussions suggested we needed to do so (see paragraph 4.9).

Category	**Number of cases**	**Reference**
1. Risk assessment		
a) No cause for concern	6	Para 4.9
b) In accordance with good practice	6	Findings 2, 7, 9, 12, 13
c) Unsatisfactory	1	Finding 3
d) Failed process	1	Finding 8
2. Second opinion and referral		
a) No cause for concern	4	Para 4.9
b) In accordance with good practice	8	Findings 15, 19, 20, 21, 22, 23, 25, 26
c) Self-referred	1	Finding 24
d) Process followed	1	Finding 17
3. Delay		
a) No cause for concern	10	Para 4.9
b) In accordance with good practice	1	Finding 29
c) No delay	1	Finding 28
d) Unnecessary delay	2	Findings 27, 30, 31
4. Communication		
a) No cause for concern	9	Para 4.9
b) In accordance with good practice	0	
c) Problem	3	Findings 34, 35, 37
d) Breakdown	2	Findings 33, 38

4. Approach and methodology

4.1 Given the difficulties in the relationship between the Leeds and Newcastle units, as described in the over-arching report, the initial set-up of the review was critical in setting the tone and needed to ensure that all parties participated in the process with constructive intentions.

4.2 Our approach to the work was initially to meet senior management at both Newcastle and Leeds to explain our terms of reference and how we proposed to undertake the work and to try to reassure both organisations that the review would be fair and evidence-based. At their request, Newcastle staff attended the initial meeting with the chief executive and expanded on their concerns about the 14 cases.

4.3 After these first meetings the review team recruited and briefed an advisory panel and then followed three main lines of work:

- interviews with staff at Newcastle and Leeds
- interviews with families of the children involved
- review and analysis of the records provided to us.

Advisory panel

4.4 The members of the panel were chosen for their expertise in treatment and management of babies, children and young people with serious heart defects and/or more general expertise in high-quality hospital systems and processes.

4.5 Our task was not only to examine the nature and quality of the systems and processes in these areas but also to consider whether the processes had been followed in the 14 cases we were asked to review.

4.6 The first meeting of the panel discussed the broad nature of the concerns raised and how best to conduct the review. We were clear that the review was about systems and processes and not about individual clinical decision-making.

4.7 We started by analysing the concerns raised by Newcastle, so that we could allocate them to categories. We considered that all the concerns fell into the following categories:

- risk assessment
- delay
- second opinion/referral
- communication.

4.8 We agreed that the case records should be reviewed in these categories and devised a template document in which to record views and findings (see appendix E). We reviewed the records provided to us by Leeds and Newcastle and individualised the questions on the template to take account of the particular circumstances of each patient. We then provided our panel members with access to all the records and asked them to answer the template questions on each.

4.9 We then met with panel members to discuss their preliminary views on the questions we had asked them to address and to identify any further information that we needed to obtain to allow conclusions to be reached. We obtained this information from our interviews and from further correspondence with Leeds. In some of the cases we agreed there appeared to be no cause for concern in some categories and did not investigate these further.

Interviews

4.10 We arranged interviews with groups of staff at Newcastle and Leeds, and also individual clinicians at Leeds. Interviews were recorded and later transcribed. All interviewees were given a copy of the transcript for them to check its accuracy and, if they wished, clarify anything they had said. Interviewees agreed that excerpts from their transcripts could be used in this report. A list of these interviewees is attached at appendix F.

4.11 We invited all the families of the patients referred to in the Newcastle dossier to meet us to give their views of their children’s care. Six families agreed to meet us. Their interviews were recorded, transcribed and given to them to check. They also agreed that extracts from the transcripts could be used in this report. We are grateful to the families who spoke to us. We know that it was upsetting for them to have to relive painful experiences.

4.12 The Family Experience Report dealt with the experiences of parents of children treated at Leeds, so we have not sought to duplicate that work. We used our interviews with parents to help us look at the systems and processes that affected them and their children.

4.13 Some of the patients are now young adults, and we invited them to meet us if they wished to do so, but they declined. However, we met two of the youngest patients when we interviewed their families.

Documentation

4.14 We sought a significant amount of documentary evidence including the case notes of the 14 children from both Leeds and Newcastle. We or NHS England obtained appropriate consent before we received the material.

4.15 A full list of documents appears at appendix G. We would like to record our appreciation for the co-operation we received from all those from whom we sought information and documentation.

Back to the advisory panel

4.16 Once we had obtained all the relevant documentation and carried out all the interviews, we sent the documents and interview transcripts to our panel and held a meeting at which we reached conclusions on the matters the report needed to address. After considerable debate we reached consensus on all matters and the findings in the report are the views of the authors and the advisory panel.

The report

4.17 We set out in section 5 an account of the individual patient summaries in the dossier of the 14 cases provided by Newcastle to NHS England in April 2013. In sections 6 to 9 we analyse these concerns raised in these summaries using the categories the advisory panel used for assessing the cases.

4.18 Our categories often overlap; for instance, where there has been delay arising from a risk assessment, or an apparent failure of communication regarding a decision to seek a second opinion, this will show up in both sections.

4.19 These cases relate to individuals, ranging from toddlers to young adults, all of whom are alive, and all of whose privacy must be protected. We have been careful not to provide any information, such as age, sex, specific diagnosis and other matters that might make it possible to identify the individuals concerned. We know that removing these details makes the report less vivid, but our first concern must be for the right of the individuals to privacy.

4.20 We have chosen to quote directly from interviews in order to show:

- the complexity of many of the problems and decisions in these cases
- the thoughtfulness of those grappling with the problems
- the reality of the difficult circumstances in which advice was given and decisions were made.

4.21 In each of the 14 cases we reviewed all the evidence; Newcastle and Leeds patient case notes, statements, transcripts, correspondence and any other relevant documents in order to substantiate the points we make. In some cases there was conflicting evidence and when that occurred we discussed this with the expert panel to formulate our findings and make our conclusions based on the balance of evidence.

4.22 NHS England, Newcastle Hospitals and Leeds were given the opportunity to comment on the factual accuracy of the full, unpublished report.

4.23 We invited anyone we criticise to comment on relevant extracts of the full report while it was in draft.

5. The concerns raised

5.1 The concerns raised by other professionals were set out in Sir Leonard Fenwick's letters, and in a dossier that provided details about the care, treatment and referral of 14 children from Leeds to Newcastle. The parents of the 14 patients had agreed to allow Newcastle to raise these concerns with NHS England. The dossier starts as follows:

> *"This dossier has been formulated following discussion of cases within the Newcastle multidisciplinary team and summarises the experience with patients and families from the Yorkshire population catchment area and concerns raised directly with us. Some of these patients have already been treated and others are waiting for treatment at the Freeman Hospital in Newcastle upon Tyne (the Freeman)."*

5.2 12 of the patients had received treatment at Leeds. The other two had been diagnosed before birth with serious heart disorders and their mothers had transferred to Newcastle for their births and subsequent treatment. All the patients are alive. All have undergone complex heart surgery. Some are still toddlers, others are young adults. Nearly all have serious congenital heart disorders which were diagnosed at or before birth, but others were either diagnosed later or they developed a heart problem in childhood. Some have a normal or nearly normal life expectancy and are unaffected by their condition in their daily lives, whereas others have differing levels of disability and a shortened life expectancy.

5.3 Of those who were treated at Leeds, the shortest period of care was five months, the longest nearly 16 years before transfer to Newcastle. Some of the patients returned to Leeds for treatment or, at time of our investigation, were being treated at both hospitals.

5.4 The concerns raised in the dossier included failing to provide timely lifesaving treatment; failure to provide treatment in time to avoid unnecessary disability; reluctance or failure to make appropriate and timely referrals; reluctance to make referrals to Newcastle when requested by parents; overly negative assessments of the risks of surgery; failure to offer appropriate surgery; and putting pressure on mother's to choose termination when severe heart disorders were diagnosed during pregnancy.

6. Risk assessment

6.1 Risk assessment is the process by which healthcare professionals determine the risks of providing or not providing certain treatments. The assessment takes account of the range of available treatments for the condition generally, the likelihood of any of them being of benefit for the particular patient at the particular time, the risk of complications if a procedure is attempted and the comparison of risk and benefit of one treatment over another.

6.2 Once the risks have been assessed, the options for the patient are explained and discussed with them and/or their parents, along with the attendant risks. This communication is covered in section 9.

6.3 We identified three distinct risk assessment processes carried out at Leeds and relevant to the 14 patients:

- risk assessments carried out by a single clinician
- risk assessments carried out by a multidisciplinary team
- risk assessments carried out by clinicians at two different hospitals, both of which are treating the patient.

6.4 Risk assessment is particularly difficult where the patient is a baby or child with a serious congenital heart disorder, for a number of reasons:

- even in similar diagnoses, the physiology of the patients varies considerably, so that a condition that can and should be treated in a particular way in one patient may require a different approach in another
- diagnosing the particular issues for a patient may involve invasive processes that carry their own risks
- paediatric heart surgery is a small specialism, with only about 30 consultant surgeons in the NHS. This reflects the relative rarity of operable conditions. It is therefore sometimes not easy or helpful to use national data on survival rates to guide risk assessment
- paediatric heart surgery is constantly improving; the survival rates are much higher than they were even 20 years ago, so the balance is often not between life and death, as it used to be. A parent told that their child will die without an operation

usually has a straightforward choice. However where the options are not operating and living with considerable physical restrictions but no imminent likelihood of death, or operating in the hope of a much better quality of life but with a real risk of death or serious disability, the decision is much more complex, and it is the surgeon who has to calculate the comparative risks.

6.5 It follows, therefore, that risk assessments are exceptionally complex in this area, and so must be carried out to a very high standard. Paediatric cardiology is a fast-moving and evolving speciality. Conditions untreatable a few years ago are now routinely treated, life expectancy is increasing year by year and survival rates for surgery are higher than they were. For instance, at the time of the Kennedy review[1] into children's heart surgery in Bristol in 2000-01, the average 30 day survival rate nationally was 96.6 per cent. Now, with surgeons treating more complex and demanding problems, the number of operations has risen from 5,943 in 2000-01 to 10,195 in 2012-13, while the national survival rate is 98.2 per cent.[2]

6.6 Cardiologists must keep up to date with developments in this specialism, because they are responsible for continuous risk assessment and for referring a patient for a multidisciplinary assessment at the right time. A Leeds cardiologist told us that they all go to the British Congenital Cardiac Association, which is their national association, and centres describe their experience, and discuss cases. In addition surgeons have both the Society for Cardiothoracic Surgeons and the British Congenital Cardiac Association.

6.7 She went on to say:

> *"There are still a number of conditions where we do not know when it is the best time to intervene and what is the best operation, and so the practice in the country is not the same everywhere. That is probably a good thing, because it allows us to continue to optimise the care for those patients. I think that as long you have regular reviews, then that is justified.*

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[1] The aim of the Kennedy review was to inquire into the management of the care of children receiving complex cardiac surgical services at the Bristol Royal Infirmary between 1984 and 1995 and relevant related issues, and to make recommendations which could help to secure high quality care across the NHS.

[2] Data from the National Institute for Cardiovascular Outcomes Research.

I also think that the practice is not the same in every part of the country, because the patient populations aren't the same. That is increasingly becoming known. There is now a study just starting, looking at co-morbidity of patients, to shed light on that.

I think that there is a lot more openness, because I believe that everyone, ultimately, is professional. We do want the best for our patients."

Finding

F1 The process by which individual clinicians kept up to date with clinical developments in their specialty was orthodox and acceptable.

6.8 We asked how the trust audited risk assessments of individual cardiologists. We were told that:

"A: We have a continual appraisal system. It is definitely something that people will receive.

Q. Therefore, it is incorporated in their overall training as part of an appraisal?

A: Yes, because, I believe you would think if people systematically under-perform in that area, they will have a complaint. Among the matters that will always come up in an appraisal is if there has been any patient feedback. Nowadays, every five years, as part of your appraisal, you have to have a 360 degree feedback from your colleagues, and from patients.

Q. Is it part of revalidation?

A: Yes. I think the issue is that sometimes we feel we are doing a good job, but what the parents or the patient picks up is something that may be different. Again, if this is something that we are made aware of, we can rectify it, but it is actually also about delivering a service in an environment that may not always be sympathetic to that. This is, for example, in clinics that are over-booked, and in notes that are not there. It is not an excuse, but I think that on the other hand, we have to realise that we are under resourced. We have

> *a wish list, and we would like a lot more cardiac nurses, because the ones we have, they work fantastically hard, but we need more.”*

6.9 These assessments at Leeds are carried out without the use of written protocols or guidance, relying on the expertise and professionalism of clinicians.

6.10 We discuss the desirability of formal protocols in our overarching report.

6.11 The Leeds diagnoses and risk assessments of the two patients who were transferred to Newcastle before birth were made by a foetal cardiologist to whom the mothers had been referred by their local hospitals after problems were noticed on routine scans.

6.12 The other 12 patients were under the care of a Leeds cardiologist before transferring to Newcastle.

Risk assessment carried out by a single cardiologist

6.13 The significant risk assessments in most of the 14 cases were made at multidisciplinary team meetings or in discussion with clinicians at other hospitals also treating the patient, and so will be discussed under those headings.

6.14 However, in the cases of three patients in our group, risk assessments were made by individual cardiologists at Leeds.

6.15 In two cases, patients were diagnosed before birth at Leeds and their families decided to transfer to Newcastle before they were assessed at an MDT meeting for treatment.

6.16 One patient was scanned and diagnosed just after 20 weeks’ gestation at Leeds. The Newcastle dossier says that she was advised to have a termination, as her baby had such a severe condition.

6.17 The patient's mother then transferred to Newcastle, so we asked the Newcastle cardiologist who took over the patient's care whether Leeds' assessment was reasonable, based on the 20-week scan:

> *"Yes, it is not an unreasonable assessment. It is one of the most challenging conditions that we deal with. There is a well-beaten track to manage these patients and the outcomes have got better over the years, but it is still not a condition that is easy to deal with…It is one of the more difficult and challenging of the surgeries that we have to do. It is fair to reflect that in your counselling of the family and include that there is an option of termination."*

6.18 The Leeds records show that in the case of the other patient whose mother transferred to Newcastle during pregnancy the cardiologist diagnosed a very severe form of congenital heart disease. We asked the paediatric cardiac specialists on our panel to evaluate the risk assessment of the Leeds foetal cardiologist, based on what was known at the time of assessment, and they agreed with the foetal cardiologist.

Finding

F2 The risk assessments made by Leeds and Newcastle about these two patients were similar on the basis of evidence available at the time, and were in accordance with good practice.

6.19 In the third case, the Newcastle dossier reported that the patient's mother had been concerned about the patient's cardiac status for some time, and that the patient was in a precarious state when transferred to Newcastle. In this case the risk assessment was carried out by the patient's cardiologist alone, and he acknowledged to us that he did not respond quickly enough to evidence of deterioration, and so delayed referring the patient for life-saving surgery. This case is dealt with in detail in the section about delay.

Finding

F3 This case identifies an acknowledged failing in the risk assessment process. If the patient's case had been considered at an MDT meeting, evidence of deterioration might have been picked up sooner. However, deterioration in patients awaiting some life-saving procedures can be sudden, so even an MDT assessment might not have spotted this. It is important to recognise the difficulty in getting the timing right for both referral to a specialist centre and listing for the procedure itself.

Risk assessment at multidisciplinary team meetings

6.20 We asked Leeds to explain their usual process for assessing the needs and risks of surgery and treatment. They told us that surgical risk assessments were carried out at weekly multidisciplinary team meetings and that as many cardiologists, surgeons, nurses, intensivists, anaesthetists and other specialist staff as possible attended these meetings.

> *"We all work together quite well as a department that has a lot of patients that get brought to the MDT because somebody's not quite sure about the way to proceed. There's no rogue, lone operator, people doing things without discussing it with their colleagues, because we all share information quite well….We don't just discuss patients for surgery, we often discuss patients who are difficult and we're not quite sure how best to manage it….. We won't discuss cases unless there is a bare quorum of people available, so a surgeon and a relevant cardiologist. We have liaison nurses sitting in and there were intensive care staff in there this morning, for example, so we have a wide range of personnel who tried to feed in to the MDT. If cases are discussed out of the MDT, which sometimes they have to be in the acute setting, we try to record it in our database so the information is there for a later perusal.. Each cardiologist or surgeon will look after their patient and will come to a decision that I think this patient needs treatment, or I would like to have other people's opinions on whether or not I should be doing anything. Those are the two reasons you bring someone forward... There were differences in the past about the timing at which patients were brought to the surgical discussion, and that's… because there are differences in opinions as to the best timing of some procedures".*

6.21 They also told us:

> *"It was a very open and friendly meeting with …really healthy debate and argument about cases. What is particularly difficult in a specialty like this is that often cases are debated where there is no right or wrong answer because it's so complex, and it's not as if you can go on the internet and look up what happened in another 500 cases just like this because there aren't another 500 cases just like that. And the difficult decisions really are very difficult. I think in those circumstances even the views – perhaps particularly the view of the inexperienced juniors – are really useful to hear. They were quite happy to just speak up, and if they didn't understand why we were arguing about something, they would say 'explain why you're disagreeing about that'. I think it was very healthy'."*

6.22 A Leeds cardiologist told us that parental views are also important:

> *"I believe there was a feeling that if they were not complaining of symptoms, then you shouldn't move them forward. One of the problems there is that the families may be very stoical and actually may accept what, I would consider to be a high level of symptoms, because it has gradually crept up on them, and when they come to review say that they are doing fine. You have to drill down a bit to discover….. symptoms …. Slowing down, becoming bluer, exercise tolerance decreasing, all of those things are key symptoms…. They quite often happen very gradually, and the family adapts. There are still a number of families around, where we have discussed the patient at the MDT and made the decision to go forward for surgery, the family does not want to go ahead with this. This may become apparent when we then see them in the outpatients clinic to discuss surgery. Also at the time of the outpatient consultation, families agreed to it, but when we call them in, we recognise that there are a number of excuses coming up for families not being available. We have had a number of those. Recently, we have leaned on them a little bit more, and we had these patients done with good results."*

6.23 We asked whether, and if so how, the unit monitored the timeliness of referrals to the MDT by the cardiologists. A consultant told us:

> *"People could bring patients to the MDT and there would then be a discussion about the timing of the procedures. The cardiologists would be the gatekeeper for their*

> *own patients. We did not have a process where we would keep a list of all the patients who'd had a Glenn procedure, for example, which was the precursor to the Fontan, and then start banging on the cardiologist's door after five years saying 'where is this patient, why haven't you brought them to the MDT?' We don't have that in place. I can't see us having that in place.*
>
> *Q "Suppose that now a cardiologist brings a case to the MDT and other people in the room think 'you should have done this ages ago'… would that then trigger some kind of debate about looking at others?"*
>
> *A "...If we felt that someone had left someone too long, I think that would trigger a question… I'm thinking back to cases that we've reviewed. We'd try and look for patterns. If we found a condition that we were getting poor results on, or we felt that someone kept bringing VSDs late, or mitral regurgitation, we'd have to replace the valve rather than repair the valve, that would trigger a question about their practice."*

6.24 However, one Leeds surgeon took a different view and told us that MDT meetings were not well organised, that it was difficult to get full attendance, that notes were sometimes not available and that waiting lists and operating lists were not properly managed. We discuss this difference of opinion in the overarching report.

6.25 We are also aware that the rapid review that reported on 9 April 2013 looked at clinical governance processes in the Leeds cardiac unit and found that:

> *"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 team has identified….as an area for improvement…the format of multidisciplinary case discussions"*

Finding

F4 On the balance of evidence presented to us Leeds' MDT decision making is in accordance with standard practice, although there is no national guidance for the speciality. There must always be a quorum for any patient being discussed by the patient's cardiologist and a surgeon, but the more people at the meeting the better. We discuss in the overarching report the desirability of having written procedures for MDT meetings.

6.26 We then turned to the specific risk assessment issues in our 14 cases. Four of the 14 patients had a condition generally treated by a series of three operations (commonly known as the Fontan pathway) and culminating in the Fontan procedure (see appendix H). It does not cure the condition, but it is hoped that it will alleviate symptoms during childhood. It is, however, expected that their condition will deteriorate with time and that further treatment will mean transplantation will have to be considered.

6.27 Views on the timing and prudence of completing the Fontan pathway vary considerably, both internationally and in the NHS. A 2007 NICE report makes recommendations in relation to techniques for the stage one procedure, but no other NICE research or guidance is available. The Fontan pathway comprises at least three stages, each of which is palliative and carries its own risks. Furthermore there are a small number of people who have not completed this pathway and have reached middle age. Others who have had the Fontan procedure have ended up unsuitable for a transplant because of other organ failure associated with this type of circulation. Others again, have had only the first one or two stages for clinical reasons. It will be some time before the data on outcomes for people who have the three operations in early childhood can be compared with those for people whose operations were completed in adolescence, or who did not have the full procedure. This is an area in urgent need of research. Nonetheless, for the period under review, the general practice of the NHS has been to carry out the three stages of surgery within the first few years of a child's life, for those in whom the physiology was deemed acceptable.

6.28 However, completing the Fontan pathway was less common practice in Leeds, during the period under review. A cardiologist told us that clinicians no longer working at the trust felt:

> *"that the Fontan operation was not a good operation. I think it would be fair to say that in some ways it is not a good operation, and Fontan operations do fail. However, I think that by the time I came in 2008, the unit was an outlier in not completing Fontans. The age when you should complete Fontans is not absolutely set in stone, but certainly Leeds was definitely an outlier with regards to the rest of the country. That has now changed….I have taken over some of the clinics, [my colleague has] taken over some. Therefore, there are patients out there who haven't had their Fontans completed who we are coming across and bringing forward. Therefore, there has been a lot of Fontan completions in the last 18 months, compared to, say, the three years before.*
>
> *We have changed the way that we prepare patients for Fontan, with a view to doing a cava-pulmonary sooner, and completing the Fontan sooner.*
>
> *I would say that for that particular operation - for a single ventricle, yes, Leeds was behind, but it was also guided, because at one point when the treatment for hypoplastic heart syndrome first came in, it was seen as an increasingly specialist operation. A few were done initially, and, actually, a number were done successfully. It then seemed to become a more specialist operation, where Birmingham had a major interest in it and the Evelina. Then, more and more came along, because it is actually quite a common condition. It then started to be rolled out again and became part of the common procedures of most surgical units. I think that Leeds didn't catch up at that moment."*

Finding

F5 We agree that Leeds was an outlier in its Fontan approach. It is not possible to say that their approach was wrong because of the uncertainties about outcomes we mention above.

6.29 Our primary concern is with systems and processes, so we asked Leeds whether it was aware at the time that its practice was not in line with much of the NHS, how this practice had arisen, whether it was deliberately engaged in, whether the whole team supported it and, if not, whether it was kept under review throughout this period.

6.30 They told us:

> *"Cardiologist: Some of it's about culture, and how units grow up. The unit here started quite small… started out with a couple of consultant cardiologists and a surgeon, then a second surgeon, and it built up. There are certain protocols that may not have been written down, but just evolve and are understood, and seem quite reasonable. I think the Fontan pathway was one of those…. We took quite a strong lead from our senior consultant surgeon, who wanted to operate perhaps later than some other units, and we also took a lead from our senior cardiologist… who was very experienced, and who was nationally known, was President of the British Paediatric Cardiac Association, set up CCAD, was in NICOR, and served on NICE, certainly the surgeon and he had views about this, and I think to a large extent we had no reason not to agree with those views, so we did, and it worked for us: there weren't any major concerns.*
>
> *…When you are looking at something from the perspective of an adult congenital heart disease specialist, you get a slightly different flavour than from a purely paediatric viewpoint. [The cardiologist] saw adult congenital patients, as did [the surgeon] and there are instances in which a more conservative surgical approach actually produces just as good a result in certain cases as more aggressive surgery… you could look back and recount, certainly anecdotally, cases who had just had an arterial shunt and were still doing very well, or the odd patient who had had no surgical intervention at all, and was doing better than you could have expected if they'd had the Fontan.*
>
> *..If there had been definite evidence that said, you must do this (the Fontan) by a certain age, then that would be very different, but that wasn't the case. It was very much, as long as it was working for you as a unit, that was fine, and I think there's always going to be some variation in timing of surgery. I think that's how it (our pathway) grew up. I don't think there was a conscious decision made, that we were going to do our completions at such and such an age. What we had were patients*

who were relatively well being followed in clinic, whose parents were quite happy to stick with their Glenn or arterial shunt, because they understood that further surgery would carry risk, and they didn't want to take that risk with their child who was relatively asymptomatic."

6.31 A surgeon with international experience recalled being at a meeting with Professor Fontan:

"all the community asked him, do you think the Fontan should be done earlier, or later? He never answered, because nobody knew at that time.

Now the techniques have been improved, we are learning a lot about hypoplastic, and most countries with a good level of this kind of surgery have started to do hypoplastic, so we learn that it probably is better to do the Fontan earlier. In time, it is something that has been changed a lot, and you have to consider that it is a high risk practice… so it's unlikely all surgeons will want to change the practice if they have had good results, because why should I change something if I have good results, if it's working?

Cardiologist: *there is no good randomised data showing that these patients do better, in fact, the groups that described the original Fontan operation, for example in Paris, a world leading centre, they are aggressively anti the early completion of Fontan. The complications that occur for patients once the Fontan is completed…you are not curing these patients, you are not making them normal, you are only swapping one set of problems for another...*

…this specialty is a specialty that's never really had randomised data,.. the culture of the specialty comes from innovation and trying things…. as younger people have come into the department it has moved, and it has moved with discussion, negotiation, talking with other colleagues, bringing people along together and discussing with patients and families as well, and in many instances, if surgeons have not been happy, asking other surgeons to do the operation if it seems the right approach on balance for that individual. I have sent a number of patients out of Leeds for Fontan when surgeons weren't keen to do that operation, but I think the background is really important.

> *…What we have is an evolution of service ….I'm not saying that we're always going to be right, I think we are willing to change and we have changed in this (the timing of Fontan completion), we've evolved, but there is very little evidential data out there, there are no randomised crossover trials…and it makes it very difficult to suddenly change practice if a practice has worked for you. If a practice doesn't, then it's very easy to change. But if it's working –*
>
> ***Cardiologist:*** *The decision-making process was satisfactory, but we've just said, there was a movement to try and change practice, but it doesn't happen by revolution… The general direction of travel was by consensus…..But as a whole, the whole governance system within the NHS has changed massively, so the processes were different in the past, and it's not quite as simple. Now we would be able to say, we do this because we've looked at this, this, this, this and this, it's all there in front of you."*

6.32 In summary, we were told that the former and current approaches on Fontan completion were thought through, discussed and agreed by the MDT but not formally written down at the time or since.

Finding

F6 This process resulted in agreed custom and practice rather than formal policy. However, the outcome of the process is surprising because it resulted in a practice at one end of the range of professional practice at the time. A number of members of the MDT would have trained and worked in hospitals that took a different approach, and it seems at least possible that the views of the most senior members of the team may have been given undue influence. However, this is difficult to judge with hindsight because it is also true that the views of those with the most experience should carry considerable weight.

In view of the fact that the practice was knowingly not in line with standard practice in other units, it would have been sensible for the process of decision-making to have been recorded. Unorthodoxy may be right, but it is likely by its very nature to receive significant scrutiny and those choosing it should be able to produce strong evidence in support of the rigour of their decision-making. This process was not validated through clinical governance.

6.33 Leeds clinicians acknowledged that in some of these cases, as a result of their policy on the Fontan procedure, the treatment some of the patients needed, and/or their referral elsewhere, was delayed beyond what would have been current best practice. This resulted in some of the patients being very physically restricted, including becoming wheelchair users.

6.34 We looked at individual cases, not just those requiring the Fontan procedure, where the assessment included high-risk options at Leeds, and asked our panel to consider whether the assessments were reasonable given the circumstances.

6.35 Where the consequences of high-risk assessments included delays in treatment/referral we deal with these cases in more detail in those sections.

6.36 The Newcastle dossier identified Leeds as having failed to provide treatment for one patient such that the patient was unnecessarily disabled. We asked this patient's cardiologist why the risk of carrying out the third stage Fontan procedure had been assessed as high, and he told us:

> *"There are 2 aspects to risk here; the risks associated with surgery and the post op period and the risks in the longer term of competing a Fontan circulation i.e. if it is the best thing in the long term in this [patient's] case or 'risk vs benefit'. This [patient had a very complex physiology and anatomy].The surgical team felt that these things made the operative risk significantly higher and there were also concerns expressed about the long term for a Fontan circulation with these additional risk factors. Whilst I am not arguing against Fontan completion, we do not know if a Fontan was definitively the correct decision for [this patient] even now. As [the patient's] cardiologist since 2005 I brought [the patient] to [the MDT] more than once and referred [the patient] for a second opinion when it was clear that [the patient's] symptoms were getting worse and [the patient and the patient's family] wished it (prior to that they had not wanted to explore this).*
>
> *There is no doubt at all that* [the patient did not have] *a standard risk profile and that this was not a totally straightforward decision……cases like these are complex and uncertainties can be considerable there are numerous interactions over many years between clinicians, families and patients and in many cases a paucity of data*

> *upon which to really balance overall risk/benefit for a particular individual. There is no absolutely "right" way to handle these cases. Sometimes families genuinely don't want to go down a particular path at a particular time no matter how inconvenient that may seem to those with a different view. This must be respected- all decisions have consequences, none of us know the future for patients, particularly in congenital heart disease.*"

6.37 The patient and the family have not complained to Leeds, nor have they spoken to us, so we cannot know what their views are.

Finding

F7 In this case the risk assessment was completed in accordance with the normal MDT process and appears to have been thorough.

6.38 The Newcastle dossier reports that the parents of another patient were quoted a prohibitively high risk for the procedure the patient needed. The patient had had one operation at Leeds and it was understood that in due course the patient would need a further serious operation.

6.39 Some years after the first operation the parents reported an episode of chest pain. The MDT decided that the patient needed an operation. The surgeon told the patient's parents of the high risk that the patient might not survive it. The patient's mother told us that this was the worst day of her life, as they had believed the risk was comparatively low, and the surgeon told them that it was very much higher, based on his own experience.

6.40 The patient's cardiologist told us:

> *"I never imagined that they would go to the outpatient appointment and get spooked so much, is my honest answer, because the [procedures of this type] that we have done have all been very good. When you go back and look at the data, I don't think I have found any deaths from [these procedures]… I never had any doubts that he would do the operation well and there would not be a good outcome."*

Finding

F8 In this patient's case the risk assessments by the surgeon and the cardiologist were different. These differences should have been identified at the MDT and a consensus reached. The risk assessment process failed on this occasion.

6.41 Another patient had been assessed as too high risk to treat at Leeds, although Newcastle had operated successfully once the patient was transferred there. We asked the cardiologist to explain why the necessary surgery had not been offered at Leeds. He told us that he knew this patient very well, and the patient had already been operated on twice at Leeds. The cardiologist had watched the patient's condition deteriorate to the point where further surgery would be needed

> *"The surgeons here felt that [the patient] would now be very high-risk for surgery, because we were dealing with a heart that wasn't very happy (looking tired) and a [complex procedure] in somebody who had already had two lots of high risk surgery, and we know that constitutes high risk. The feeling was that [the patient] could need ECMO or LVAD support after* [the] *operation, so it would be appropriate for the person to be done in Newcastle or Great Ormond Street*."

6.42 At the time, Leeds did not have the equipment to provide either of these supports, but it now has ECMO equipment.

Finding

F9 In this case the risk assessment was carried out in accordance with good practice.

Risk assessments carried out by clinicians at two hospitals treating the patient

6.43 We asked Leeds who was in charge of risk assessments in these cases, and were told that risk assessment was the responsibility of the clinician treating the patient. We asked how this worked and a Leeds cardiologist told us:

> *"When you are an inpatient in a hospital, you are under the care of that clinician at the time, and the clinician will ask for advice. You were asking earlier about [another] patient and I said sometimes the clinician will be on the other end and they are not happy with your advice, so you end up seeing the patient anyway. The clinician has the right to say, I am really not happy about this because of this and this, and you often do see the patient, because until the patient is in front of you, it can be quite difficult."*

6.44 A consultant at a local hospital offering direct access also explained the system to us:

> *"That is a system we have in paediatrics here, which allows children who usually have complicated or serious medical problems direct access in the sense that if there is a worry their family can ring the ward for advice and, if necessary, the child can come straight to the ward rather than having to go through the normal channels, having to go to the GP or to A&E ...*
>
> *I have many patients who have a cardiac problem. Most of these babies are diagnosed soon after birth or before they are born so, to start with, the parents don't really know what problems to expect. In those early weeks, they might bring them in for fairly minor problems, but then we would see them and reassure them. As they become more confident with the management, they will probably ring up less, and often it is because the children are getting better. So it does depend very much with the family. Some families we would give direct access to because of a particular condition, but hardly ever see that patient because they are well and the family know how to manage it. Some children can be in on almost a weekly basis because the condition means they are very unstable or the family need a great deal of support. So it does vary a lot amongst that group, and there are some families who, as things develop, build up a good relationship with their GP. There are some things the GP is happy to manage and we try not to exclude the GP, so if there are*

minor problems that you would normally go to your GP for, we encourage them as much as possible to make a normal appointment with the GP to avoid a non-serious trip to the hospital… So each family works out for themselves what suits them best…We are fairly flexible in the system…

"...if they are unwell, it is better for them to let us know, come to the ward so they can have an emergency treatment they need and then we would discuss with that specialty whether it is cardiology or whatever else, if necessary ... I can't really think of any examples of times when somebody would have rung us and we would have said you need to go straight to Leeds. We would see them here first and take them there...

***Q:** Does that system work well in your view?*

***A.** Yes, I think it works very well because what you find is children with even quite complex heart problems, particularly when they are babies, most of the problems they come in with aren't directly related to their heart. They may be worse because of the heart problem, but it is normally coughs and colds, tummy bugs, so things that we can quite easily sort out. If we took Leeds as an example of a specialist centre say, if all their patients went to them directly for every little thing, they would be swamped and actually, from a cardiac point of view, the last thing you want is many children with infections coming on to your ward, so I think it suits everybody on the whole ... If there was a question about their specialist management, we would talk to Leeds or whichever hospital they were being looked after in, but many of the minor admissions we wouldn't even routinely discuss with Leeds. We would just sort it out, get them home.*

***Q.** Would there be a named cardiologist at Leeds that you would talk to or would you just talk to the consultant on-call?*

***A.** It depends on the situation. If it is an emergency ... treatment, then we would speak to the on-call team. Say, somebody came in and it was felt that that patient's consultant needs to know about it the next working day, the registrar on call in Leeds would take a message back to [the cardiologist] ... If the consultant, who was on call here, felt the patient needed to go, they would talk to Leeds ... There will* *be situations where it will be very clear that they do need to go to Leeds. They see the sickest patients.”*

Findings

F10 Consultants at both hospitals we spoke to were clear where the responsibility lay in making treatment decisions when care was shared. The evidence suggests that the system worked well and that the specialist centre was appropriately respectful of the views of the generalist centre. However, as we expand on in the section on communication, some families seemed to be unaware about this sharing of responsibility.

F11 This system of risk assessment accords with good practice.

6.45 We considered the cases of two patients who were in their local hospitals at the time or shortly before they went to Newcastle, to see if this system worked properly.

6.46 The first patient’s family had open access to the children’s ward at their local hospital. They became increasingly concerned at the patient’s deteriorating condition and went to the children’s ward with increasing frequency in the weeks before care transferred to Newcastle. The family told us that towards the end of this period they understood that the consultant at the local hospital shared their concern and had contacted Leeds to ask that the patient be admitted as an emergency and that Leeds rejected his request. We asked the patient’s cardiologist at Leeds if she would have responded positively to such a request. She said yes, and that she had done on a previous occasion when the local hospital consultant was concerned about the patient’s health. She confirmed that while the patient was in the local hospital the key responsibility was that of the local clinicians, who could seek her advice but were not bound to accept it. If they had said that the patient needed to come to Leeds, she, or her on-call colleagues, would have accepted this, and responsibility for the patient would have been transferred to Leeds.

6.47 We spoke to the patient’s consultant paediatrician at the local hospital and a consultant colleague who was on duty there when the patient was transferred to Newcastle. The paediatrician explained that he probably saw more of the patient than the cardiologist did, because he saw the patient in his own clinics as well as on the ward and in the joint clinics with the Leeds cardiologist.

> *"There was a plan for moving forward. First of all, [the patient] was having more scans in Leeds, and then they were going to plan what surgery to offer, so that all seemed to be in hand really. I think in the weeks leading up to [the patient] being transferred to Newcastle [the patient] had more admissions. There was plenty of discussion with the family and with Leeds that the appropriate things were happening. [The patient] was having a scan and they were going to review the scan, and then discuss it at a surgical conference so, from my point of view, I felt that things were happening. Although [the patient] was in and out quite a bit, I remembered that quite often when [the patient] came to the ward [the patient] was relatively well and it was often this reassurance of [the patient] being assessed by us on the ward to check there wasn't any acute problem that needed [the patient] to go to Leeds. I think there may have been a time when [the patient] did go to Leeds a couple of weeks before…"*
>
> ***Consultant colleague**: "Most of the time [the patient] comes in and goes home the next day. Some days there was nothing to do."*
>
> ***Q**: "[The patient] saw [the cardiologist a few days after] the scan had been done, but they didn't have the results of it… There was a surgical conference [three weeks later]."*
>
> ***The patient's paediatrician**: "And certainly from my point of view, at that time, that seemed to be fine. I remember [the patient] was coming in and out quite a bit at that time of year, and there would be some times when we would perhaps speak to Leeds and there would be other times when we checked [the patient] over and [the patient] was fine and went home again, and perhaps they just wanted that reassurance of having [the patient] checked over. In the time going up to when [the patient] went to Newcastle, clearly, they were getting more anxious, and I think we did end up probably speaking to Leeds more than we had done previously, partly to reassure ourselves and partly to reassure* [the] *family that yes, we have spoken to Leeds, they do know what the situation is, and agree whatever plan needs to be done. So that was the few weeks leading up to that time."*

Q: *"When we spoke to [the patient's] Mum and [family member], they were very clear about the fact that they were becoming increasingly anxious because they thought that [the patient] was very dangerously ill, and they seem to think that you might have agreed with them and that you were pressing Leeds to take [the patient] in and that Leeds were saying sorry, we do not have a bed."*

The patient's paediatrician: *It would partly depend on who saw [the patient] at the time. For example, from my point of view, seeing [the patient] more often, I was perhaps less worried in the sense that I had seen [the patient] on some good days and bad days and wouldn't be as worried. When you have a child with a complicated cardiac problem, some of the other doctors on call, who perhaps didn't see [the patient] as much, are going to have a lower threshold for ringing Leeds for advice. Certainly, from my recollection, I was quite happy with the plan that they were going to do the MRI, they were going to review that and then plan what surgery. I also know that if at any point we had said we wanted [the patient] over, if [the patient] needed to be transferred, I am sure Leeds would have taken [the patient].*

Q: *And if you had decided look, you really do need to see [the patient]….*

The patient's paediatrician: *Yes…there was a weekend where [the patient] was quite unwell and did go to Leeds for a few days...*

Q: *Do you think the family understood the relationship between you and Leeds?*

The patient's paediatrician: *Yes, I think so. Certainly, I had plenty of discussions with them about the plan and, like I said, there were times when they were worried and we spoke to Leeds, and we would communicate back that we had had a discussion with Leeds. To me, I don't remember it being particularly any different to any other patients I have had in terms of how we work with Leeds. Certainly, they usually came to us first with the direct access, which gives me the impression they were quite happy for us to see [the patient] and do that initial assessment, knowing that we would talk to Leeds if there was a problem".*

6.48 The local hospital nursing notes have an entry that shows that they were well aware of the patient's state of health, had carried out a risk assessment and had had a careful transfer of care to the ambulance crew who had been booked to take the patient to Newcastle.

6.49 The ambulance belonged to a private company that the Yorkshire Ambulance Service called on when needed. The ambulance was equipped for A&E, with the same provision as an NHS front-line ambulance, including oxygen. It had two crew, a driver and a fellow crew member, a qualified paramedic who travelled in the back of the ambulance with the patient and the patient's mother.

6.50 We contacted the driver of the ambulance that took the patient and the patient's mother to Newcastle from Leeds. The driver was the chief executive of the company and a qualified ambulance technician.

6.51 The driver remembered the journey well, because it was unusual to go so far.

6.52 He recalled that they passed the patient and mother in the corridor outside the ward when he arrived at the local hospital, not realising who they were. Staff introduced them. The patient was walking, and seemed *"reasonably cheerful in the circumstances"*. The driver recalls being told about a 'wrangle' about which hospital the patient was to go to, but could not recall if it was the mother or ward staff who mentioned it.

6.53 The driver explained that they phoned Newcastle when they left the district general hospital and were asked to bring the child straight to the children's ward at the cardiac centre. The journey was uneventful and the ambulance crew observed no signs of deterioration in the patient. When they arrived at Newcastle they followed their usual practice and took the patient to the ward on the ambulance stretcher.

6.54 He said they had radio communication with the Yorkshire Ambulance Service (YAS) and that if the patient had deteriorated or if they had felt that the patient needed urgent attention, they would have contacted YAS to get directions to the nearest suitable facility.

6.55 Also, if they were worried about the patient as they approached Newcastle, they would have rung the ward to see if the patient should be taken directly to A&E on arrival. The driver saw no need to make such a call and the patient was delivered to the children's ward as originally agreed.

6.56 We discussed the patient's arrival with Newcastle, who told us that the patient had been very blue on arrival at the ward:

> ***Newcastle**: 'I had to take [the patient] to theatre at seven o'clock in the morning to do an operation, because [the patient] nearly died. The patient was transferred to the intensive care unit and we had to do an operation, starting at seven o'clock, an operation which … [the patient] could have had electively a few months ago."*
>
> *… **Q**: If [the patient] had not come to you and had remained at [the local hospital], would [the patient] have died?*
>
> ***Newcastle**: [the patient] would have died. I am surprised [the patient] did not die because they transferred [the patient] without oxygen, a two hour journey"*

6.57 Newcastle's nursing notes show that the patient arrived at 11.30pm and was treated with oxygen. The following day the patient was very tired and slept for most of the day, but was able to play for short periods. The plan was for the patient to be transferred to the paediatric intensive care unit (PICU) following invasive diagnostic procedures. The intensive care unit discharge summary shows that the patient was admitted to the PICU on the morning of the fourth day of admission, having had the diagnostic procedure, during which the patient's oxygen levels dropped profoundly. This resulted in the patient being hand ventilated. The patient was then operated on as indicated by the diagnostic procedure.

Finding

F12 Neither Leeds nor the local hospital consultant paediatrician thought that the patient needed emergency treatment, although Leeds agreed that the patient needed surgery within a few days. The Newcastle notes showed that the patient received surgery on the fourth day after admission, which suggests that the Leeds/district general hospital assessment had been accurate, and the joint assessment process with the local hospital had worked well.

This is reinforced by the fact that the surgery that the patient had in Newcastle was one of the options the patient's mother was offered at Leeds.

6.58 The other patient whose case raised issues about the effectiveness of risk assessments where the patient was receiving joint care was a patient at Leeds who was being monitored over a number of years to see whether the time had come for a necessary operation. The Newcastle dossier reported that the patient's mother was unhappy with the treatment plan which she perceived as delaying providing active treatment whilst she observed a persistent deterioration in the patient's condition. The patient was advised by Leeds not to engage in strenuous activity but otherwise lived normally. The patient's mother had felt for a number of months that the patient's health was deteriorating but said the advice the Leeds cardiologist gave her was that nothing had changed to justify organising the operation. Five weeks after a routine outpatient appointment with the cardiologist, the patient was admitted to the local hospital after experiencing worrying symptoms.

6.59 The patient's mother recalled that the local hospital, after carrying out a scan, felt that the patient was very ill, and should be transferred to Leeds the next day for surgery, but that when the local hospital spoke to the Leeds cardiologist on the phone he did not consider the patient could have gone downhill so quickly since he had last seen the patient.

6.60 The records of the local hospital show that the local hospital did contact the Leeds cardiologist, who gave advice. The patient was kept in overnight and discharged home the next day. About three weeks' later, at the patient's mother's request, the patient was referred to Newcastle as the patient's mother did not want the patient to have to wait for a routine appointment at Leeds.

6.61 The patient was seen at Newcastle a few weeks later, had a palliative procedure a few months' later and a major operation about a year after the referral to Newcastle.

Finding

F13 In this case the risk assessment, and communication between Leeds and the local hospital were in accordance with good practice.

Conclusion about risk assessment

6.62 Risk assessment processes were generally in line with accepted NHS practice but sometimes mistakes were made. We make recommendations about the risk assessment process in the overarching report.

7. Second opinions and referrals

7.1 In this section we consider the cases that seem to reveal an unusual referral process.

7.2 The orthodox method of transferring care from one team to another is by referral between cardiologists, so that all relevant information can be transferred as well. It is also acceptable (but not ideal) for a referral to be made by a GP to a cardiologist. In such a case, contact would need to be made by the new cardiologist to the previous one, so that relevant information could be provided to the new hospital.

7.3 Leeds provided us with a note about its current referral policy for paediatric heart patients (appendix I). It shows that heart transplant patients are referred to Newcastle or Great Ormond Street Hospital; patients with pulmonary hypertension to GOSH; patients with hypoplastic left heart syndrome to Birmingham or Evelina Children's Hospital in London, the two centres with the highest volume of cases; and for a few conditions, such as congenitally corrected transposition, to Birmingham, which has particular expertise in this procedure. The policy is dated April 2013 but Leeds told us the process had been custom and practice for the past 10 years.

7.4 Other referrals are made by individual cardiologists and surgeons to colleagues they know and trust, but this is custom and practice, rather than a formal policy.

7.5 Leeds has a second-opinion policy that is given to all parents of cardiac patients and appears at appendix J. This shows that parents can either ask the cardiologist or GP to request a second opinion. The policy was written in 2010 and updated in April 2013, but we have not seen any earlier policy.

7.6 We asked Leeds how they would respond if a parent specifically asked for a referral to Newcastle. We were told that this request would be respected.

Finding

F14 The second opinion and referral policies are in accordance with good practice.

7.7 In two cases the initial referral to Newcastle was directly by the parents. We looked at these to see if there was evidence of any breach of Leeds' referral policy.

7.8 The first patient had a diagnostic procedure which was discussed at a MDT meeting a month later, at which point the patient was placed on the acute list for surgery.

7.9 However, in the meantime the patient's family had grown increasingly anxious that Leeds was underestimating the seriousness of the condition and the need for urgent surgery. They went online and contacted a support group for parents of children with heart problems who had been treated at Newcastle. Some of these parents became worried about what they were told and contacted Newcastle. Nurses from the unit there told us:

> *"The first thing that happened… was I started to get emails of conversations that parents were having on Facebook, parents from all over were taking snapshots of this and sending it to me saying 'We are very worried about [this patient]… could we do anything?' At this point I advised the parents to speak to [the patient's family] and to get a referral, ask for a second opinion, not necessarily from Newcastle, but they could have a second opinion from another unit.*
>
> *I then had another email from a parent saying that [the patient] had deteriorated… They were worried again, [the patient] wasn't receiving any care and they were really, really worried at this stage.*
>
> *In the interim to this, one of the parents, who is part of this virtual group, had given [the patient's] mum [Newcastle liaison nurse's] contact details, her telephone number, and so at the time when I was being bombarded by emails from our parents who were talking with other parents not just from our region but from all over the country, [a liaison nurse] then received a phone call from Mum… "*

7.10 The nurses told us that they had talked to the patient's mother, who was desperate about the patient's deteriorating health, which Leeds did not seem to be acknowledging. They spoke to their on call cardiologist who said that if Leeds would agree the referral, they would take the patient immediately.

7.11 The hospital records show that there was considerable communication between the hospitals and with the family over a period of two days. When the family confirmed that they wished the patient to be transferred at once to Newcastle, and when Newcastle confirmed that they had a bed waiting, arrangements were made for the patient to be transferred to Newcastle the same day, and Leeds arranged for the patient's data and images to be couriered to Newcastle.

Finding

F15 The referral process was unusual in that it involved the intervention of other parents and a provisional acceptance by Newcastle without input from those treating the patient at Leeds. However, once the patient's mother asked for the referral, Leeds acted promptly to ensure a smooth transfer, sending all necessary information to Newcastle as soon as possible.

7.12 The Newcastle dossier reports that the mother of the other patient where a self-referral was made, had to insist on care being transferred to Newcastle. This patient was diagnosed before birth with a severe cardiac disorder with a possibility that no surgery would be possible and that without surgery the baby would not live long.

7.13 The day after the diagnosis the family sent an email to other units, asking for help.

7.14 The Leeds records show that a few days after the diagnosis the cardiologist wrote to Birmingham Children's Hospital asking for a second opinion, which she said the mother had asked her to request. In this letter she mentioned that the mother had an appointment at Newcastle a few days later to find out what could be offered there.

7.15 However, in the meantime the patient's mother had been to Newcastle and had a scan, and had been accepted for care by Newcastle. A few days later Newcastle confirmed to the mother's GP that the mother had chosen to transfer her care and that of her unborn child to Newcastle, and a few days after that the mother informed Leeds of her decision.

Finding

F16 The parents in this case made a wide-ranging appeal for help from other units, to which Newcastle responded, accepting the mother for treatment.

7.16 In several cases the referral was made by the GP, which is an accepted route of referral and mentioned in the information Leeds gave parents. Good practice suggests that where a GP makes a referral, the cardiologist should be involved so as to ensure that the doctor to whom the referral is made has all necessary information.

7.17 The first of these patients had undergone two unsuccessful attempts by Leeds to carry out an operation. The parents had been told that no further surgery was possible at Leeds, and that in due course the patient would be referred to Newcastle for a life-saving operation, but that it was too early to do so at the time this decision was communicated to them.

7.18 Subsequently the patient's parents asked their GP to make a referral to Newcastle for a second opinion and potential consideration for the life-saving operation. The correspondence in the notes shows that Leeds co-operated fully in sending data, though they had difficulty finding all of it and other data was on corrupted discs and so inaccessible.

7.19 The patient's parents did not make a complaint, nor did they talk to us, so we do not know why they went to the GP for a referral rather than asking the Leeds cardiologist to refer.

Finding

F17 The referral was by the GP, in accordance with accepted guidance to parents, and the cardiologist assisted the process once she was aware of the referral.

7.20 In another case of a GP referral the family explained that they had been told that the risk to their child of the operation that they knew was necessary was very much higher than they had expected it to be. They had been too upset at the time to ask for a second opinion, but later wanted to do so and were directed to Newcastle by someone who knew of its reputation. They asked their GP to make the referral, and subsequently told the patient's cardiologist what they had decided to do. The cardiologist recalled:

> *"I referred to Newcastle. Mum rang me because she was really worried about the high mortality rate, and they had spoken to a friend… who is one of our paediatricians with an expertise in cardiology whom I know very well. He knows some of the Newcastle team and he said: why don't you get a second opinion? Therefore, mum rang me and asked me to make the second opinion".*

7.21 At this stage she was not aware that the GP had already made the referral.

7.22 We asked the cardiologist to comment on the parents' view that a second opinion should have been offered without having to be asked for when the risk quoted was so high. She agreed, and said that if she had known what the surgeon was going to say about the level of risk she would certainly have offered a second opinion without being asked.

Finding

F18 The cardiologist would have asked for a second opinion if she had been aware of the surgeon's advice to the family. The referral by the GP was in accordance with good practice.

7.23 The next patient was born with a heart condition that was likely to need a corrective operation at some point. The timing of the operation would depend on the symptoms that developed. The Newcastle dossier reports that the patient's mother asked for a GP referral because she was unhappy with the Leeds treatment plan.

Finding

F19 The referral was by the GP in accordance with the second opinion policy.

7.24 Another patient underwent complex heart surgery at Leeds within the first few months of life, and the parents knew that further surgery would be necessary. Subsequently, after the patient had had a diagnostic scan, the parents were informed that the operation they had hoped to carry out would not be possible, as the patient's physiology would not allow it.

7.25 The parents were extremely upset and asked for a second opinion. Leeds was happy to arrange this, but was unable to agree to the parents' requests about how this would be done. Leeds made a referral to another centre in the orthodox way, but in the meantime the parents sought advice from a charity, which recommended Newcastle.

7.26 The mother asked her GP for a referral to Newcastle for a second opinion; Newcastle accepted the patient and Leeds responded by sending all the data when requested to do so.

Finding

F20 The patient's parents specifically wanted to avoid a referral by Leeds because they were concerned that any doctor to whom a referral was made would give undue value to the professional opinions of the Leeds cardiologist, with which the family disagreed. Asking their GP for a referral was therefore sensible and in accordance with Leeds guidance to parents.

7.27 We examined the remaining cases where there was concern that the referral/second opinion policy might have been breached.

7.28 The Newcastle dossier reported that the next patient's family had said they had encountered obstacles when seeking a second opinion. The Leeds records show that the patient was considered by the multidisciplinary team at Leeds, which decided that the necessary surgery was high risk, and the patient should be referred elsewhere. We asked the cardiologist how the referral was made:

> *"Where we see a potential need for ECMO support we tend to refer patients to Newcastle unless there are particular complicating reasons why a paediatric setting,*

like GOS, would be better. There are occasions where that would be the case, but this wasn't one of those.

We discussed [the patient] and I made a referral about six days after [the MDT], after I had met and spoken to the family in clinic; so basically we had the JCC discussion, I saw them a week later in my clinic, talked to them about what we needed to do, what our surgeons had said – that we were potentially looking at [an unusual alternative] if they (Newcastle) felt the [conventional option] was such a high-risk procedure that it would be better to go down that route.

They weren't really happy with [the new option] at the time, because I don't think they were in quite the right place for that, but I said "Let's refer you there". I wrote to [Newcastle cardiologist] having already called him first (as I usually will do); I recollect I got on the phone to him and said "We have this difficult case because [the patient] has these [other] problems as well, what do you think?" I can't remember the complete conversation I had with him because it was quite a while ago, but that is the way I would do it.

I would ring up first and say "Can you help us out with this one, we have a problem with?", and then I put it in writing and send them down the pictures and stuff like that so they wouldn't have to repeat the investigations – so I don't think this case was any different…. I think the family were very happy with our care. Certainly I have seen them since… I have not had a problem, and I suppose that is how it is meant to work isn't it? You discuss a [patient] because [they] had already had surgery here, the feeling was that [the patient] would be high-risk, maybe [the patient] is better off being treated in a centre where they can offer additional support with ECMO transplantation, and it is appropriate. If we had done the operation here and it had all gone wrong we would have wished we had sent [the patient] off to a centre that did ECMO."

Finding

F21 The referral was in accordance with the second opinion policy.

7.29 It is not clear from the dossier what Newcastle felt the problem was with the next case, but in interview with us it emerged that they felt Leeds was trying to avoid referring this patient to them. The patient was born with a serious heart condition, exacerbated by other congenital problems which made cardiac treatment very difficult. The patient needed a complex operation that the NHS had carried out only twice before on someone so young.

7.30 The greatest expertise in treating children with this combination of difficulties is in another country, and both the family and the Leeds team were in contact with experts in that country to seek advice. The Leeds team hoped that the leading expert might come to Leeds to carry out the operation. They also contacted a surgeon elsewhere in the UK whom the foreign expert had recommended.

7.31 The foreign surgeon said it would be best if the patient was operated on in his hospital. The total cost of travel and treatment would be in six figures. The family immediately started fundraising, and at the same time Leeds applied to the NHS Exceptional Treatment Panel. The panel said that before deciding whether to fund the treatment abroad, enquiries should be made within the NHS. It suggested a list of surgeons to contact, with a well-known cardiac surgeon being top of the list. Leeds promptly contacted him and followed his advice that a referral should be made to Newcastle.

Finding

F22 It was good practice to consult the experts for advice, and to invite them to come to England to carry out the operation. It was also good practice to take the advice of the well-known surgeon.

7.32 The Newcastle dossier shows that the family of the next patient reported that the patient was put on a palliative care pathway and the parents were unhappy with this.

7.33 The notes show that the patient had a diagnostic procedure to see whether a particular operation could be offered, and Leeds concluded that the patient's physiology made this operation impossible at that stage. The family obtained advice from a charity which recommended Newcastle for a second opinion, and Leeds then made the referral at the family's request. In the referral letter the Leeds cardiologist explained why they did not think the hoped-for operation was possible, and said they had explained to the family that there were other, short-term, procedures that could be undertaken until the patient was old enough for an unconventional and problematic, but more long-lasting procedure. The cardiologist hoped that the family would be reassured by the second opinion from Newcastle.

7.34 Subsequently Leeds wrote to Newcastle, asking them to take over the patient's care, as the family were moving much closer to Newcastle than Leeds.

Finding

F23 The referral was in accordance with the second opinion policy.

7.35 The Newcastle dossier said that the mother of the next patient had had to insist on care being transferred to Newcastle from Leeds. This patient was diagnosed before birth at Leeds, and the patient's mother had referred herself to Newcastle, which had accepted her.

Finding

F24 The patient's mother had been accepted by Newcastle before Leeds was asked to make a referral.

7.36 The Newcastle dossier reported that the next patient's mother had asked for a referral while the patient had been on the waiting list for surgery, and Leeds had agreed. This took place in April 2013, when the unit had suspended surgery, and the mother had lost confidence in Leeds. The referral had taken place promptly.

Finding

F25 The referral was in accordance with the second opinion policy.

7.37 The Newcastle dossier reports that the next patient's mother wanted surgery to take place at Newcastle but Leeds refused to transfer the patient and the operation took place at Leeds. It goes on to say that the patient was transferred to Newcastle some time later as the patient's mother lost confidence in the on-going care the patient was receiving.

7.38 The Leeds records show the cardiologist and surgeon made a number of attempts to obtain the mother's consent for necessary surgery, but that she was desperately anxious about the risks, which she knew included death and brain damage. She agreed in principle, to the operation, but then put forward reasons why the series of dates offered were unsuitable.

7.39 During this period, which lasted nearly a year, there were discussions about getting a second opinion, which Leeds was happy to facilitate, but which did not take place as the patient's mother was still unsure about what best to do. During this time the mother had been in touch informally with Newcastle, where the nurses had urged her to stay with Leeds.

7.40 In the end, with the patient's mother still undecided, a date for surgery in Leeds having been set again, and the patient's mother still thinking of seeking a second opinion from Newcastle, Leeds explained to her that they would willingly make a referral to Newcastle, but that if they did so they would take the patient off their waiting list and not offer another date. As a result, the patient's mother agreed to the surgery at Leeds, which took place successfully.

7.41 We did not speak to this patient's mother because she did not respond to our invitation to meet. The Newcastle team liaison nurse told us:

> *"[The patient's] mother requested to come over and have a look, a visit, to Freeman to see if she liked the unit and would be able to get on and manage at Freeman ... She wanted to come to Newcastle, but I did actively encourage her, if she had been given the surgical date in Leeds, to stay in Leeds, because she did have family … it would be easier for her to manage in Leeds. She specifically said that she had not lost faith in the surgeon in Leeds. She went back to Leeds and the next thing we know is [the patient] had had the operation."*

Finding

F26 We found no evidence that Leeds failed to follow its policy of complying with parents’ wishes for a referral to be made to their choice of hospital.

Conclusion about second opinions and referrals

7.42 The medical records, which contained notes made at the time showed no evidence that Leeds was unwilling to make referrals to centres outside Yorkshire, nor that it was unwilling to refer to Newcastle in certain circumstances.

8. Delay

8.1 A number of parents complained to Leeds and to us that Leeds had unnecessarily delayed making referrals.

8.2 We considered:

- whether any systems and processes unnecessarily delayed referral when this was requested by a patient or parent
- whether systems and processes existed to ensure that treatment or referral were not unnecessarily delayed when there had been no request from a patient or parents.

Whether any systems and processes unnecessarily delayed referral when a patient or parent requested it

8.3 We know that a number of parents had complained to Leeds, told Newcastle, or told us that their request that their child be referred to Newcastle had been resisted and that this had caused delay.

8.4 This would appear to amount to a breach of the policy respecting a parental request for a referral to Newcastle. We therefore looked in detail at the cases where this had been asserted.

8.5 In one case Leeds had explained to the patient's family that the patient would need a life-saving operation that would require a referral to Newcastle when the time was right.

8.6 The patient's mother was informed that the patient was moving towards needing the operation. She told us that she was torn between her recognition that her child needed the operation and her fear of the risks, which were considerable.

8.7 The Leeds records show that the cardiologist was raising the possibility of a referral to Newcastle many months before the referral actually took place. He told us that the patient's mother had had great difficulty accepting that her child was moving towards needing the procedure:

"At the time I broached the subject… mum was still not willing to talk to [the patient] about it. She found it too difficult, and I felt that we had time because [the patient] was asymptomatic...

... So here we had somebody who was on very little medication at that stage... We weren't at the stage for the [procedure], but eventually we would be...

At that point I said "Maybe talking to one of our psychologists would be the way forward", because you can't go sending people off for [the procedure] if they don't want it... "...tomorrow you having [the procedure]". [The patient] wasn't stupid, and would know that something was happening. I thought we had a time to work the family through coming to terms with the fact that [the patient] would need [the procedure]….

... However, I believe what happened was that after initially failing to meet with the psychology team they eventually did, and then they came round to the idea that "Yes, it (referral for the procedure) was appropriate", and then I made the referral...

... It is interesting that I was away just before [the patient] went on to Newcastle and my pacing clinic was run by a colleague of mine. When I came back from holiday [he] said "We had a bit of a to-do with [the patient], they weren't keen to go up to Newcastle even at this late stage", and it was certainly the case that he was having to convince them, "No, you do need to go up there, [the patient] has deteriorated", but at that stage the parents, or mum certainly, was still not wanting [the patient] to go off for assessment. I have read [my colleague's] letter and it clearly says that he was having to convince her. So it has always surprised me that mum says that she was having to push for it [the referral] all the time because that was not the impression at any stage...

... I suppose the criticism that could be levelled at me is that I should have pushed the parents harder at the beginning, but I did think that we still had some time – and I wanted to bring the family along, because they needed to be there to support [the patient].

> *... maybe I should have pushed harder, but that would have meant potentially if the parents weren't there having Social Services involved, which would never be a good outcome for [the patient]..."*

8.8 A Newcastle surgeon confirmed to us that Leeds cardiologists generally made timely referrals, and that this late referral was "*an outlier… I can tell you there are a number of cases where they have referred appropriately, so I don't think they have a huge problem of knowing when to refer for [this procedure] in general, because it is difficult in any case*".

8.9 The cardiologist did not notice that during this period the patient's condition deteriorated, such that by the time of the referral she was in urgent need of the procedure.

Finding

F27 In this patient's case there was an inappropriate delay as the clinical needs of the patient were not sufficiently monitored while Leeds was seeking parental consent for the referral.

8.10 The next patient where delay was alleged was diagnosed before birth at Leeds, the patient's mother was scanned at Leeds and a serious heart condition was diagnosed. The cardiologist considered that the baby should be delivered at Leeds if the mother wanted to continue with the pregnancy. The mother was scanned again six weeks later and the Leeds records show the cardiologist suggested that in light of the results, the baby should be delivered in a centre where more specialist surgery could be carried out.

8.11 At this meeting the mother asked why she could not go to Newcastle, which also carried out the surgery. The records show that the cardiologist explained that the recommended centres were the national centres with the greatest experience, but that if she wanted to be referred to Newcastle, the cardiologist would do this. The notes record that the patient's mother chose Birmingham, so the cardiologist made the referral there three days after the second scan.

8.12 The Leeds records show that the mother told Leeds two weeks later that she had decided that she wanted the baby to be delivered at Newcastle. The cardiologist made the referral by letter on the following day.

8.13 The mother made a complaint to Leeds that the referral was not made until she was five or six weeks before her due date. However, the records show that the Leeds cardiologists made the referral a day under eight weeks before her due date.

Finding

F28 There was no unnecessary delay.

Whether systems and processes existed to ensure that treatment or referral were not unnecessarily delayed when there had been no request from a patient or parents

8.14 We identified two cases where Leeds had reached the conclusion that further surgery was impossible in Leeds and that the patients would need to go to Newcastle for a very specialist procedure. These patients transferred after some years to Newcastle, who then carried out the surgery that Leeds had considered impossible. We looked for evidence to see if the delays in referring had resulted from poor systems or good systems poorly used.

8.15 Leeds confirmed that it had no formal or informal system or process for triggering a referral or a request for a second opinion in cases where they felt there was no more they could do surgically. Our focus, therefore, was on whether there had been unnecessary delay in these cases and, if so, whether a formal process could have prevented it.

8.16 In the first case the patient had undergone complex surgery at Leeds, and it was understood by Leeds and the family that another operation would probably be necessary at some stage. The patient was regularly monitored by the cardiologist, who noted that the patient's health was gradually deteriorating. The question of the next operation was actively discussed after diagnostic tests several years later. The conclusion was that the operation was too difficult and therefore too risky, and that the patient's only surgical option was transfer to Newcastle for the very specialist operation when it became appropriate.

8.17 Two years later the patient's cardiologist sought a second opinion to see if the 'too risky' operation could be legitimately attempted. Diagnostic investigations were carried out, and a Leeds surgeon agreed that the surgery was now possible, but high risk, and that, because of the patient's anatomy, he would know only once the operation had started whether it would be possible to carry out the procedure. He confirmed he was willing to offer the operation to the patient.

8.18 A few weeks later, at the parents' request, the patient was referred to Newcastle for assessment for the specialist operation. After further tests, the decision was made to attempt the operation that Leeds had offered, with the specialist operation an option if it did not work. The Newcastle cardiologist wrote to the Leeds cardiologist that if the operation did not have long term benefits for the patient there would still be the option of the specialist procedure, for which the patient was suitable. He also acknowledged that although the operation could be carried out at Leeds, it would be safer to do it at Newcastle in case the specialist procedure was needed as back up, and because Newcastle had specialist equipment that Leeds at that time did not.

8.19 The procedure was successfully carried out at Newcastle, over a year after referral.

8.20 We asked why the Leeds cardiologist why he waited two years before getting a second opinion. He told us:

> *"The surgical team felt the operation wasn't going to be possible. If I had completely shared that view I wouldn't have brought [the patient] back to [MDT] or sent [the patient] for a second opinion… My memory was that at this stage the parents were not keen. I had had discussions with them about where we were going with [the patient] and the family did not want to consider further intervention, particularly if it meant risk. [The patient] also had symptomatic benefit from [other causes] and ultimately I had to persuade them it was better to obtain a second opinion- [The patient], when older, wanted this too.*
>
> ***Q.** Why did it take so long for the patient to be reassessed?*

> *A. My memory was that the family were happy with the decisions, and on a number of occasions we discussed investigations and treatments that they did not want to have done-decisions that I respected.*
> *Ultimately it wasn't until [the patient] was old enough to really speak up… that this changed- then [the patient] was clear about what [the patient] wanted and we acted".*

8.21 The patient and the patient's parents declined our invitation to talk to us so we do not have their views on the events described.

Finding

F29 Leeds did not seek a second opinion for some time but continued to discuss options with the family. Leeds intended to refer the patient for the specialist operation in due course, and this was recommended to the parents about nine months before they agreed that the referral should be made. Both teams agreed with the decision that the agreed operation should take place at Newcastle.

The timing of the transfer was in accordance with good practice.

8.22 The next patient had successful surgery at Leeds and it was anticipated that another operation would be necessary in due course. An attempt was made to carry out this operation a few years later, and a further attempt was made a few years after that. On each occasion the operation was begun but the surgeon was unable to complete it because of the patient's anatomy.

8.23 Before the first unsuccessful attempt, the cardiologist had asked two other hospitals to carry out the procedure because the patient had been on the waiting list for so long. They were not willing to do so. Before the second attempt, and at the request of the patient's parents, the cardiologist sought a second opinion on the suitability of making a further attempt and the second-opinion doctor confirmed his support for the plan.

8.24 After the second failed attempt, the cardiologist considered that the only surgical option for the patient would be referral to Newcastle for a specialist operation, but that it was too soon to consider it.

8.25 The parents then asked their GP to refer the patient to Newcastle, and a Leeds cardiologist, writing to the GP, said that he welcomed the opportunity for Newcastle to provide a second opinion.

8.26 The operation that Leeds had been unable to complete was carried out successfully at Newcastle a little over a year later.

8.27 We asked the cardiologist why he had not sought further opinions after the second unsuccessful operation*:*

> *"I can't remember exactly what went through my head at the time…I had great respect for [the surgeon's] expertise and huge experience. I had already asked the views of others, and what I do remember asking [the surgeon] why was it not possible this time and he said it was not possible to do it without interfering with the blood from his right lung, I think, but from one of his lungs, so in that setting I thought well having been there and done it and planned it, also all the surgeons involved felt that it looked as if it was technically possible, there are occasions when things that looked possible with investigation, and when the surgeon actually gets there he finds there are subtle anatomical difficulties which you can't get round. That is what [the surgeon] said to me when he said he couldn't do it on that occasion. I think, at that stage, we almost certainly felt we had pretty much exhausted the second opinion route; we'd been down that, and hadn't just been to cardiologists, it had been to surgeons as well.*
>
> *I'm not sure it wouldn't happen again today. We really had asked for an awful lot of opinions here. It's not as if I would be shy about asking for another. You've seen from the records for this particular case that had I absolutely no problem in asking for second or even third opinions. I think that the information I was given was that this was technically impossible because of fine abnormalities of detail which were not visible on the MRI scan or cardiac catheterisation; I had no reason to ignore that advice, really."*

Findings

F30 In this case there was unnecessary delay.

F31 There was no formal system or agreed process in existence to ensure that patients who would not be offered further surgery at Leeds were considered for referral elsewhere.

8.28 This is a complex area. Some patients have no conventional surgical options, or exhausted the ones they had. If parents then ask for a second opinion from another hospital, this will be arranged, but it seems excessive to suggest that a second opinion should always be sought when a service can offer no more surgical interventions. The resource implications would be considerable, and time spent providing an opinion that nothing could be done might be better spent providing treatment for someone who would benefit from it.

8.29 Nonetheless, this case shows that a patient considered untreatable in one hospital is treatable in another. We consider in the overarching report what could be done to ensure that such patients are actively managed.

Conclusion about delay

8.30 Some delays in operating were caused by Leeds' approach to the timing of the operations, which was acceptable but unusual compared to the standards at the time in other cardiac units in the UK. Other delays were caused by the views and wishes of families, which were respected in accordance with good practice and policy. One delay revealed an inadequacy in the second opinion policy.

9. Communication

9.1 We reviewed the standard of communication between the staff and parents in these cases. We consider that the standard was consistent with what would be expected in other units, based largely on the NHS experience of the advisory panel, in that parents had face-to-face meetings with healthcare professionals when necessary; liaison nurses attended meetings when significant information was being imparted or significant decisions were being discussed; patients were written to and copied into letters sent to other healthcare professionals such as their GP; and they had ready access to the liaison nurses if they wanted to discuss anything.

Finding

F32 The formal communications between professionals and families was consistent with normal practice in the NHS.

9.2 However, communication cannot be judged only from the standpoint of the one providing information; it must also be judged from the position of the recipient of the information. We identified a number of occasions where communication was unsuccessful, and either the healthcare worker failed to understand the parent or vice versa.

9.3 Our impression was that all the people we spoke to, parents or professionals, wanted to communicate properly. We therefore consider it worthwhile to look at the areas where communication was not successful in the hope that our examination might help overcome or at least minimise problems in the future for the benefit of all centres.

Breaking bad news

9.4 All these families had been through the dreadful experience of being told that their child has a serious heart condition.

9.5 We were told that the foetal team was given training in antenatal counselling and feedback from parents and patients was reviewed at annual appraisal.

9.6 Parents suddenly found themselves in the new, alien and perhaps frightening environment of hospitals; risk assessments; discussions with medical experts; and having to make decisions about matters about which they knew only what they had just learnt - decisions that could mean life or death for their child.

9.7 Over time, they became knowledgeable about their child's condition, and expert in what their child needed, but the early days were confusing.

9.8 A number of them had to deal with the information that their unborn child would need lifesaving open-heart surgery shortly after birth but that the baby might not be suitable for it or might not survive it. The mothers in these cases were given information about terminating the pregnancy and had to decide, sometimes within a few days, whether to continue with the pregnancy.

9.9 When a mother has to make a hugely important decision, the cardiologist has an obligation to be clear about the possibilities, so that she knows the consequences of whatever decision she makes. The cardiologist must not be directive and must be as objective as possible.

9.10 Healthcare professionals understand that in these situations mothers may perceive that they are being pressurised into having a termination and that if they continue with their pregnancy the cardiologist disapproves of their choice.

9.11 The very fact of the diagnosis puts them under pressure; these mothers are made aware that if they continue with the pregnancy they can expect a difficult and worrying time, as they care for, protect and fight for a child who may nonetheless die before adulthood.

9.12 These mothers may interpret even the most objective guidance as the personal view of a cardiologist.

9.13 One of the mothers who transferred to Newcastle before her baby was born told us that she felt she was strongly and unprofessionally pressurised by the cardiologist to have a termination as the scan had revealed very serious, life threatening, problems to her baby.

She also said that the cardiologist expressed strong disapproval when she said she would not have a termination.

9.14 The Leeds notes show that on the day of the scan the cardiologist had written to the mother's GP setting out the options she had discussed with the mother; having the baby and going the surgical route, having a termination, or having the baby and not choosing surgery, which would mean a short but comfortable life for the baby. The surgical option was mentioned first in the letter.

9.15 It is hard to reconcile this apparent open mindedness by the cardiologist with the recollections of the patient's mother, who seemed to be reliving events in some distress when she told us of her experience.

9.16 The cardiologist told us: "*This is a patient who I saw more than once and had telephone conversations with so I recall it really well. I find this really difficult because I find that some of the allegations are really upsetting. I deal with people in this situation all the time and I haven't used those words. I can absolutely, clearly say I haven't used those words.*"

9.17 The cases we looked at where a mother felt pressurised or disapproved of by the cardiologist are only a small proportion of the cases where bad news of this kind was broken to a pregnant woman.

9.18 We do not know how many others felt pressurised, and, if so, whether their perception changed over time. We also do not know how many women felt that the bad news was broken well to them, and who felt properly supported in whatever decision they made.

9.19 It may be that amongst those cases where the women felt well treated there will be clues as to how such an outcome could be achieved for the mothers in the cases we have looked at, who felt so strongly that they had been pressurised into deciding on a termination.

9.20 We discuss this further in the over-arching report.

Finding

F33 There was a communication breakdown.

Discussing risks and benefits of treatment options

9.21 This is another area fraught with the risk of communication failure.

9.22 Staff and parents who spoke to us confirmed this understanding of the difficulties of these meetings.

9.23 The mother of one of the patients told us how frightening it was being told by the surgeon not only of the risk of death from an operation, but also the risks of stroke, brain damage, and other problems. It was also difficult for her that the surgeon referred to the operation as being palliative, which to her mind was associated with dying.

9.24 The records show that there was no liaison nurse present at the meeting with the Leeds surgeon where these matters were discussed, nor were the parents contacted by the liaison nurse after the meeting to discuss what had been said in the meeting.

Finding

F34 The liaison nurses should have contacted the family after the meeting with the surgeon.

9.25 In another case, the patient's mother was told of all the risks of having a particular procedure, which she explained to us was very frightening.

Finding

F35 The patient's mother did not understand why she was being given complex and frightening information, nor what she was supposed to be doing with it.

9.26 A cardiologist told us:

> *"We talked last time about the difficulties of consent and how it isn't a one-off thing. I have been reflecting on some of the patients who die where the families struggle. As you said last time, it doesn't matter whether the mortality is 50%, 5%, 1% or 0.1%, if it is your child that it affects. The consent process, putting mortality into perspective for an elective operation for a patient who is apparently completely well is really difficult. For someone with a Ross where you have aortic regurgitation, they are apparently well but you know that, if you leave them, you may miss the boat and they may end up with an irrevocably damaged heart, trying to get that balance across to the parents is difficult. Also the tick list, which is what consent has now become in that you have to go through death, stroke, renal damage, brain damage and so on, is really brutal for parents. I have sat in with the kindest surgeons and you know they have to go through it all as it is a genuine risk. At the same time, they have to try to balance it by saying, despite all of those risks, we still believe that this is the right thing to do. I believe that the consent process for parents is brutal, particularly for the parents of a child who is asymptomatic."*

9.27 These two examples and the comments of the cardiologist show how easy it is for miscommunication to occur in stressful situations. We discuss in the over-arching report what might be done to minimise the risk of miscommunication.

Communicating care planning

9.28 The patient's care pathway in some of the cases we investigated was uncertain for many years. This is an inevitable consequence of having to wait and see how a child develops before being able to say when and whether an operation might be necessary, and, if so, which would be best. This uncertainty was difficult for some families.

9.29 Generally, the Leeds approach was to delay operations if the patient appeared to be coping reasonably well without. The thinking was that all operations carry a risk and that some may help the patient for only a limited number of years, after which a heart transplant will be the only option, a procedure that is itself risky, requires complex post-operative management and holds an uncertain future.

Finding

F36 This approach is within the range of reasonable professional practice.

9.30 The uncertainty around their child's care pathway caused considerable stress to some parents. One patient's mother complained to Leeds that she had been told that her child would not need another operation until a particular symptom became more obvious, which might be soon or might not be for years. This meant she was anxiously looking all the time to see if this symptom had become more prominent, and was very frequently asking other people for their perception as well.

Finding

F37 The family did not find the information they were given to be helpful.

9.31 The family of another patient told us that they were desperately worried that their child's increasing obvious signs of ill health, including becoming increasingly blue, did not seem to be given due weight with the clinicians for the patient.

9.32 We had the following exchange with the cardiologist:

> **Q:** *"Is it very dangerous for a baby to be very blue?*
> *A: Well, it depends on why they are blue.*
> *Q: What happens here is that [the patient] was pretty blue by the end.*
> *A: You can be blue and well, or you can be blue and poorly.*
> *Q. Right. If you are becoming increasingly blue, is that a bad sign?*
> *A: Some of our children do get increasingly blue because you expect it as they grow and that is what happens. It is often a sign that they are getting towards surgery. Some of our children stay a steady state of blue. Some of our children get pink when*

they get worried. So you can be blue and well and there are children throughout the whole world who function, go to school and who are blue.

Q. *As one of the mothers said about her child, 'Sometimes she looks like a little Smurf when she comes in!'*

A *Yes, exercise will make you a lot bluer and then you rest and become pinker again. That is often why you can get quite marked swings in saturations because it depends on what you are doing. Infections can make you bluer, so there are many different things.*

Q *: So a blanket blue does not equal very poorly?*

A *No.*

Q. *Because that was obviously what the family here felt, that [the patient] was getting bluer so [the patient's] life was more and more at risk, but that was not necessarily your view? Your view was that [the patient] was moving towards needing surgery?*

A: *Yes, it was definitely that [the patient] was moving towards needing surgery, which is why we discussed – For a particular operation…, you need them to be a certain size to improve the success of it…That is why [the patient] was of that age, because that is the right age to do the sort of operation that [the patient] had."*

Finding

F38 The family did not understand the logic of the Leeds approach, and Leeds did not fully appreciate how frightened and anxious the family was. This amounts to a failure of communication.

Social media

9.33 A few years ago, much was made of the opportunities that the internet gave for people to explore and learn about matters of interest and concern to them. Healthcare workers grew accustomed to having discussions with patients who came well primed with questions gained from an infinitely greater resource than their local library could offer. Now we have social media as well, and anyone with access to the internet can share their concerns and obtain support, information and advice from others.

9.34 Access to social media can benefit the family of a baby or child with a life-threatening or life-shortening condition. They can share experiences; get responses from other families who have been through the same experience; get coping advice; and all the support an online community can offer.

9.35 The families of children with congenital heart defects have a number of such online communities. Some cover a particular geographical area (such as the Children's Heart Association), some are for the families of children with particular conditions (such as Little Hearts Matter), and some are for the families of children being treated at a particular hospital (such as the Parents' Group at the Children's Heart Unit at the Freeman Hospital in Newcastle).

9.36 However, information on the internet may be good or bad, and advice on social media can create difficulties as well as solve problems.

9.37 One of the features of the complex congenital heart defects we looked at is that they are all different. Some of the patients may share a diagnosis but their anatomies - cardiac, vascular and pulmonary - differ.

9.38 These patients have different treatment needs, as we see from the variety of medications, therapies and operations each has received. So it would be a mistake for anyone to assume that an operation that has helped a child with a particular diagnosis, carried out at a particular age, will necessarily be suitable for another child with the same diagnosis at the same age.

9.39 The benefit of sharing similar experiences, of being in the same situation as other families with a child with a similar condition, can become a problem if the individuality of each child's clinical needs is not understood, or if someone has their own agenda.

9.40 For instance, we saw online correspondence between a member of one patient's family and the mother of another child with heart problems who was treated at Newcastle. This mother makes diagnostic and prognostic suggestions as well as abusive derogatory and hostile comments about Leeds. There is no evidence that the author of the comments had personal experience of the service provided at Leeds.

9.41 Such comments can only have undermined this patient's family's confidence in the Leeds clinicians.

Conclusion

9.42 We accept that the formal methods of communication between Leeds and the parents in these cases was in line with standards in other units. However, the standards expected of healthcare units treating children with severe and long-term healthcare problems need updating to take account of the changes in expectations, approaches, access to information and availability of social media over the last 20 years.

9.43 We discuss in the over-arching report some approaches that might work.

Appendix A

Report abbreviations

ECMO – Extra Corporeal Membrane Oxygenation (see also appendix H)

GOSH – Great Ormond Street Hospital

LGI – Leeds General Infirmary

LTHT – Leeds Teaching Hospitals NHS Trust

LVAD – Left Ventricular Assist Device (see also appendix H)

MDT meeting – Multi-Disciplinary Team meeting

NICE – National Institute for Health and Care Excellence

YAS – Yorkshire Ambulance Service

Appendix B

Letters from Sir Leonard Fenwick to Dr Mike Bewick

The Newcastle upon Tyne Hospitals
NHS Foundation Trust

Headquarters
Freeman Hospital
High Heaton
Newcastle upon Tyne
NE7 7DN
Tel: 0191 233 6161

LRF/109/1

12th April 2013

Dr M Bewick
Regional Medical Director
NHS England
4th Floor
3, Piccadilly Place
Manchester
M1 3BN

In Confidence

Dear Dr Bewick

Further to the meeting here in Newcastle on 3rd April 2013 and when I handed over on a need to know basis the draft dossier that the senior health care professionals were bringing together. I am writing to now formally disclose the dossier of case histories which it is felt warrant further consideration from a quality of care and treatment perspective.

At the meeting you explained why time was of the essence hence the need to have disclosure of this document.

You will note that there are some fourteen patients where parental consent has been secured to release this information to NHS England.

If called upon the healthcare professionals involved are prepared to explain and address the issues and questions that may well arise therefrom.

Please do not hesitate to come back to either myself or Mr Andrew Welch, Medical Director in this respect.

Yours sincerely

Sir Leonard Fenwick CBE
Chief Executive

The Newcastle upon Tyne Hospitals
NHS Foundation Trust

Headquarters
Freeman Hospital
High Heaton
Newcastle upon Tyne
NE7 7DN
Tel: 0191 233 6161

LRF/AW/109/1

18th April 2013

IN CONFIDENCE

Dr M Bewick
Regional Medical Director
NHS England
Blenheim House
Duncombe Street
Leeds LS1 4PL

Dear Dr Bewick

I am responding to your letter of 15th April 2013.

We have previously provided you with a document detailing the patients who have come to our attention having been under the care of the Leeds General Infirmary (LGI). This document was a distillation of our concerns relating to those cases.

We would wish to clarify that this is not the first time some of these issues have been raised. We previously outlined concerns in a witness statement for the Judicial Review held in the High Court. London in February 2013. Arising out of an internal review of the cases being referred from Leeds, we were most understandably left with no choice but to pinpoint at a national level the increased frequency and urgency of clinical problems associated with the quantum caseload cohort that was presenting under less than normal circumstances (see Exhibit 1). We felt that this was entirely appropriate to bring to the attention of those who have responsibility for standards of care within the NHS. In essence the much heralded ‘Duty of Candour’ was being exercised.

We should also point out that, but not directly related to this caseload scenario, that we did raise concerns as to the availability of surgical expertise at a particular point in time when it became known to us that one of the Paediatric Cardiothoracic Surgeons was “suspended” from operating in Leeds and also with the most senior Consultant Paediatric Cardiothoracic Surgeon being away on annual leave with the consequence being that the only surgical expertise for children with congenital heart disease was via two locums. This would be regarded as a rather unusual situation hence we felt obliged to raise this at a senior level in the Commissioning Board. We now know that also at this time there were some fundamental concerns surrounding surgical intervention outcomes at LGI.

The concerns we wished to highlight to your goodself regarding practice by the team at the LGI does not relate to surgery outcome per sé, although we are aware that this continues to be an issue for NHS England. The patients scheduled serve to suggest that there are issues with how LGI has dealt with certain categories of patient and in particular the pathways when the intervention is deemed under the given circumstances to be too high a risk and when the Leeds team suggested to parents/carer that a palliative care route was the most appropriate route to follow.

Arising out of our review of the caseload there was a dawn of realisation things were not as they should be, at least from our perspective.

The pattern that has emerged with Leeds is very different to the practice observed in other Centres who refer to Newcastle. The sequence of events in some cases begins with a fetal diagnosis of a relatively complex lesion and in other cases at the time when further surgery as part of staged surgical pathway is being contemplated.

At whichever decision making point, the information that appears to have been relayed to the family is that even though the child is often symptomatically unwell or at risk of major deterioration, the operative risk offered at LGI is deemed to be too great to contemplate. At this juncture, either in the fetal or surgical pathway, communication appears to break down and this is evidenced by the information given to us by many families, and as can be seen by the history of the individual cases. Instead of the Leeds team seeking second professional opinions in a proactive way, the families appear often to be left in a dilemma and in a most uncertain situation in terms of treatment options. In some cases, the information we have been given by the parents is that a palliative care pathway has been suggested as the most appropriate way forward when, as shown again by the cases involved, alternative surgery was in fact available and subsequently undertaken with successful outcome in another Centre.

The specialist staff here in Newcastle do acknowledge that some of these cases are rather challenging to say the least however different treatment strategies could be reasonably offered. However, the very distinct route of palliative care, which appears to have been the understanding of some families, or alternatively no active treatment whatsoever, does not appear to be defensible when realising that after eventual referral to another Centre and at times via a circulatory route intervention was successfully achieved.

There is recognition within Paediatric Cardiology that for Centres to confidently perform complex surgery, the caseload volume and casemix does need to be such that these operations can be undertaken on a relatively frequent basis. The whole healthcare professional team needs to function as an inter-active unit and it goes without saying that the treatment pathway involves more than just the operating Surgeon. At the Freeman Hospital we have continued to develop our expertise over the past decade and we do realise that taking on complex cases can take considerable planning and skilled inputs at each and every level.

We very much believe that the challenges encountered in the pathways of care in Leeds would be unlikely to manifest in Centres who carry out these complex procedures on a regular, more routine basis. In an era where operative results are of paramount importance there may well be a tendency to avoid taking forward care and treatment regimes for patients perceived to be of a "higher risk".

It is only fair that complex surgery, if appropriate, is available to all and irrespective of geography and if Centres who do not perform such surgery on a regular basis are going to remain open, it will be imperative that pathways for assessment in more experienced Centres are put in place.

We do not wish to criticise individual Clinical Practitioners but many of the problems encountered justify the very basis of the now frustrated 'Safe & Sustainable' endeavour to rationale such service provision. We are concerned that this rather entrenched scenario where there is reluctance to offer complex surgery locally shall remain.

There are some additional issues raised through review of these cases:

1. LGI does not undertake the full repertoire of evidence based interventions and procedures which are performed in most other Centres.

2. LGI sends some of these complex cases (1 above) to other Centres in the UK.

3. Despite not operating on such cases (1 above), there have and it does appear to be, a yet to be resolved issue apropos excess mortality and failure to consider morbidity.

4. As an example the number of patients undergoing a Fontan completion appears to be low in comparison to other Centres in the UK and some of the cases we highlight raise the concern that the families have been offered a palliative care pathway when conventional surgery could have been (and subsequently was) offered by another Centre (Exhibit 2 refers)

5. LGI do not currently have expertise in undertaking ECMO – a procedure which is now seen as essential to Centres carrying out complex infant cardiac surgery

6. The parents report a reluctance to refer patients out of the Yorkshire region and this has resulted in delays in delivering what we believe to be the most appropriate care and treatment.

Here in Newcastle we take no satisfaction whatsoever in highlighting these concerns. We recognise that many of these problems are a function of a system where Centres operate on relatively small numbers of complex cases rather than individual operator expertise. We have stated on a number of occasions that we are very happy to help in tackling waiting lists and the interventions so obviously called for in complex cases hence hope that we shall be perceived as constructive in bringing about more effective national planning and well informed commissioning.

We have obtained consent from all parents in this case study document for disclosure of information to you and this information is attached (Exhibit 3 refers). We are aware from these parents that most have already either individually or as a group raised their most fundamental concerns with the Care Quality Commission (CQC) and also the Independent Reconfiguration Panel (IRP) within the last few months therefore we can only assume many of these concerns are being addressed accordingly in a timely and fully informed manner. In this context however, we have received no follow through contact from either CQC or IRP.

Since July 2012 we have done everything that we can to engage with Leeds at an Executive/Board level. Sadly such approaches have been rebuffed pending the outcome of the High Court action.

Please do not hesitate to come back to me on any issues of detail or interpretation.

Yours sincerely

Sir Leonard Fenwick CBE
<u>Chief Executive</u>

Exhibit 1: Timeline of Patients from Leeds to Newcastle upon Tyne

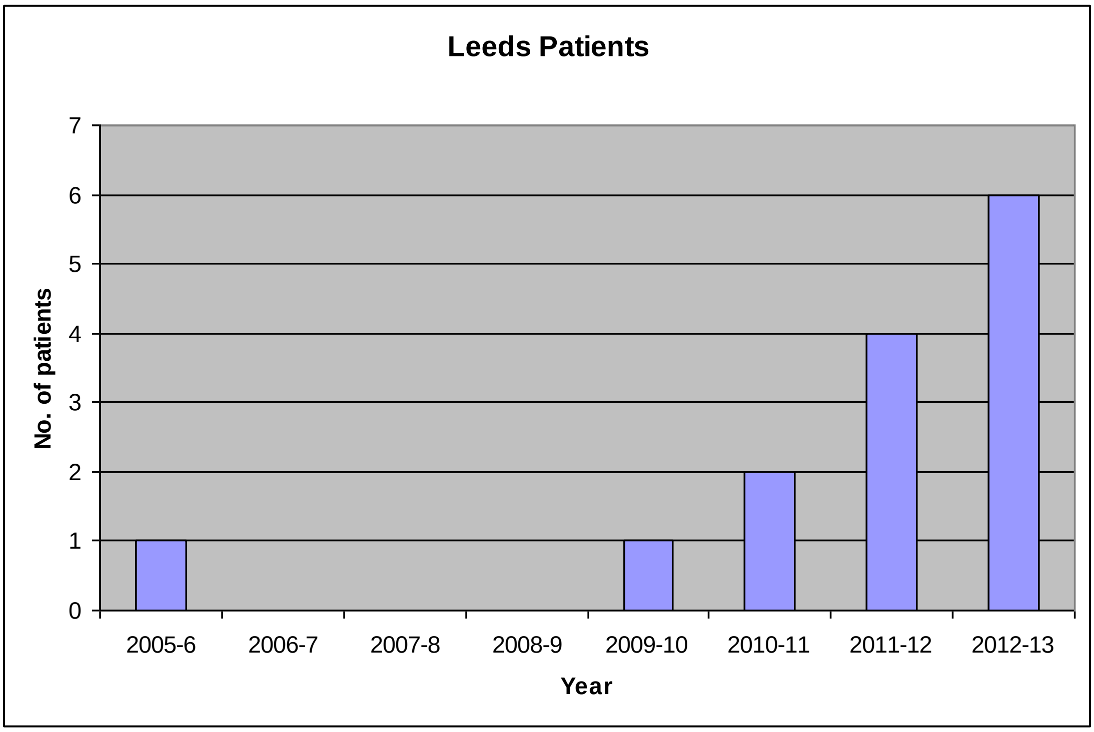
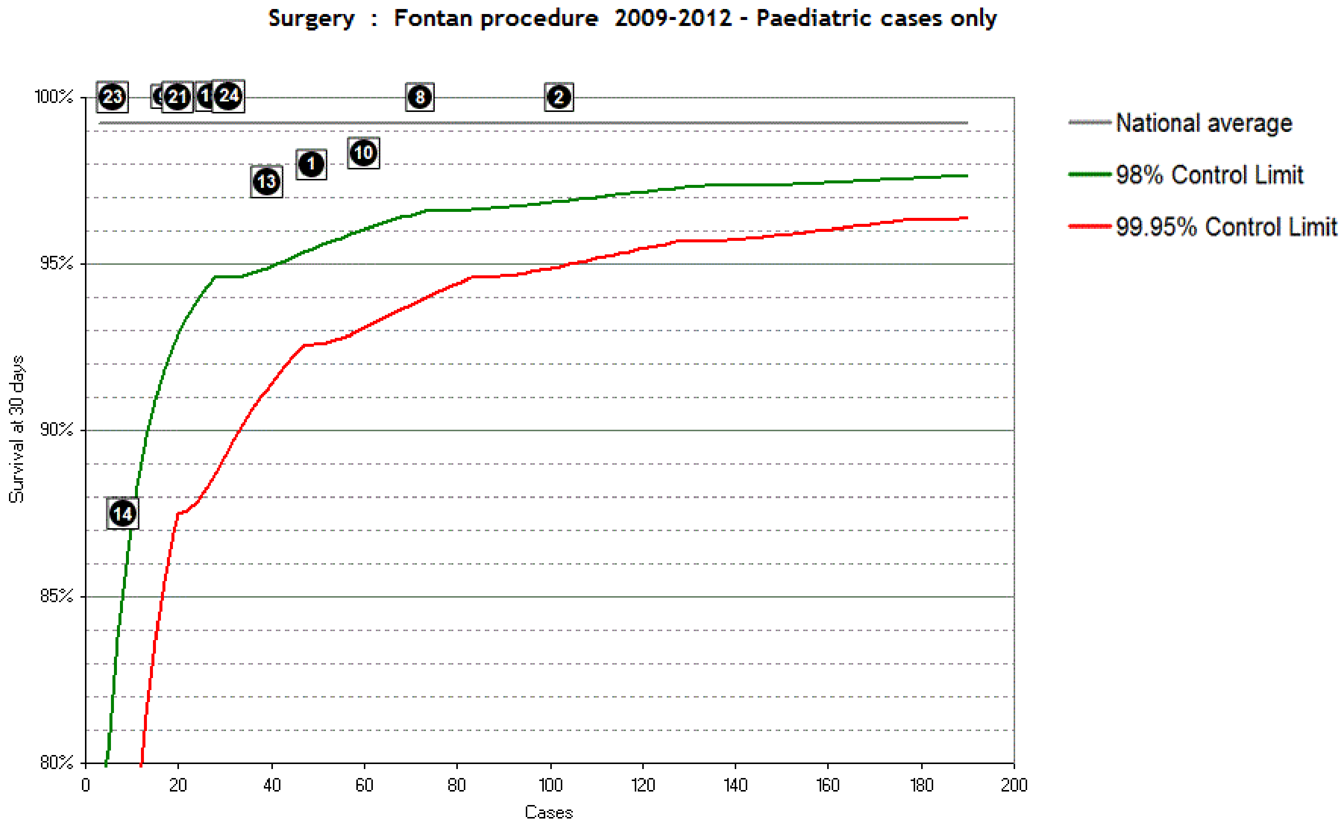


Exhibit 2: CCAD Fontan Data



		Cases	Alive 30d	Dead 30d	Survival 30d
2	Birmingham Childrens Hospital	102	102	0	100.0%
8	Great Ormond Street Hospital for Children	72	72	0	100.0%
10	Evelina Children's Hospital	60	59	1	98.3%
1	Alder Hey Hospital	49	48	1	98.0%
13	Harley Street Clinic	39	38	1	97.4%
24	Southampton General Hospital	31	31	0	100.0%
4	Bristol Children's Hospital	30	30	0	100.0%
6	Freeman Hospital	30	30	0	100.0%
18	Royal Brompton Hospital	27	27	0	100.0%
30	Our's Lady's Dublin	25	25	0	100.0%
21	Royal Hospital for Sick Children	20	20	0	100.0%
9	Glenfield Hospital	17	17	0	100.0%
14	Leeds General Infirmary	8	7	1	87.5%
23	Royal Victoria Belfast	6	6	0	100.0%
20	John Radcliffe Hospital	1	1	0	100.0%

Appendix C

Team biographies

Lucy Scott-Moncrieff CBE

Mental health and human rights lawyer, Lucy Scott-Moncrieff is a long-term associate of Verita. She is a former president of the Law Society of England and Wales, and chairs its Equality and Diversity Committee. She is a Commissioner with the Judicial Appointments Commission and a part time judge for the Mental Health Tribunal. She is co-chair of the International Bar Association's Access to Justice and Legal Aid Committee.

Her voluntary work includes being a trustee of LawWorks and of the Howard League for Penal reform and a member of the Prime Minister's Dementia Challenge Group.

Lucy has written and broadcast regularly on legal issues over the years.

For Verita she has carried out a number of complex and high profile reviews including the death of a patient during routine day surgery, the action of a SHA in relation to the dismissal of a trust chief executive, and the care and treatment of serial killer Daniel Gonzales.

Barry Morris

Barry joined Verita soon after it started in 2002. He previously worked as a consultant in financial and general management where he specialised in working with companies and charities in the areas of finance, change management and organisational development. He is a trustee of PAC, a charity working in the field of adoption. Barry has a wide range of experience gained over the last 10 years in investigations and reviews. He is currently leading the sampling team supporting Kate Lampard in her oversight of the NHS investigations into matters relating to Jimmy Savile.

Jessica Martin

Jess Martin has worked at Verita since 2011. As a consultant she has worked on a number of high-profile cases. She is a member of the team providing national oversight and assurance to investigations into allegations about sexual abuse by Jimmy Savile in healthcare, educational and social care settings. Other cases include a review of a specialist paediatric service in the north of England, a governance review of a leading private healthcare provider, an investigation into allegations of misreporting of A&E performance figures and a review of GP performance issues. Jess has recently completed the John Hopkins University Science of Safety in Healthcare course.

Kenneth MacArthur

Kenneth MacArthur is the lead clinician for paediatric cardiac services in Scotland. He has been a consultant cardiac surgeon in Glasgow for the last 25 years, with a largely paediatric and adult congenital practice. He has an interest in education and is an assessor for the cardiothoracic exam board. He is the past secretary of the exam board. He has a research interest in valve development.

Dr Tony Salmon

Tony has worked as a consultant congenital cardiologist in Southampton for the last 24 years responsible for the care of children and adults with congenital heart disease. He has a large clinical practice and was president of the British Congenital Cardiac Association until November 2013. He has had a number of roles on the Council of BCCA previously. He has previous experience in reviewing clinical practice. Tony was involved with the Safe and Sustainable Paediatric Cardiac Services Review and is currently a member of the NHSE 'New Review'. He is chairman of the Standards Group and a member of the Clinical Advisory Panel.

Katrina Cooney

Katrina has been a deputy chief nurse in London for the last eight years. This role gives her experience in relation to standards and practice, quality and productive and education. Katrina has many years' experience in reviewing incidents and complaints. She was previously a head of nursing in renal and urology.

Dr Jelena Stojanovic

Jelena is a paediatric nephrology subspecialist trainee in London; the only one appointed in UK in 2012. She is an apprentice in Medical Leadership Program at a leading Foundation Trust in the country. Jelena is elected trainee representative at British Association for Paediatric Nephrology and UK Renal Registry; prior to this she was a general paediatric trainee representative. She is a core representative at Clinical Reference Group - assurance body for new or amended clinical processes at Guy's St Thomas' NHS Foundation Trust. Jelena is a junior doctor patient safety officer where she leads and facilitates quality improvement projects in an international subspecialty high volume hospital.

Terms of reference

Review into the Concerns about Paediatric Cardiac Surgery at Leeds Teaching Hospitals NHS Trust (LTHT)

Overview:

Sir Bruce Keogh has asked Deputy Medical Director Mike Bewick to undertake a review into concerns about paediatric cardiac surgery at LTHT. The external consultancy Verita has now been appointed to investigate the governance processes around the care of children at Leeds, and the specific cases detailed in the letter from Sir Leonard Fenwick. Work will start imminently and should be completed by January 2014.

Background:

During 2013 concerns were raised in relation to the quality of care offered to patients undergoing surgery for congenital cardiac conditions at Leeds Teaching Hospitals NHS Trust.

The concerns arose from 3 sources:

1. Mortality data released by staff from the National Institute for Cardiovascular Outcomes Research ("NICOR") in March 2013. The data gave a partially risk-adjusted analysis of patients who died in the 30 days after a surgical procedure and who were operated on in the years 2009 to 2012.

2. Complaints and concerns expressed by families of children treated in the Unit and reported to the Care Quality Commission or to NHS England.

3. Concerns relating to patient care expressed to NHS England from another NHS Trust.

The initial data released by NICOR staff, appeared to show that LTHT children's cardiac surgery unit had a mortality rate much higher than other comparable units. This led to a temporary cessation of surgery commencing 28th March 2013. Following a Risk Summit convened by NHS England on 4th April 2013, it was agreed that investigation of the concerns relating to the LTHT Unit would be undertaken in two phases.

Phase 1 would be a rapid review of the LTHT Unit clinical standards, patient pathway management, and clinical governance. This was undertaken by an externally-led team of investigators and is now complete.

Phase 2 would have the following components:

(a) a detailed mortality case review of the deaths identified by NICOR by an externally-led team of specialist clinicians. This is now complete.

(b) detailed interviews and investigations of parental concerns; the interviews for this phase are complete and a report imminent.

(c) investigation of the concerns raised by other professionals.

These ToR relate to Phase 2c) above. The review team will ensure that they do not duplicate any of the work previously undertaken in the earlier phases.

Aims of the Review:

The aims of the review are to

1. Investigate the governance and communication processes around the care of children at the unit in Leeds, with particular reference to transfers to other trusts

2. Undertake specific clinical reviews of the 14 cases identified in Sir Leonard Fenwick’s letter (unless the review team consider they have been adequately covered by previous phases)

3. Determine the actions necessary to secure and assure the safe and effective management of paediatric cardiac services at Leeds

4. Agree how the work of the review will be communicated to patients and public, including the conduct of any necessary patient recall exercises

Governance

The review team will report directly to Dr Mike Bewick, Deputy Medical Director, NHS England, and to senior members of the regional and area teams.

All members of the review team will coordinate actions and take no significant action without the knowledge and/or agreement of other team members as appropriate.

The review team will maintain a log of all decisions, timescales and actions completed and outstanding.

Outcomes of the Review

- A report setting out
    - the lessons to be learnt (or already learnt) from the management of the 14 cases
    - what (if any) aspects of best practice have been identified
    - recommendations for any further actions that could be taken to improve patient management and patient pathways, inter-unit referrals, professional relationships and communications

    - any potential wider implications identified for other parts of the NHS

Communication and Administration

The review team will communicate weekly initially, by telephone with Dr Mike Bewick and the administration support.

The review will be administered by Verita, with support from NHS England

Appendix E

Template document to record views and findings

Independent review into concerns about paediatric cardiac surgery at Leeds Teaching Hospital NHS Trust

Child:

Panel member: Date:

Please give reasons if your answers are simply ‘yes’ or ‘no’.

Question	**Answer**
Risk assessment	
1) Based on X’s problems identified at Leeds, and the records of the treatment at Newcastle, did Leeds accurately assess the risk of operating against a national standard/their own standard?	
2) Should Leeds have had the expertise to carry out the surgery that Newcastle carried out?	
3) Should the reports of [medical issue] have produced a more urgent response than it did?	
4) Did the risk assessment process, as far as you can ascertain, comply with existing guidance or established best practice?	
5) Are there any questions to be put to individuals or teams at Leeds to clarify the risk assessment process?	

Delay	
1) Is there evidence of undue delay in diagnosing, treating or transferring X?	
2) Is there any evidence that the delays in this case did not accord with existing guidance or accepted good practice?	
3) If there were unacceptable delays, are there any questions to be put to named individuals or teams to clarify processes or procedures?	
Second opinion	
1) X's family were asking for a referral to Leeds by X. Should this have been requested by Leeds before X?	
2) Should Leeds have sought a second opinion themselves at an earlier stage?	
3) Is there evidence that Leeds was reluctant to refer to Newcastle? If so, did the reason(s) for this appeared reasonable/justified in light of what Leeds should have known about Newcastle's expertise?	
4) Did the referral process, both procedurally and chronologically, comply or not comply with existing guidance or existing good practice?	
5) Are there any questions to be put to individuals or teams about the second opinion process used by Leeds?	

Communication	
1) Please comment on the quality of communication between Leeds and X's family.	
2) If there is any guidance or accepted good practice, please indicate if any of the communications here reveal a failure to comply with such guidance/accepted good practice.	
3) Are there any questions to be put to individuals or teams about their communication processes in general and in this particular case?	
Miscellaneous	
Please set out here any other matters, queries, comments that will assist us in understanding the issues in this case and asking the all the right questions to get a proper picture of what happened, and why. In particular, please give details of any evidence of a lack of formal process where it should exist; poorly designed processes; or processes poorly understood and/or not complied with.	

Appendix F

List of interviewees

NHS England:

- Dr Mike Bewick, deputy medical director, NHS England
- Dr Damian Riley, acting medical director, NHS England North
- Andy Buck, director, West Yorkshire
- Gill Harris, chief nurse, NHS England North

Leeds:

- Julian Hartley, chief executive
- Dr Yvette Oade, chief medical officer
- Dr Bryan Gill, medical director, quality and governance
- Miss Carin Van Doorn, head of congenital surgery
- Dr Elspeth Brown, lead clinician for Congenital Heart Disease services and consultant paediatric cardiologist
- Dr Michael Blackburn, paediatric cardiologist (two interviews)
- Dr John Thomson, paediatric cardiologist
- Dr Fiona Willcoxson, paediatric cardiologist (two interviews)
- Dr Alex Perez, paediatric cardiologist (locum)
- Dr Helen Michael, paediatric cardiologist (locum)
- Dr Shuba Barwick, paediatric cardiologist (two interviews)
- Dr Dominic Hares, paediatric cardiologist
- Dr Kate English, adult congenital cardiologist
- Dr George Ballard, adult congenital cardiologist
- Mr Stefano Congiu, congenital cardiac surgeon
- Dr John Gibbs, retired congenital cardiologist
- Mr Nihal Weerasena, congenital cardiac surgeon

Newcastle:

- Sir Leonard Fenwick, chief executive
- Liz Bailey, directorate manager, cardiothoracic services
- Mr Asif Hasan, consultant paediatric cardiothoracic surgeon

- Dr John O'Sullivan, consultant paediatric cardiologist
- Sister Paddy Walsh, children's specialist cardiac sister
- Dr Milind Chaudhari, consultant paediatric cardiologist
- Dr David Crossland, consultant paediatric cardiologist
- Dr Richard Kirk, consultant paediatric cardiologist
- Angie Johnson, matron

District General Hospital:

- Dr Gary Savill, consultant paediatrician
- Dr Matthew Babirecki, consultant paediatrician

Families:

- Six families

Appendix G

Documents reviewed

Clinical notes

- LTHT clinical notes and nurse liaison notes
- Newcastle clinical notes

Policies and procedures

- Embrace Yorkshire & Humber Infant and Children's Transport Service, Call Coordination Form
- Embrace Yorkshire & Humber Infant and Children's Transport Service, Planned Transfer Booking Form
- Embrace Yorkshire & Humber Infant and Children's Transport Service, Parent Information Leaflet
- Leeds Teaching Hospitals NHS Trust Parent Information leaflet on second opinions, 2010 (updated 2013)
- Leeds Teaching Hospitals NHS Trust Procedure for second opinions, December 2013
- Leeds Teaching Hospital NHS Trust Process for External Referrals, April 2013
- Leeds Teaching Hospitals NHS Trust, complex single ventricle pathway
- University Hospitals Bristol NHS Foundation Trust Paediatric Congenital Joint Cardiac Conference Operating Protocol, 10 August 2011
- University Hospitals Bristol NHS Foundation Trust Fetal Cardiology Referral form, February 2011
- University Hospitals Bristol NHS Foundation Trust Fetal Cardiology Service Clinical Guideline, March 2012
- University Hospitals Bristol NHS Foundation Trust Fetal Cardiology Handbook, June 2012
- University Hospitals Bristol NHS Foundation Trust CNS role in cardiac patient journey
- University Hospitals Bristol NHS Foundation Trust Bereavement Pathway Guideline (Non-clinical), Version 1.1
- University Hospitals Bristol NHS Foundation Trust Examples of Information given to Families

Reports

- NHS Foundation Trust, Children's Heart Surgery, Summary of 14 Cases, April 2013
- LTHT's view on 14 cases from Newcastle, March 2014
- *Trends in Fontan surgery and risk factors for early adverse outcomes after Fontan surgery: The Australia and New Zealand Fontan Registry experience Journal of Thoracic and Cardiovascular Surgery*, Ajay H. Iyengar, et al., 2013
- Newcastle's response to cardiac centre questions, February 2014
- Alder Hey response to cardiac centre questions, February 2014
- University Hospitals Bristol NHS Foundation Trust's response to cardiac centre questions, February 2014

Correspondence

- Letters from Sir Leonard Fenwick to Dr Mike Bewick regarding Newcastle's concerns dated 12 and 18 April 2013
- Correspondence between families in regards to referrals

Appendix H

Glossary of terms

Hypoplastic left heart syndrome

Children with hypoplastic left heart syndrome have a single effective ventricle supplying blood to the lungs and the body. They are delicately balanced between inadequate blood supply to the lungs (causing cyanosis) and oversupply to the lungs (causing heart failure). In addition, the single ventricle is doing nearly twice the expected amount of work because it has to pump blood for both lungs and body. As a result, these children can have trouble gaining weight and are also vulnerable to decompensation in the face of otherwise minor illnesses (even a common cold). Sometimes medications can help them through this stage.

Fontan procedure

The Fontan procedure, is a palliative surgical procedure used in children with complex congenital heart defects, including hypoplastic left heart syndrome. It involves diverting the venous blood from the right atrium to the pulmonary arteries without passing through the morphologic right ventricle.

Alternatively treatment for hypoplastic left heart syndrome requires either a three-step surgical procedure called staged palliation or a heart transplant. Staged palliation is considered one of the major achievements of congenital heart surgery in recent years. The survival rate for children at age 5 is about 70 percent and most of these children have normal growth and development. This three-step surgery procedure is designed to create normal blood flow in and out of the heart, allowing the body to receive the oxygenated blood it needs.

The three steps consist of the following procedures:

Norwood procedure

This procedure is performed shortly after birth. It converts the right ventricle into the main ventricle pumping blood to both the lungs and the body. The main pulmonary artery and the aorta are connected and the main pulmonary artery is cut off from the two branching pulmonary arteries that direct blood to each side of the lungs. Instead, a connection called a shunt is placed between the pulmonary arteries and the aorta to supply blood to the lungs.

Bi-directional Glenn operation

This operation usually is performed about six months after the Norwood to divert half of the blood to the lungs when circulation through the lungs no longer needs as much pressure from the ventricle. The shunt to the pulmonary arteries is disconnected and the right pulmonary artery is connected directly to the superior vena cava, the vein that brings deoxygenated blood from the upper part of the body to the heart. This sends half of the deoxygenated blood directly to the lungs without going through the ventricle.

Fontan operation

This is the third stage, usually performed about 18 to 36 months after the Glenn. It connects the inferior vena cava, the blood vessel that drains deoxygenated blood from the lower part of the body into the heart, to the pulmonary artery by creating a channel through or just outside the heart to direct blood to the pulmonary artery. At this stage, all deoxygenated blood flows passively through the lungs.

Cardiac catheterisation

Cardiac catheterization involves passing a thin flexible tube (catheter) into the right or left side of the heart, usually from the groin or the arm.

A larger thin plastic tube called a sheath is placed into a vein or artery in the leg or arm. Then longer plastic tubes called catheters are carefully moved up into the heart using live x-rays as a guide. This allows the doctor to:

- collect blood samples from the heart
- measure pressure and blood flow in the heart's chambers and in the large arteries around the heart
- measure the oxygen in different parts of the heart
- examine the arteries of the heart
- perform a biopsy on the heart muscle.

Ross procedure

The Ross procedure is a cardiac surgery operation where a diseased aortic valve is replaced with the person's own pulmonary valve. A pulmonary allograft (valve taken from a cadaver) is then used to replace the patient's own pulmonary valve.

ECMO (Extracorporeal Membrane Oxygenation)

ECMO is a treatment that uses a pump to circulate blood through an artificial lung back into the bloodstream. This system provides heart-lung bypass support outside of the patient’s body. It may help support patients who are awaiting a heart or lung transplant.

LVAD (left ventricular assist device)

LVAD is a kind of mechanical heart which is placed inside a person's chest, where it helps the heart pump oxygen-rich blood throughout the body. Unlike an artificial heart, the LVAD doesn't replace the heart. It just helps it do its job. This can mean the difference between life and death for a person whose heart needs a rest after open-heart surgery or is too weak to effectively pump on its own or who is waiting for a heart transplant.

Inferior vena cava

The inferior vena cava is the large vein that carries deoxygenated blood from the lower half of the body into the right atrium of the heart.

LTHT's referral policy

LEEDS TEACHING HOSPITALS NHS TRUST

LTHT external referrals

All patients are entitled to a second opinion and enclosed information regarding this has been included in the patient held record since 2010.

Transplant and pulmonary hypertension services are nationally commissioned services so all patients requiring those are referred to the national service, Newcastle or GOSH for transplant, GOSH for pulmonary hypertension.

Historically the surgical team in Leeds felt that Hypoplastic left heart syndrome should be performed in high volume centres and so previously we have referred our cases to Evelina or Birmingham which are the 2 highest volume centres.

There are still a few conditions eg Congenitally corrected transposition where one centre (Birmingham) has particular expertise and we would send patients there for second opinion.

In any individual case, particularly high risk cases the cardiologist or surgeon may seek a second opinion from a high volume centre.

Elspeth Brown
23/12/2013

Appendix J

LTHT’s second opinion policy

SECOND OPINION

Everyone has the right to be given the best possible care. If you have any concerns about the care or treatment your child is receiving, you may want to get a second opinion.

Why ask for a second opinion?

Reasons for asking for a second opinion include:

- wanting another cardiologist to confirm the initial diagnosis
- wanting another cardiologist's opinion on your child's treatment
- having an operation by a surgeon who works at a different unit
- having concerns about some aspect of the care or treatment your child is currently receiving

Your right to a second opinion

Whatever your reason, the NHS entitles you to ask for a second opinion. In Leeds we have no problem at all with you seeking a second opinion. Indeed, you will sometimes find that your cardiologist or surgeon will want to seek a second opinion on your behalf, particularly if your child's case is especially complicated.

How to get a second opinion

There are two main routes for getting a second opinion:

1. Ask your GP to arrange an appointment with a cardiologist at a different congenital cardiac unit. Your GP will then contact the centre to arrange for up to date information about your child's care.

2. Ask your cardiologist. The cardiologists will be happy to help you get a second opinion and will often suggest another cardiologist you can see.

Please do not feel uncomfortable talking to us about this subject. The most important thing is to make sure your child is getting the best possible care. Please make sure that the cardiologist or surgeon you are planning to see is from another specialist congenital heart disease unit in England. We are happy to give you advice regarding this.

For more information, or any advice, please contact the Paediatric Congenital Nurse Specialists at Leeds General Infirmary on 0113 3925467.

Written by the Congenital Team 2010, updated April 2013.

VERITA

IMPROVEMENT THROUGH INVESTIGATION

Leeds Teaching Hospitals NHS Trust
Overarching report about paediatric cardiac surgery

A report for
NHS England

October 2014

Authors:
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Verita is a management consultancy that works with regulated organisations to improve their effectiveness and levels of service. It specialises in conducting independent investigations, reviews and inquiries.

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Contents

1. Introduction 4
2. Executive summary 7

Details of the investigation

3. Chronology 13
4. Congenital heart disease and delivery of services 17
5. Political background 19
6. Suspending surgery 21
    6(a) Family concerns 22
    6(b) NICOR data 23
    6(c) Other concerns 27
    6(d) The decision to suspend surgery 29
7. Lifting the suspension of surgery 32
8. The three reports 37
    8 (a) Mortality review 37
    8(b) Family Experience report 39
    8(c) Verita review of the 14 cases in the Newcastle dossier 42
9. Conclusions, lessons and recommendations 44

Appendices

Appendix A Terms of reference 74
Appendix B Team biographies 77
Appendix C Documents reviewed 79
Appendix D List of interviewees 82
Appendix E Report abbreviations 84
Appendix F Glossary 85
Appendix G Letter of invitation to participate in the Cantrill review 89
Appendix H Joint statement on behalf of Guy's and St Thomas', Great Ormond Street Hospital and Royal Brompton and Harefield NHS Foundation Trusts 92

1. Introduction

1.1 NHS England commissioned Verita in November 2013 to review concerns about paediatric cardiac surgery at Leeds Teaching Hospitals NHS Trust (Leeds).

1.2 They commissioned the review after the paediatric cardiology unit at Leeds General Infirmary (LGI), part of Leeds, agreed to a temporary cessation of surgery on 28 March 2013 because of concerns from three sources:

1. Mortality data released by staff from the National Institute for Cardiovascular Outcomes Research (NICOR) in March 2013.
2. Complaints and concerns of families of children treated in the unit and reported to the care quality commission (CQC); Sir Bruce Keogh, medical director at the Department of Health[1]; the Safe and Sustainable Review[2] Team: Heartline; Children's Heart Federation (CHF) and Little Heart Matters (LHM).
3. Concerns about patient care that other NHS professionals passed to Sir Bruce Keogh.

1.3 Verita was commissioned to review the concerns of the other professionals which were raised by Newcastle upon Tyne Hospitals NHS Foundation Trust (Newcastle). This report is published separately. NHS England also asked us to produce an overarching report to:

- summarise the events around paediatric surgery in Leeds over the last two years
- summarise the findings of the three independent reports about Leeds paediatric cardiac surgery (see sections 8-10)
- comment on background and context which is implied/relevant to all three reports
- set out lessons to be learnt and recommendations.

1.4 The full terms of reference for the review of Newcastle's concerns and of this overarching report is at appendix A.

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[1] On 1 April 2013 NHS England came into being and Sir Bruce Keogh became the medical director.

[2] 'Safe and Sustainable' was a three year review of children's congenital cardiac services in England published in July 2012.

1.5 Verita is a management consultancy that works with regulated organisations to improve their effectiveness and levels of service. It specialises in conducting independent investigations, reviews and inquiries.

1.6 The review team was led by Lucy Scott-Moncrieff, supported by Barry Morris, Jess Martin and administrative staff from Verita. Their biographies can be found at appendix B.

Approach and structure of the report

1.7 This review has built on the knowledge and information gained during the review of the 14 cases in the dossier of concerns assembled by Newcastle and interviews with individuals and groups of staff at Newcastle and Leeds, NHS England, NICOR and others.

1.8 We reviewed three independent reports in order to summarise their findings:

- *Children's Congenital Cardiac Surgery Services at Leeds Teaching Hospitals NHS Trust, Mortality Case Review for the period 2009-2013 Overview Report, March 2014*
- *Family Experience Report, A thematic analysis of the experience, views and concerns of some of the parents whose children received care from Leeds Teaching Hospitals NHS Trust Children's Cardiac Services between 2009-2013, Pat Cantrill, March 2014*
- *Independent review into concerns about paediatric cardiac surgery (the 14 cases) at Leeds Teaching Hospitals NHS Trust (LTHT), July 2014*

1.9 A full list of documents we considered is an appendix C.

1.10 We asked to interview key individuals who were relevant to the events with which we are concerned (full list is at appendix D). We also had telephone calls to clarify information. The review had no power to compel attendance but nobody to whom we wished to speak refused to attend.

1.11 Interviews were recorded and transcribed and interviewees were given the opportunity to confirm the accuracy of interview transcripts or to add to them.

1.12 NHS England, Newcastle and Leeds and Professor Pat Cantrill were given the opportunity to comment on the factual accuracy of either the draft report or extracts of the draft report.

1.13 We invited anyone we criticise to comment on relevant extracts of our final report while it was in draft.

1.14 For ease of reading we refer to the Leeds Teaching Hospitals NHS Trust and the Newcastle Hospitals paediatric cardiac units as 'Leeds' and 'Newcastle' respectively.

1.15 An executive summary follows this introduction and the report is in four main sections. First is a chronology of the main events both in Leeds and affecting Leeds; second is the background to these events; third, a brief summary of the three reports published so far and section 4 summarises our conclusions and recommendations. The sections other than the chronology are broken into sub-sections for ease of reading.

1.16 There is a table explaining abbreviations in the report at appendix E and a glossary of terms at appendix F.

1.17 In our review of the 14 cases we had a number of sources of evidence. In some cases we only had medical notes and information from healthcare professionals as evidence, but in others we also had statements provided by the families of child patients, and in six cases we also spoke to families. We have also had the benefit of reading the Family Experience Report which contains the views of some of the families of the 14 children. We were moved by the strength of feeling and sincerity of those families with whom we spoke, and, where relevant, struck by the consistency between what they told us and what they had written in earlier statements and/or told Professor Cantrill. Some of our findings do not support some of the recollections and beliefs of these families, but this should not be seen casting any doubt on the sincerity of the families concerned.

2. Executive summary

2.1 Verita was commissioned in November 2013 to review concerns raised by Newcastle about 14 cases that they compiled into a dossier for Sir Bruce Keogh. In addition Verita was asked to write an overarching report, pulling together three independent reports about Leeds paediatric cardiac surgery.

2.2 Leeds agreed to suspend their paediatric heart surgery on 28 March 2013. The decision was taken after a meeting with Sir Bruce Keogh, then NHS medical director at the Department of Health and representatives from CQC and others. The meeting was told of concerns about mortality data for the unit, parental concerns and issues raised by other NHS professionals.

2.3 A rapid review of the LTHT children's cardiac unit was carried out between 5 and 7 April and found *"no 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"*.

2.4 As a result of the outcomes of the data analysis and rapid review, the suspension of surgery was lifted on 8 April 2013 and surgery resumed on 10 April 2013.

2.5 The suspension of children's heart surgery at Leeds in March 2013 caused a storm of controversy and concern. The suspension occurred the day after the High Court quashed the decision of the Safe and Sustainable review that the reconfiguration of paediatric heart surgery should include closing the service at Leeds.

2.6 Understandably, many people believed that there was a connection between these two events and we examined closely the sequence of events that led to the suspension. We concluded that the suspension was made in the interests of patient safety rather than for any other reason.

2.7 Three further reviews were commissioned by NHS England. A detailed mortality case review by an externally-led team of specialist clinicians of the deaths NICOR identified; detailed interviews regarding parental concerns; and the investigation of the concerns of other professionals.

2.8 The mortality review was carried out by a team of independent experts and concluded that *"clinical management of the cases examined showed medical and surgical care to be in line with standard practice"*.

2.9 The Family Experience review was carried out by Professor Pat Cantrill and concluded *"...Those families who wished their experiences views and concerns to be heard have been listened to. Their stories were all heartfelt, moving and sincere. All the families were saddened to find themselves in a position where they had lost confidence in the care provided for their children and for them as a family"*.

2.10 The concerns of other professionals were raised by Newcastle in a dossier of 14 cases. Twelve of these were of children who had been treated at Leeds and transferred to Newcastle. The other two cases were of pregnant women whose children had been diagnosed with Congenital Heart Disease (CHD) following a foetal scan at Leeds, and who had transferred to Newcastle for the birth and subsequent care of their children.

2.11 The review of the Newcastle dossier was carried out by the authors of this report with an advisory panel of experts. It found evidence that in two cases the risk assessment process had not been satisfactory, that in two cases there had been unnecessary delay in seeking second opinions or making referrals and there had been failures in, problems with, or breakdowns in communication in five cases. The medical records showed no evidence that Leeds was unwilling to make referrals to centres outside Yorkshire, nor that it was unwilling to refer to Newcastle in accordance with its referral policy or when requested to do so by families. The balance of the evidence did not support some of the situations described by families and by Newcastle.

2.12 Parents of children with CHD have the responsibility of making treatment decisions on behalf of their children. Very often these decisions will involve balancing the risks and benefits of different options.

2.13 Statistical information on outcomes and research conclusions offer very limited assistance in making these decisions. One reason for this is that numbers are too low to provide robust data. Another is that many advances in treatment are so recent that reliable long term outcomes are not yet available. Another difficulty is that variations in the physiology of each child means that average outcomes may have little relevance in reaching a particular decision for a particular child.

2.14 Therefore parents are almost entirely reliant on the expertise and the judgement of those treating their children for professional advice on the risks and benefits of different options.

2.15 This advice includes guidance on whether and when to operate and whether a referral should be made to another centre.

2.16 We found that the Safe and Sustainable process put centres in competition with each other. This damaged the trust that some parents had in the neutrality of the advice given to them by those treating their children.

2.17 We also found that the competition set up by the Safe and Sustainable process has damaged the trust and confidence that we are told used to exist between the practitioners in this specialty.

2.18 Maintaining staff morale while radical change is being considered is an obvious element of maintaining quality while improvement is being planned. The potential disruption to careers and lives must be acknowledged and addressed and staff should know that contingency planning, looking at their legitimate expectations as well as those of patients, is taking place.

2.19 We have made 17 recommendations under four headings as shown below. Our final recommendation relates to restoring trust and confidence in the service. We consider this to be the most important recommendation in our report, and all the other recommendations are intended to assist in this process.

Recommendations

We make a series of recommendations throughout the report that appear in the relevant sections and are set out below for completeness.

Data submission and record keeping

R1 All NHS organisations need to give the accuracy and completeness of their data a high priority, for their own assurance and to assure patients, regulators and commissioners that their information can be relied upon.

R2 When important discussions are held, important decisions are made, and irreversible actions are taken, medical records should be written so as to pass the 'pick-up' test: that a colleague (or investigator or reviewer) with no knowledge of the case could pick up the file and understand why and how decisions were made, not simply know that they were made. This is not necessarily a bureaucratic or time-consuming process because it can be included in a simple template, checklist or aide-memoire that ensures all relevant information is captured.

R3 Written guidance for carrying out and recording risk-assessments and decisions at Multi-disciplinary Team meetings should be prepared, in the interests of consistency and clarity. This applies across the NHS. These need not and should not be bureaucratic or time-consuming but should distil the existing best practice of decision-making at the centre. The pro forma for these meetings should reflect the process.

R4 Centres should develop written clinical care pathways for the various congenital heart disease conditions of the patients they treat. Written individual treatment plans should be prepared for each patient by reference to the clinical care pathway. They should be regularly updated and given to and discussed with the patient's parents or carers. The pathway should be open about the many variables that influence treatment options but create a framework to help ensure consistency, clarity and open communication.

Communications and complaints

R5 Leeds should review its communication policies to ensure that they meet current patient expectations. This should include how to give families an opportunity to raise concerns anonymously because some families fear that anything construed as a complaint may affect their child's care. Resources should be put into this because dealing with the consequences of poor communication is inevitably upsetting for parents and clinicians. The cost of doing so would be better spent on improving communication.

R6 We recommend that NHS England should give consideration to having a service-wide discussion about referral policy, so that common standards can be agreed, or, at least, that the differing policies at different centres are understood by all centres.

R7 We recommend that any centre that accepts self-referrals develops and publishes a protocol for managing the transfer of care. Such a protocol should include notifying the hospital previously treating the patient.

R8 Regulatory bodies should consider including evidence of robust referral protocols and their effective use as markers of quality services.

R9 Where families raise concerns other than by way of complaint to the relevant provider trust, those receiving the concerns should establish whether the families are looking for answers or raising quality concerns. If the former the concern should be investigated as a complaint. If the latter the family should be invited to raise concerns with the appropriate regulator and if they are willing to do so with the relevant trust.

Managing consultations on major reconfiguration

R10 Any review that leads patients or their families to reasonably believe that clinical advice from a doctor could be coloured by his or her self-interest is not well structured. We recommend those setting the terms of reference of such reviews should be alert to this risk.

R11 Where such anxiety by parents is expressed or is likely, staff at both hospitals affected by the review have a duty to minimise it. They should anticipate the possibility of such fears and offer convincing reassurance that all advice is given simply in the interests of the child. Leaders in the organisation should anticipate such problems and prepare for them.

R12 Those making decisions where reconfiguration is being considered have a responsibility to ensure that relationships between medical and nursing staff at ‘competing’ trusts are not damaged. This should be built into the systems and processes.

R13 Managers at affected trusts also have a responsibility to ensure that strong, respectful relationships are maintained between staff at ‘competing’ trusts.

R14 During the course of any review, consultation or implementation of reconfiguration a trust’s management must give a high priority to minimising the understandable anxiety in staff likely to be affected.

Restoring trust and confidence

R15 Professionals should make clear when they pass on concerns about other professionals whether those concerns are their own or those of patients or families.

Before professionals pass on the concerns of patients or families, they should establish whether the patient or family has complained formally to the trust concerned. If the families have complained, the professionals should include any response from the trust when they pass on concerns. If they have not complained, the professionals should find out why, and provide that information when passing on the concern.

R16 NHS England should publicise the fact that all cardiac units in the UK undertake sufficient numbers of operations for safety, as currently measured. This should help reassure families that their children are not being treated in units with sub-optimal numbers.

R17 NHS England should act to dispel the “almost morbid sense of spectatorship and foreboding that hangs over these services”, ensuring that all stakeholders, service-users and their families are involved.’ This could be done during, and as a part of the New Review[1].

The leaders of trusts containing these services also have an important role in providing accessible information about the safety and quality of their service. We recommend that they work together on this, to avoid any element of competition that would give rise to the very worries they should all be trying to dispel.

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[1] The *New review of congenital heart services* has been commissioned by NHS England to consider the whole lifetime pathway of care for people with congenital heart disease (CHD), to ensure that services for people with CHD are provided in a way that achieves the highest possible quality within the available resources.

3. Chronology

2008 NHS medical director Sir Bruce Keogh requests on behalf of the NHS management board that the NHS National Specialist Commissioning Group (NSCG) review the provision of paediatric congenital cardiac services. The review became known as the 'Safe and Sustainable Review'.

1 March 2011 The NSCG publish a consultation document *Safe and Sustainable: A New Vision for Children's Congenital Heart Services in England*. It proposes reducing the number of centres providing paediatric congenital cardiac surgery from 11 to seven and reconfiguring paediatric congenital cardiac services. It proposed that Liverpool and either Newcastle or Leeds remained open as part of the reconfigured services in the North of England.

4 July 2012 The outcome of the Safe and Sustainable consultation is announced; Alder Hey Children's NHS Foundation Trust (Liverpool) and Newcastle are chosen to remain open for the North of England.

2 October 2012 Save Our Surgery Ltd, an independent charity in Leeds, applies for a judicial review to challenge an aspect of the consultation process on the basis that it was carried out unfairly.

22 October 2012 Secretary of State for Health Jeremy Hunt asks the Independent Reconfiguration Panel (IRP) (see glossary) to review the Safe and Sustainable Review proposals.

11, 12, 18 February 2013 The judicial review hearing takes place at the Royal Courts of Justice in London.

7 March 2013 The judge rules the Safe and Sustainable Review consultation was flawed and confirms another hearing will take place on 27 March to consider redress.

15 March 2013 Jeremy Hunt, Secretary of State for Health issues further instructions to the IRP to take account of the judgment on redress.

19 March 2013 A Leeds cardiac surgeon voluntarily agrees to stop operating.

23 March 2013 Nine families, the children of five of whom had been treated at Leeds before transfer to Newcastle, send a letter to Jeremy Hunt challenging the delay in implementing the reconfiguration.

26 March 2013 Mr Asif Hasan, a leading paediatric cardiac surgeon at Newcastle and Mr Bill Brawn, a leading paediatric cardiac surgeon at Birmingham, raise separate concerns about the Leeds unit with Sir Bruce Keogh.

27 March 2013 The judicial review further judgment about redress quashes the Safe and Sustainable Review decision.

27 March 2013 A meeting of senior managers takes place at Quarry House (the Department of Health's office in Leeds) to discuss the Safe and Sustainable process. Sir Bruce Keogh outlines concerns that two clinicians made to him about Leeds the previous day and refers to information given to him the same day that data from NICOR showed Leeds was an outlier in its paediatric cardiac surgery mortality outcomes. Concerns parents raised about care at Leeds were also discussed.

28 March 2013 Sir Bruce Keogh gives the chair, chief executive and interim medical director mortality data at a meeting at Leeds. The data from the Congenital Cardiac Audit Database (CCAD) shows Leeds's children's cardiac surgery unit had much higher mortality rates for 2010-11 and 2011-12 than other children's cardiac units in England. He also tells them two senior clinicians have independently raised concerns, one about medical staffing levels at the unit, the other about the quality it delivered. A representative of the CQC tells Leeds that families have raised concerns that patients are being refused timely referrals to other units for either a second opinion or other treatment such as transplant. During this meeting Sir Bruce Keogh (in his role as the NHS medical director) advised Leeds that they should consider suspending paediatric heart surgery while the concerns were investigated. Later that day the Leeds board met and decided to act on this advice.

1 April 2013 NHS England is created.

2 April 2013 NHS England, the CQC, the NHS Trust Development Authority (TDA) and Leeds City Council meet as a Quality Surveillance Group (see glossary) to discuss the concerns about Leeds.

3 April 2013 Deputy medical director of NHS England Dr Mike Bewick visits Newcastle to hear details of their concerns.

4 April 2013 NHS England, Leeds, CQC, and the TDA hold a risk summit and agree to carry out a review in three distinct phases:

- a detailed mortality case review by an externally-led team of specialist clinicians of the deaths NICOR identified
- detailed interviews and investigations of parental concerns
- investigation of the concerns of other professionals.

5-7 April 2013 NHS England conducts an urgent safety review of the Leeds unit clinical standards, patient pathway management and clinical governance.

8 April 2013 NICOR publishes an analysis of paediatric cardiac surgical mortality for 2009-12, showing that no cardiac unit was a statistically significant outlier for mortality.

8 April 2013 A second risk summit agrees Leeds can resume children's heart surgery based on the outcome of the urgent safety review.

9 April 2013 The urgent safety review report finds no evidence of immediate significant safety concerns in clinical governance, staffing or in the management of the patient pathway for surgical care in the unit or for referral to other units. It finds data management is generally adequate, but identifies lapses in data uploading and export to national databases, in particular to CCAD. It recommends lifting the suspension on surgery in a safe and structured way and improvements, which it says would apply to many other centres.

10 April 2013 Surgery resumes at Leeds children's cardiac unit.

12 April 2013 The chief executive of Newcastle Sir Leonard Fenwick sends Dr Bewick a dossier containing details of 14 children whose care had been transferred from Leeds to Newcastle where Newcastle clinicians were concerned about how Leeds had dealt with aspects of these cases.

18 April 2013 Sir Leonard Fenwick writes another letter to Dr Bewick, expanding on the concerns of his staff.

12 June 2013 Jeremy Hunt suspends the Safe and Sustainable review. He says he has received a report from the IRP, which he had asked to review the Safe and Sustainable proposals. The IRP concluded that the continuation of the existing arrangements for provision of paediatric cardiac was not an option, but that ground already covered should not be gone over again. He therefore asks NHS England to consider how best to proceed.

12 June 2013 The IRP publishes proposals for a new review of children's congenital heart services (see glossary).

November 2013 NHS England commissions Verita to undertake a review primarily into the concerns Newcastle raised (the Newcastle dossier) and to produce an over-arching report.

11 March 2014 Mortality review and the Family Experience reports published.

4. Congenital heart disease and delivery of services

4.1 The following information about congenital heart disease comes from the IRP report.

4.2 *Congenital heart disease (CHD) refers to defects in a child's heart that develop in the womb and are present at birth. CHD is a life-long condition that can be life-threatening. It affects one in 133 children, so about eight in 1,000 babies will have some form of CHD. To put this in context, of 723,913 live births in England and Wales in 2011, about 5,800 babies were born with CHD. The number of children born with CHD is set to rise with projections of higher numbers of births in the period to 2025.*

4.3 *There are two main types of CHD:*

- *cyanotic heart disease, where the patient appears blue, results in low blood oxygen levels*
- *acyanotic heart disease, where patients have normal blood oxygen levels but abnormal blood flow can cause high blood pressure in vessels supplying the lungs.*

Caring for children with CHD

4.4 *CHD can be diagnosed in the womb in some cases. In others it is not identified until after birth and may even remain undetected until adulthood.*

4.5 *An obstetrician or sonographer who suspects that a baby has a heart problem during a routine antenatal scan would refer the mother to a fetal cardiologist for a specialist assessment.*

4.6 *Prenatal diagnosis of major CHD improves results for children and can help prevent serious complications such as brain damage. It also enables parents to consider whether to terminate the pregnancy. Improvements in diagnosis and the range of available interventions and outcomes have led to a reduction in the percentage of pregnancies terminated in recent years.*

4.7 *If CHD is diagnosed before birth, the fetal cardiologist would put a care plan in place for mother and baby including where clinically indicated, for the birth to take place in or near a cardiac surgical centre.*

4.8 *A GP or paediatrician at a local hospital might initially see children diagnosed later in life before referring them to a paediatric cardiologist.*

4.9 *Most children with CHD need monitoring and advice about their condition and its impact on daily life. Almost half of children with CHD do not need surgery but do need long-term expert cardiological support. A few children need medication for their condition. About 25-30 per cent of children with CHD have other significant healthcare needs.*

4.10 *Many children with CHD have problems eating and gaining weight and have a special diet. They are more susceptible to illnesses like chest infections.*

4.11 *A wide range of interventional cardiology procedures and more than 150 surgical procedures are used to treat children with CHD. Surgeons and cardiologists sometimes operate together and sometimes two surgeons operate together. Procedures range in complexity from day cases to surgery for complex conditions that need multiple operations throughout life. Most operations are planned, but some are emergency procedures. Some children stay in hospital for many weeks or even months. This can have a significant impact on them and their families.*

4.12 *A range of specialists such as paediatricians with expertise in cardiology, cardiac liaison nurses, psychologists, paediatric cardiologists and congenital cardiac surgeons support children with CHD. A team of specialists including cardiac anaesthetists, perfusionists, intensivists and specialist nurses is required for surgical and interventional cardiology procedures.*

4.13 The care and treatment of children with CHD in England and Wales is concentrated in 10 NHS hospitals in Birmingham, Bristol, Leeds, Leicester, Liverpool, London (3), Newcastle and Southampton. Cardiac surgery is carried out at these hospitals, but other treatment for CHD and any other medical problems the children have can be provided by paediatric cardiologists from the specialist centres seeing children in outreach clinics at their local hospitals; by paediatricians and other specialists working at the local hospitals; and by GPs.

5. Political background

5.1 The following events occurred between late 2012, when families complained to the Children's Heart Federation (CHF), and 2013, when children's heart surgery at Leeds was suspended and later resumed. This was a time of highly charged feelings in Leeds and Newcastle, in the hospitals and the communities they served.

5.2 The Safe and Sustainable team announced on 4 July 2012 that after national reconfiguration of services, Liverpool and Newcastle, but no longer Leeds, would provide north of England children's heart surgery services.

5.3 Save Our Surgery Ltd set up a campaign to raise funds to challenge this decision and started judicial review proceedings against the Safe and Sustainable team in October 2012. The hearing took place in February 2013. The written High Court judgment on 7 March 2013 accepted the decision had been flawed, and the decision of 4 July 2012 was quashed at another hearing on 27 March 2013.

5.4 Secretary of State for Health Jeremy Hunt also asked the Independent Reconfiguration Panel (IRP) to review the Safe and Sustainable proposals in October 2012. The IRP published its report on 12 June 2013 and Jeremy Hunt announced that day he was suspending the Safe and Sustainable review.

5.5 The IRP report analysed the Safe and Sustainable consultation in detail, and concluded that its proposals would not achieve their aim of providing safe, sustainable and accessible children's heart services. It made a series of recommendations for putting this right, which at the time of writing are being taken forward by NHS England in the new review. It also identified inconsistency, lack of transparency and lack of recognition of the link between adult and child services in the Safe and Sustainable consultation process.

5.6 The report also acknowledged the emotional effect of the lengthy consultation and the various legal challenges to it:

> *"The phrase 'waiting for the next Bristol'*[1] *captures the almost morbid sense of spectatorship and foreboding that hangs over these services. ….The nature of the*

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[1] 1 Refers to events in the mid-1980s to the mid-1990s at the Bristol paediatric cardiac unit that led to the report by Sir Ian Kennedy.

> *service and the high level of public interest over a long period means that centres will, from time to time, find themselves under close scrutiny irrespective of the presence of any underlying causes for concern. It is also the case that services will give real cause for concern at times for patients, commissioners and regulators."*

5.7 Clinicians at Leeds told us they had always felt pessimistic about the outcome of the Safe and Sustainable review. They knew Leeds was not represented on the consultation's steering group and that people and organisations involved in the consultation had made remarks suggesting they had made judgements before the formal assessment of options. This included a statement the Children's Heart Federation (CHF) made in 2010 supporting reconfigured services being provided at the seven centres eventually chosen.

5.8 The campaigning in 2012, the mounting of the judicial review and news of the IRP review gave Leeds hope that their service would be reprieved.

5.9 It was inevitable that Newcastle would be implicated in the judicial review both because one of the premises of the Safe and Sustainable consultation was that either Leeds or Newcastle would have to give up surgery, and because Leeds applied for a judicial review to get the 4 July decision overturned. Under the terms of the consultation, Leeds' gain would be Newcastle's loss.

5.10 Newcastle had not intended to take part in the judicial review, but the judgement records that "*following the service of a number of witness statements by [Leeds] which were said to contain inaccurate and professionally derogatory information the trust felt an obligation to set the record straight."*

6. Suspending surgery

6.1 The Leeds trust board agreed to suspend children's heart surgery on 28 March 2013 after a meeting with the medical director of the NHS, the CQC and others. This meeting took place the day after a High Court judge quashed the Safe and Sustainable review's decision that the trust should lose its children's heart surgery service.

6.2 We asked Sir Bruce Keogh how the meeting had come about. He told us that on 26 March he had received a call from Bill Brawn, who he described as "*a well-respected cardiac surgeon, probably number one in this country*". Sir Bruce told us that Mr Bill Brawn was concerned that one consultant paediatric cardiac surgeon at Leeds had been suspended[1]; two of the remaining three consultants were relatively junior and were locums; the long Easter weekend was coming up; and the senior surgeon, Mr Watterson, was away. He felt that this was not a safe situation.

6.3 On the same day Mr Asif Hasan, senior consultant paediatric cardiac surgeon at Newcastle, also rang him and told him that he was very worried about Leeds, who he said were referring patients they should not be referring and not doing the right operations on patients.

6.4 The next day, 27 March, Sir Bruce Keogh was attending a meeting at Quarry House, the Department of Health offices in Leeds, to get an update on the Safe and Sustainable process, as he was aware that the judicial review judgment on redress was due to be handed down that morning. As he arrived at Leeds and was walking to the office he received a phone call from Sir Roger Boyle, at the time co-director at NICOR, informing him that preliminary data from Leeds suggested that its mortality outcomes for paediatric heart surgery were very worrying.

6.5 Sir Bruce raised these issues at the meeting at Quarry House on 27 March. The meeting was also told about concerns raised with CQC and the safe and Sustainable team by parents of children who had been treated at Leeds. As a result of this discussion it was decided to have an urgent meeting with senior managers at Leeds early the next morning.

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[1] Leeds told us that this surgeon agreed voluntarily to stop operating in March 2013

6(a) Family concerns

6.6 Andy Buck was the chief executive of Rotherham, Sheffield, Doncaster, Barnsley and Bassetlaw primary care trusts before the formation of NHS England on 1 April 2013 and was also on the body that commissioned children's congenital heart services at Leeds. He also chaired the specialised commissioning group, so he sat on the national Joint Committee of Primary Care Trusts (JCPCT) for the Safe and Sustainable review.

6.7 He told us that at the end of 2012 and in early 2013 he became aware of concerns some parents had raised about the service at Leeds.

> *"These concerns were coming to us often second-hand. They were often coming via charities that represent parents who are interested in these services and we were considering what to do about these concerns. That was slightly complicated because the Safe and Sustainable process was in judicial review and subject to the referral to the Secretary of State and the review by the Independent Reconfiguration Panel, so there was both this sort of strategic review process going on and these concerns being raised. Some of the concerns, it would appear, had been raised in the context of the review rather than simply in their own right as it were, so it was a bit of a complex mixture here."*

6.8 Dr Damian Riley, medical director West Yorkshire, told us about concerns families had raised:

> *"Some of the complaints…or concerns that were raised to CQC were from complainants' families, who had first of all complained to the Trust then received a response back they were not really happy with, and had then gone to either the Safe and Sustainable process and said 'I understand you guys are looking at children's cardiac, you need to see my complaint response, I am not happy with it', or they had gone to the CQC saying 'I tried to complain to Leeds Hospital but I received this poor response back. Will you please try and do something'. So I think it was a reflection from these other organisations hearing that the Trust wasn't handling patients' complaints very well and, when I say patients' complaints, I mean family or carer complaints."*

6.9 Parents were reporting their concerns to charities, to the Safe and Sustainable board's PR company, Graylings, and to the CQC. The families of nine children, including five of those whose cases are in the Newcastle dossier also raised their concerns in a letter to Jeremy Hunt on 25 March 2013 criticising the failure to reconfigure services.

6.10 Mr Buck sent an email to Sir Bruce Keogh and others on 26 March, reviewing the information on Leeds which had come in:

> *"There is a real risk of confusing the concerns about quality (which are about the current service) with the Safe and Sustainable process, the JR and the IRP (which is about the future of the service) - and it would appear that some stakeholders may be intent on doing just this, which is understandable but not helpful."*

Comment

The ways in which some of the parental concerns were expressed and communicated were clearly intended to affect decisions about the reconfiguration process and the future of children's heart surgery at Leeds. Campaigning is legitimate, but must be treated separately from specific concerns about safety. This is difficult when the campaigning raises safety issues.

We find that NHS England was aware of the charged political atmosphere in which these family concerns were raised and dealt with them sensibly. The family concerns were part of the reason for the suspension of surgery at Leeds, were seen by NHS England as needing investigation, but were not seen as sufficient to prevent surgery from resuming after the rapid review had deemed that the service was safe.

6(b) NICOR data

6.11 NICOR is responsible for a number of national clinical audits designed to improve the quality of care and outcomes of patients with heart disease. NICOR is part of the institute of Cardiovascular Science at University College London.

6.12 Clinical audit is a quality improvement process which aims to improve patient care. NICOR collects and analyses data to provide health professionals with information to help them to review the quality and outcomes of care against national standards and guidance.

6.13 In 2012 NICOR introduced a system for the analysis of outcomes following paediatric heart surgery, in which outcomes are adjusted for risk using a model (Partial Risk Adjustment in Surgery: PRAiS) that estimates the risk of death within 30 days of a surgical procedure based on specific procedures, age, weight and a patient's recorded diagnoses and co-morbidities.

6.14 NICOR told us that its records show that:

> *"LGI [Leeds] had not successfully submitted any data to the National Congenital Heart Disease Audit between March 31 2012 and 26 November 2012. Subsequently LGI started importing data in preparation for the data validation visit scheduled for February 28th 2013. The data quality index (DQI) is a measure of the accuracy and completeness of data entry (across four domains: demographics, pre-procedure, procedure and outcome) into the NICOR outcomes software when comparing to actual patient records during a site validation visit. Typically, NICOR would expect the DQI to be greater than 90%."*

6.15 Leeds overall DQI was over 90% in each year between 2009 and 2012. However, a comparison of data completeness for key variables between Leeds and the national average showed that it was a significant outlier in providing information about the weight of the patients whose data was submitted.

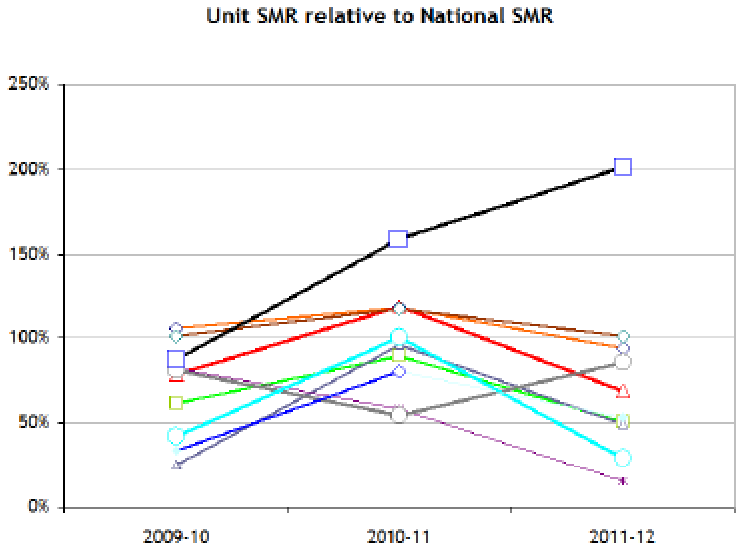
6.16 NICOR told us that there was a trend since 2006-2007 showing that all other centres except Leeds had improved their data quality with regards to weight.

6.17 Sir Roger Boyle was co-director of NICOR in March 2013. He had previously been national clinical director for heart disease in the Department of Health. Sir Bruce Keogh told us:

> *"I think he has done more for heart disease… in this country than anybody else; an outstanding individual."*

6.18 Sir Roger told us that he had been alerted by a colleague at the beginning of March 2013 about worrying preliminary data submitted by Leeds. He was also aware of concerns being expressed by families whose children had been treated at Leeds, and by concerns of colleagues at Newcastle and Birmingham. He was particularly worried that the surgical cover at Leeds was inadequate, with one senior cardiac consultant surgeon withdrawn from surgery and another on holiday and about to retire. The remaining two consultant surgeons were more junior locums, and he felt that this was a potentially unsafe situation.

6.19 On 27 March 2013 he and the other members of the NICOR steering group were emailed anonymised information (in the graph below) on the Standardised Mortality Rates (SMRs) for each of the centres undertaking paediatric heart surgery for the years from 2009 to 2012.



6.20 From his conversations with his colleague Sir Roger Boyle knew that Leeds was the unit showing a worrying rise in its SMR.

6.21 Sir Roger Boyle told us that he knew the figures were preliminary and that Leeds was well known for failing to submit full data in a timely manner, but nonetheless he felt he had to pass this information on. In light of all the other concerns that had reached him, he felt it was his duty, in the interests of patients, to alert Sir Bruce Keogh to the data. He spoke to him on the phone and subsequently emailed him the data.

6.22 He told Sir Bruce Keogh the data was unvalidated but he felt the concerns it raised still needed to be addressed promptly.

6.23 We asked Dr Riley why NHS England had not tried to verify the data before it advised Leeds to consider suspending surgery. He told us that the information had only just been received, and that it would have taken some time to validate:

> *"you can validate things and have people really focused on giving you important information when it is really, really critical, so when the service was suspended, people pulled out all the plugs to try and find the right data, to get it uploaded and to correct all the problems. I think if you'd said 'We have this data, it looks a bit like it might or might not be correct, would you help us sort it out?' the Trust might have put someone on it and come up with an answer three weeks later, in which case if it really had been proven to be correct data, another child may have unnecessarily died. I think the fact that the service was suspended could be viewed as precipitous, on the other hand could be viewed as the one most precipitating event which actually spurred people into the necessary action."*

6.24 Dr Bewick told us:

> *"It was put down as a pause and not a cessation. In other words, we're saying we just want to take stock and do that as quickly as possible. We were trying to give the benefit of the doubt to the organisation in many ways that we weren't shutting it. It wasn't as if CQC had been in and had basically said 'this is unsafe, we're stopping it today'. We advised the trust to do that and, therefore, they had a choice… Most fire engines go to false alarms and not to fires, but we're very glad they go and that's how I would portray it.*
>
> *The fact that we could put in another plan fairly rapidly to deal, particularly with children, and we didn't stop them completely operating…. We have tried to minimise disruption to families and to minimise the effects and maintain resilience in the system. Actually this has taught us that you can maintain resilience because there's a whole host of reasons why a unit might have to shut temporarily and we live in that world as it is…had we not acted and that following Tuesday a child had gone under the anaesthetic for whatever reason and the public knew that we had*

> *problems and that child had died, we would have been accused of gross negligence as an organisation."*

Comment

Sir Bruce Keogh and his colleagues had to act promptly once they had the NICOR data, even though it had not come through the proper channels.

6(c) Other concerns

6.25 Dr Bewick explained to us that Mr Bill Brawn, a respected paediatric surgeon in Birmingham, phoned Sir Bruce Keogh on 26 March. Mr Brawn told us that he had been motivated to ring Sir Bruce Keogh when he discovered that the senior consultant paediatric cardiac surgeon in Leeds, Mr Watterson, was away, and the remaining consultant surgeons were fairly junior locums.

6.26 Mr Brawn's view is that both patients and staff have to be protected from undue risk, and that the situation at Leeds was unfair on the two locums, who would be vulnerable if anything went wrong. He was aware that the other cardiac surgeon at Leeds had very recently voluntarily withdrawn from surgery and so could not provide support or cover.

6.27 Dr Bewick explained to us:

> *"There were only two permanent members of staff and one of them was already on what we call 'gardening leave'. There was a temporary surgeon, who would come in doing sessions, from abroad and there were two other posts with locums. When we actually looked at this in more detail, of course, we found that both of them would have had the equivalent of their CCT, their Certificate of Training in this country, but they'd both qualified abroad. Both had, in the opinion of the original review panel, the appropriate skills to run that unit if the two of them were on their own as opposed to with a senior surgeon who had been there a while.*

> *We didn't know that at the time and there was considerable concern that there were inexperienced surgeons there who were not able to do the full gamut of care that would be required. Now, again because of the issues around Safe and Sustainable it was very, very difficult to know the truth of that and there was an automatic assumption that they were inexperienced. We easily dismissed that by the second day and we realised then that the reason they couldn't substantiate the post was because of Safe and Sustainable and that people would not take on permanent posts. That's quite understandable and not atypical of hospitals that are under threat for any services at the time."*

Comment

The concerns about staffing turned out to be unfounded, but NHS England could not ignore them.

6.28 Mr Hasan notified Sir Bruce Keogh of his concerns on 26 March 2013. Mr Hasan told us:

> *"I had spoken to Bill Brawn regarding advice as to what I should do knowing the circumstances prevailing at the time. Bill then spoke to Sir Bruce and I was provided with a number to ring him [Sir Bruce]. I do not recall the exact mechanism of the number being passed to me, I think my secretary was given the number either by Bill or by Sir Bruce or one of his team."*

6.29 Sir Bruce Keogh told us that it was an unsolicited call from Mr Hasan.

6.30 Mr Hasan told Sir Bruce Keogh that Leeds was not providing the service it should to children, and it was not referring patients to other centres appropriately.

6.31 This was a significant conversation. Sir Bruce Keogh said in an email to Mr Hasan on 31 March:

> *"Last Tuesday you called me in confidence, to express your grave concerns regarding the quality of advice families were receiving from colleagues in Leeds. You asked me to intervene as a matter of urgency.*
> *I have done so, based on your concerns and those of others.*
> *I was clear you would need to back up your assertions, given that in my position I would have no alternative but to act"*

6.32 Sir Bruce Keogh asked Mr Hasan to provide written evidence for a risk summit to be held in the week of 15 April. In fact, the risk summit took place on 4 April, urgent safety reviews were started and as a result, surgery restarted on 10 April. The written evidence from Newcastle was provided on 12 April.

6(d) The decision to suspend surgery

6.33 Dr Riley told us:

> *"What we are looking at was the first meeting I had been to of a new way of working which NHS England has adopted very successfully many times since…When we had a concern about a hospital in the PCT days, the PCT would have just gone down to the hospital and we would have a meeting in a room with PCT directors and the hospital. The new way…the NHS England way, is to hold some sort of quality summit where you bring in all interested parties. So you would bring in the CQC, you would contact these other organisations and you would say do you have anything about Leeds Teaching Hospital…that you can come to the table and share…..So that first meeting was clunky, but it was the inaugural way of a process that has now been shown to be quite successful for us in managing quality issues."*

6.34 Dr Bewick reminded us these meetings took place soon after the second Francis report on Mid Staffordshire Hospitals NHS Trust was published (February 2013). One of the recommendations of the Francis report was that safety concerns should be responded to when they arise, without delaying to debate the accuracy of the information giving rise to them.

6.35 At the meeting at Quarry House on 27 March the decision was made to meet senior management at Leeds the next morning. At that meeting Sir Bruce Keogh (in his role as medical director at the Department of Health) advised Leeds that they should consider suspending paediatric heart surgery while the concerns were investigated. Mr Buck told us everyone present was aware of how it would be perceived by the public:

> *"…it is not at all surprising that given the legal position that opponents of the [Safe and Sustainable] decision believed that this was an attempt to…subvert other processes.*
> *Equally we were faced….with serious concerns that we were bound to act upon and that the failure to act upon those concerns could itself have been the subject of subsequent very serious criticism... What do you do? Well, you think through very carefully what the right thing to do is in the interests of securing safe service delivery in the interests of patients and act accordingly. Then you have to deal with fallout from that if there is fallout, which there was."*

6.36 Later that day the trust board met and decided to suspend children's heart surgery.

6.37 He told us that the practical and reputational consequences of suspending surgery were discussed at the meeting: a contingency plan would allow surgery to take place in an emergency, and the Embrace Service could take children to other centres if necessary. He explained the Embrace Service:

> *"a neonatal and paediatric intensive care on wheels. Babies and children receive just as good intensive care in the back of an ambulance as they do in a neonatal or paediatric intensive care unit. It is a fantastic, state-of-the-art service…"*

6.38 We were reminded by several interviewees of the context in which the decision to suspend surgery was made.

6.39 The context was:

- the Francis report had been published less than two months earlier
- feelings in Leeds and Newcastle were running high because of the Safe and Sustainable Review and the judicial review

- NHS England was about to come into existence and wanted to show it was responding to concerns about patient care swiftly and effectively.

6.40 The evidence was:

- data that Leeds' mortality rate for children's heart surgery was unacceptably high
- families were worried about the care their children were receiving or had received
- senior clinicians at other units were worried about the quality of care and competence of surgeons.

Comment

We consider the advice offered to Leeds about suspending surgery while a safety and data review took place was reasonable. Suspending surgery was the clearest possible indication of the priority given to patient safety. An urgent safety review while surgery continued would have given a different, mixed message.

7. Lifting the suspension of surgery

7.1 28 March 2013 was Maundy Thursday and over the long Easter weekend, Leeds gave NICOR more data. This allowed them to make an accurate analysis of mortality.

7.2 Dr Bewick wrote in an email to Sir Bruce Keogh on 1 April 2013 "*we need to verify evidence via a risk summit and consider all risks, not concentrate purely on mortality*" and a summit was arranged for 4 April.

7.3 It was agreed at the risk summit on 4 April that investigations would be in two phases:

- **Phase 1** would be a rapid review of the Leeds' clinical standards, patient pathway management and clinical governance. An externally led team of investigators would undertake this.

- **Phase 2** would cover:
  - a detailed mortality case review of the deaths identified by NICOR by an externally-led team of specialist clinicians
  - detailed interviews and investigations of parental concerns
  - investigation of the concerns raised by other professionals.

7.4 The phase 1 rapid review and NICOR update took place 5-7 April.

7.5 A further risk summit took place on 8 April. It considered the NICOR analysis and the draft rapid review findings and decided in light of these that surgery could resume.

7.6 The NICOR report concluded:

- *"Using data available on 05/04/13, no centre crosses the standard criterion for an 'alert', neither in individual years nor for the pooled 3 year period.*
- *By definition, around half of all Units will have more deaths than 'expected'. It is therefore inappropriate to label centres as 'blameworthy' for these deaths, as the analysis does not show a significantly increased mortality rate.*
- *In 2011-12, LGI experienced nine 30-day deaths compared to 6.5 expected (recalibrated). This is compatible with chance variation.*

- *Over the pooled 3-year period 2009-2012, LGI experienced 24 deaths compared to 16.5 expected (recalibrated), a relative risk of 1.46. With this pooled data; they were very close to the 'alert' threshold, as were 2 other centres.*
- *These findings do not indicate a 'safety' problem in any centre.*
- *However, centres with 3-year outcomes approaching the alert threshold may deserve additional scrutiny and monitoring of current performance."*

7.7 It also commented:

- *Data submission by Individual Trusts to NICOR has been very variable. Leeds have underperformed consistently in this regard. The data submission could be considered as a measure of the organisation and commitment to Quality Service delivery and excellence by Trusts. Additional data from all centres is being submitted, with a 'window' until 19 April 2013 to allow full PRAiS methodology to be used. We do not, however, expect this to change materially the output of the current analysis of 7 April 2013.*
- *The data in this analysis provides a good guide to centre performance with respect to operative mortality. The data should, however, not be considered in isolation when judging unit overall performance.*

7.8 The report of the rapid review[1] was finalised on 9 April. Its remit was:

"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"*

7.9 Its objectives were:

"With regard to Governance Process

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[1] The full report can be seen at http://www.england.nhs.uk/wp-content/uploads/2013/04/leeds-ext-review-rep.pdf.

- *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* [Multi-Disciplinary Team - 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"*

7.10 The summary of its findings included:

"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.

> *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."*

7.11 It concluded:

> *"Data Management internally in the Unit and by Leeds 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.*
>
> *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."*

Comment

1. We were not asked to comment on the conclusions of the rapid review and updated NICOR data, and as far as we know neither has been challenged. We therefore proceeded on the basis that their findings can be relied upon.

2. We consider that the decision to resume surgery before the specific concerns raised by families and Newcastle had been investigated was reasonable. Some of these concerns related to alleged failures of good practice rather than of safety. Safety had

been scrutinised by independent experts before surgery resumed, and found to be within normal limits. It was therefore reasonable to decide that the interests of patients would be best served by continuing to provide surgery locally, while also looking into the specific allegations made by families and by Newcastle.

7.12 Of the three reviews in phase two, agreed at the risk summit in April (see paragraph 7.3) the first two were published and the investigation of the concerns raised by other professionals is published with this report.

8. The three reports

8.1 Below we review and summarise the findings of the *Mortality review*, *Patient Experience report* and our *Independent review into concerns about paediatric cardiac surgery (the 14 cases) at Leeds Teaching Hospitals NHS Trust*.

8 (a) Mortality review

8.2 This was carried out by a group of clinicians and was jointly commissioned by Leeds and NHS England[1]. It was published on 11 March 2014 at the same time as the Patient Experience report. Its purpose was to review the 24 deaths NICOR included in their comparative 2009-2012 analysis and to review the 11 cases known to Leeds where a patient had died in the 30 days after a primary surgical procedure in 2012-2013.

8.3 Its methodology was:

> *"The expert external review team consisted of a congenital cardiac surgeon, a children's congenital cardiologist, and a paediatric intensivist, was established. They declared no conflict of interest. The review team were joined by the NHS England (West Yorkshire) Medical Director and the LTHT Medical Director (Quality and Governance) in undertaking the review process who declared no conflict other than their role in their employing organisations.*
>
> *… the team reviewed the clinical case notes, relevant imaging, minutes of discussions at multidisciplinary case conferences and details from the presentations and conclusions at the LTHT unit's clinical governance meetings ….*
>
> *Interviews were also held with the lead surgeon and lead cardiologist."*

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[1] The full report of the Mortality Review and the Family Experience report can be found at http://www.england.nhs.uk/wp-content/uploads/2014/03/leeds-review.pdf

8.4 Its remit concerned surgery performed in Leeds on children up to and including 16 years of age for congenital cardiac conditions:

- *"to review and comment upon the quality of care delivered to patients who died after surgical intervention from 2009 to 2012 focusing on the cohort of cases used to create the PRAiS comparative data analysis released by NICOR*
- *to review and comment on the process of mortality review undertaken as part of the Unit's Clinical Governance Mortality and Morbidity Review Meetings*
- *to identify any additional learning opportunities (over and above the outcome of the specialty level mortality review) on the said cases."*

8.5 Its executive summary concluded that the clinical management of the cases examined demonstrated medical and surgical care in line with standard practice. The review team proposed a number of recommendations, principally in relation to the development of standardised protocols and further audits to be undertaken. They said "*these represent opportunities for further quality improvement in the unit.*"

8.6 The review team made a number of detailed recommendations for continuing quality improvement in the unit, and commented that many of these could apply more widely in the NHS. A number of these relate to standardising the processes and protocols at Leeds and at other units:

> *"It is recognised by the review team that an undisputed evidence base for some of these may be lacking, but the adoption of a standardised unit approach could enhance staff training, audit, cost effectiveness and inter-unit comparability."*

Comment

The review's remit and methodology focused on the relevant issues and the investigation was robust and reliable. Our own investigations have built on and complement some of the findings in this report.

8(b) Family Experience report

8.7 This review was undertaken by Professor Pat Cantrill.

8.8 The terms of reference were to review *“the effectiveness of the support given by Leeds Trust to parents and children receiving cardiac care who approached NHS England and the CQC. To listen to parents of children who have used services at LTHT for children needing cardiac care to identify areas that have provided a positive and negative experience”* and to produce *“a report which identifies key issues and patterns related to parental concerns. This will be used to inform future changes to services and to identify areas of further investigation and/or development.”*

Comment

The terms of reference may give the impression of being interested in the views of parents who had used services at Leeds for their children. However, as the introduction to the report makes clear, only those who had expressed concerns were invited by NHS England to give evidence to Professor Cantrill.

8.9 The report says that, in addition to contacting families directly it:

> *“contacted key patient support groups serving families and children with congenital cardiac conditions. These groups included:*
>
> - *The Children’s Heart Foundation*
> - *The Downs Heart Group*
> - *Little Heart Matters support group*
> - *Leeds Children’s Heart Surgery Fund*
> - *Fragile Hearts group.*
>
> *Each of the above groups were contacted directly and asked to consider sharing the NHS England letter of invitation* (see appendix G) *to be part of the review with any families they felt may wish to take part. In this way the families contacted were self-selecting. The families were provided with the aims of the review and asked to consent in writing to participating.”*

Comment

The wording of the letter of invitation shows that the involvement of the charities was simply to identify other parents who might have concerns about Leeds, rather than parents who might have other views about the service they and their children had received at Leeds. So it is true that those who gave evidence were self-selecting, but they were from a pre-selected group.

8.10 The work involved:

- *"Reviewing written information already obtained from parents and from other key individuals.*
- *Undertaking one to one or group interviews, telephone conversation or a listening event with parents to identify key issues. The method used will be based on individual parental preference.*
- *Reviewing and analysing information gained from listening to parents to identify issues and patterns associated with the support that parents and children have received."*

Comment

Because the report focused on the experiences of families with concerns about Leeds, it did not include hearing from those members of staff who were the subjects of the parental concerns.

8.11 The report makes a number of findings and recommendations under the headings of:

- antenatal diagnosis and care
- provision of child centred and family centred care
- end of life care
- openness, transparency and candour
- responding to complaints and feedback.

8.12 It concludes:

> *"Those families who wished their experiences views and concerns to be heard have been listened to. Their stories were all heartfelt, moving and sincere. All the families were saddened to find themselves in a position where they had lost confidence in the care provided for their children and for them as a family. They want the services for children with congenital heart conditions both nationally and locally to learn from their experience. They want services for children and their families to improve.*
>
> *The experiences, views and concerns identified by the families have been used to establish a number of recommendations for NHS England, Leeds Teaching Hospitals NHS Trust and other heart units to assess the quality of services provided for children with congenital heart conditions and families.*
>
> *It is likely that there will be other families with different stories about their experiences of children's heart services in Leeds, including some with completely positive stories. However this must not be allowed to stand in the way of hearing and acting upon the stories that underpin this report. It is imperative that our focus remains on improving health outcomes for children with congenital heart abnormalities and their families.*
>
> *We have learned throughout 2013 as a result of the Francis report of the great importance and value of listening to patients, their carers, and their families. This report is yet another opportunity to do so."*

Comment

This conclusion very fairly sets out the views of the families interviewed, and makes it clear that the recommendations in it are based only on the views of those 16 families.

The report has obvious limitations:

- ***the only people interviewed, or invited to interview, were those who had concerns about Leeds***
- ***the terms of reference did not allow those about whom concerns had been expressed to comment on the concerns***
- ***the terms of reference did not allow any access to the medical records of the children.***

The terms of reference made it inevitable that the report would be one sided. This does not invalidate the report's findings and recommendations but they need to be understood in context and are not a general critique of the way in which Leeds offers support to patients and families.

8(c) Verita review of the 14 cases in the Newcastle dossier

8.13 The aims of the review as set out in the terms of reference were to:

1. Investigate the governance and communication processes around the care of children at the unit in Leeds, with particular reference to transfers to other trusts

2. Undertake specific clinical reviews of the 14 cases identified in Sir Leonard Fenwick's letter (unless the review team consider they have been adequately covered by previous phases)

3. Determine the actions necessary to secure and assure the safe and effective management of paediatric cardiac services at Leeds

4. Agree how the work of the review will be communicated to patients and public, including the conduct of any necessary patient recall exercises

8.14 After the start of the work the review team agreed with Dr Bewick, on behalf of the regional Quality Surveillance Group, that the report on the 14 cases Newcastle identified should focus on systems and processes and not on individual clinical decision-making, except insofar as such decisions provided evidence relating to systems and processes. It would also identify any examples of good practice.

8.15 The case studies, Sir Leonard Fenwick's letter and the initial interview at Newcastle led the review team to identify four potential issues with the Leeds systems and processes:

- that Leeds assessed the risk of some surgical interventions too highly, and consequently failed to offer suitable treatment and/or failed to make a referral to another centre
- that Leeds delayed treatment or referral to the detriment of patients
- that Leeds was unwilling to make referrals to centres outside Yorkshire, particularly Newcastle
- that communication between Leeds and families broke down at times when families needed to make crucial decisions, leaving them unsure of their options.

8.16 The review team found evidence that in two cases the risk assessment process had not been satisfactory, that in two cases there had been unnecessary delay in seeking second opinions or making referrals and there had been failures in, problems with, or breakdowns in communication in five cases.

8.17 The medical records showed no evidence that Leeds was unwilling to make referrals to centres outside Yorkshire, nor that it was unwilling to refer to Newcastle in accordance with its referral policy or when requested to do so by families.

8.18 The balance of the evidence did not support some of the situations described by families and by Newcastle.

8.19 The situations in other cases were unusual and did not accord with good practice but Leeds had no control over the circumstances.

9. Conclusions, lessons and recommendations

9.1 We have considered a great deal of written and oral evidence in writing this report, and our conclusions, findings and recommendations fall under five headings:

1. Data submission and record-keeping
2. Communication and complaints
3. Managing consultations on major reconfiguration
4. Whistleblowing
5. Restoring trust and confidence.

9.2 Each of these is explained below.

Data submission and record keeping

The importance of full and accurate data

9.3 The main trigger for the decision to suspend surgery in March 2013 was the disclosure to Sir Bruce Keogh of mortality data that showed Leeds had many more baby and child deaths within 30 days of heart surgery than average. The data were unvalidated and incomplete. Correct data provided later showed that Leeds was not an outlier, but by this time the alarm had been raised and children's heart surgery at Leeds had been suspended.

9.4 Information on the activities of hospitals serves many purposes including:

- monitoring patient outcomes and experience
- allowing comparison between past and present performance in a trust/department or individual
- allowing comparisons between trusts, departments and individuals
- providing safety assurances
- tracking the effects of changes in resource or skills
- monitoring the effect of new policies.

9.5 The NHS has been in a state of fairly constant change for some time and is still dealing with the effect of the biggest reorganisation in its history, which took effect on

1 April 2013. Even without political initiatives, the needs of a changing population, the advances in treatment options and in community support mean that reconfiguration of services will continue for the foreseeable future. People need information to help them assess the cogency and validity of proposed changes. Full and accurate data are important for this; facts and figures that have not been misleadingly interpreted, misrepresented or used selectively have great power. Inaccurate data are worse than useless and can be positively damaging. At Leeds incomplete information was instrumental in causing the suspension of surgery and great consternation both at the hospital and in the community it serves. Leeds senior management at the time should have ensured that data was full, accurate and submitted on time.

9.6 We are aware of controversy about how unvalidated information was used in this way, and NICOR confirmed that systems and protocols have been tightened to improve and speed up the validation process as well as clarifying how it will deal with units that do not provide sufficiently full and accurate data in good time.

9.7 However, events in Leeds show that hospitals will be held accountable for data they submit, whatever its quality.

Recommendation

R1 All NHS organisations need to give the accuracy and completeness of their data a high priority, for their own assurance and to assure patients, regulators and commissioners that their information can be relied upon.

Comprehensive record-keeping

9.8 The rapid review recommended that Leeds show greater consistency in record-keeping. We endorse this because some of the records we looked at were too limited to be understood without input from those who had made the notes.

9.9 Good Medical Practice, the standard reference book for doctors, sets out the required knowledge skills and performance:

> *"Documents you make (including clinical records) to formally record your work must be clear, accurate and legible. You should make records at the same time as the events you are recording or as soon as possible afterwards"*

9.10 This standard was not always met at Leeds because even where notes about decisions and actions were detailed, they did not always record why or how certain decisions were made and why something was done or not done. The notes show that when doctors are explaining a decision made by the multidisciplinary team, perhaps in a letter to the patient's GP, they give their reasons. However, when a decision was made following discussion with the family, it is not always clear why that particular decision was made.

Recommendation

R2 When important discussions are held, important decisions are made, and irreversible actions are taken, medical records should be written so as to pass the 'pick-up' test: that a colleague (or investigator or reviewer) with no knowledge of the case could pick up the file and understand why and how decisions were made, not simply know that they were made. This is not necessarily a bureaucratic or time-consuming process because it can be included in a simple template, checklist or aide-memoire that ensures all relevant information is captured.

9.11 The rapid review and the Mortality Review also recommended the introduction of protocols to help decision-making. We noted in our report on the 14 cases that Leeds carried out risk assessments without written protocols and guidance. This creates the risk of inconsistency and misunderstanding. We also noted that the records of decisions taken at Multi-disciplinary Team (MDT) meetings were not always recorded.

9.12 For instance, in the case of one patient[1] the operation risk quoted by the surgeon was higher than the cardiologist expected and caused the patient's parents such distress and anxiety that they sought a second opinion at Newcastle. This discrepancy between the surgeon's view and that of the cardiologist was more likely to have been identified and sorted out before the surgeon met the patient's parents if an agreed process had been followed and recorded.

9.13 We also noted that Leeds had no formal protocol for considering individual cases at MDT meetings, where important decisions are made on what treatment to offer patients. Those contributing to these discussions have different skills and levels of expertise. Protocols ensure that all relevant information is covered, and recorded, in a systematic way.

Recommendation

R3 Written guidance for carrying out and recording risk-assessments and decisions at Multi-disciplinary Team meetings should be prepared, in the interests of consistency and clarity. This applies across the NHS. These need not and should not be bureaucratic or time-consuming but should distil the existing best practice of decision-making at the centre. The pro forma for these meetings should reflect the process.

9.14 Our review of the 14 cases included lengthy discussions with clinicians on the previous and current policies on Fontan completion (see glossary). Leeds acknowledged it had carried out the second and third stages of the procedure on patients later than other paediatric cardiac centres in the UK, but assured us that it was aware of this and that it was an agreed and understood clinical pathway. However we found no written records of this. We commented in our report that unorthodox protocols might be correct but that those developing them should be able to produce strong evidence to support their decision-making.

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[1] Paragraphs 6.38-F8 (page 32-33) of the Verita review of concerns about paediatric cardiac surgery (the 14 cases) at Leeds Teaching Hospitals NHS Trust

9.15 We also considered the case of another patient who had successful conventional surgery at Newcastle after it had been attempted but not completed on two occasions at Leeds. This patient remained under the care of Leeds after the second unsuccessful attempt, awaiting a referral to Newcastle to see if a more radical procedure might be appropriate, until the patient's parents asked their GP to make the referral to Newcastle. This is an example where a written treatment plan should have ensured timely decision making.

Recommendation

R4 Centres should develop written clinical care pathways for the various congenital heart disease conditions of the patients they treat. Written individual treatment plans should be prepared for each patient by reference to the clinical care pathway. They should be regularly updated and given to and discussed with the patient's parents or carers. The pathway should be open about the many variables that influence treatment options but create a framework to help ensure consistency, clarity and open communication.

9.16 This recommendation develops the recommendation in the Family Experience report that the trust should "*review the processes for keeping families informed at all stages of care, in relation to the treatments being provided, changes in their child's condition and for providing clarity about palliative treatments*".

Communication and complaints

The importance of good communication between a service and its users

9.17 The Family Experience report describes the distress and anxiety of parents who felt they were not given the right information in the right way at the right time; or that they were not supported properly or at all.

9.18 Our report on the 14 cases in the Newcastle dossier identifies misunderstandings and miscommunications that led to families losing confidence in the advice and decisions of Leeds clinicians.

9.19 Communication is much more complex and sophisticated than it used to be even a few years ago, and people's experiences and expectations have changed accordingly. Good communication is an essential element of the patient experience.

9.20 Face-to-face meetings, letters, phone calls and leaflets continue to have their place but hospitals must use electronic communication, particularly social media, if they are to be effective communicators with those for whom social media is a normal and important part of life.

9.21 We were impressed by Newcastle's pro-active communication with parents for children with CHD. We heard about their willingness to visit parents at home to make sure they understood what had been discussed in meetings with consultants, and about the online group for these parents so they could support each other while remaining in contact with the liaison nurses. We know that they put time, effort and commitment into a communication strategy that ensures that patients and families feel well supported.

9.22 Leeds has a different approach. It does not use social media and liaison nurses do not make home visits. We see from the notes that great care is taken to offer support when it is sought, particularly by the liaison nurses, but this is largely a reactive rather than pro-active approach. We understand that this is typical in the NHS.

9.23 We discuss in the review of the 14 cases some of the problems that relying on social media for information can throw up, but social media are here to stay and trusts need to take advantage of them.

9.24 With the right intelligent and wholehearted approach, trusts and their staff should be able to do more to provide reliable information, avoid misunderstandings, and offer valuable support than they do at the moment. Trusts should aim to be the first site that parents looking for online help and information visit, and to which they regularly return.

9.25 An advantage of communicating online is that the parent and the professional have a written record of what was discussed. The parent can go back to it, ask for clarification or raise other issues, and the whole dialogue remains for reference. Online communication also gives the professional an opportunity to provide links to useful sites, and to provide generic information about care pathways for different conditions, information on how to raise concerns and how they will be responded to.

9.26 Enabling liaison nurses to engage with parents online is highly desirable.

Recommendation

R5 Leeds should review its communication policies to ensure that they meet current patient expectations. This should include how to give families an opportunity to raise concerns anonymously because some families fear that anything construed as a complaint may affect their child's care. Resources should be put into this because dealing with the consequences of poor communication is inevitably upsetting for parents and clinicians. The cost of doing so would be better spent on improving communication.

9.27 This develops the recommendations in the Family Experience report that the trust should "*review the ways in which bad news is delivered*" and that it should "*review the content of its website to assess if it meets the information needs of parents and children*".

The importance of good communication between services

9.28 One of Newcastle's major concerns, expressed in Sir Leonard Fenwick's letter to Dr Bewick in April 2013 and then to us in meetings was that Leeds was referring cases to Birmingham or London when the obvious place to refer was Newcastle because of its location and reputation.

9.29 Our review of the 14 cases looked closely at how these patients had reached Newcastle from Leeds. We reviewed Leeds' referral policy, which was to recommend to parents that referrals be made to centres that most often undertook the procedure needed in their particular case, unless parents chose differently in which case that would be respected. Parents were told of this right to choose and that they could ask their child's cardiologist or GP to make the referral.

9.30 Leeds also told us that clinicians would sometimes suggest to parents that a referral be made, or a second opinion sought from colleagues with particular expertise at other centres.

9.31 Our expert panel thought this was a reasonable policy. We reviewed the records that Leeds keep of referrals to other units, which suggests that the policy was adhered to. Leeds told us that none of the parents of children referred to hospitals other than Newcastle had complained about the referral process (or any other aspect of the care their child received).

9.32 We explained the basis of the Leeds policy to Newcastle. They fundamentally disagreed with it. They considered that referrals should be based on evidence of outcomes rather than volume, which would make their service the first place to which to refer in many cases.

Recommendation

R6 We recommend that NHS England should give consideration to having a service-wide discussion about referral policy, so that common standards can be agreed, or, at least, that the differing policies at different centres are understood by all centres.

9.33 Some children included in the 14 cases were referred by their parents to Newcastle, which accepted them for treatment before any referral from Leeds. We understand that this was done in an effort to help desperate families, but it led to Leeds being blamed for not making referrals that it was not aware were being requested.

Recommendation

R7 We recommend that any centre that accepts self-referrals develops and publishes a protocol for managing the transfer of care. Such as protocol should include notifying the hospital previously treating the patient.

9.34 The IRP report considered whether every centre should be able to undertake every type of procedure, including rare and complex ones. It commented that it:

> *"saw evidence of a shift away from the historical pattern of certain rare and complex procedures being undertaken in only a few centres… The Panel is mindful of the fact that the definition of what is a 'complex' procedure changes over time as clinical practice develops….*
>
> *Rather than expecting every centre to be undertaking every type of procedure, the more likely pattern to be observed over time is a cycle of innovation, dissemination and some sub-specialisation. The Panel considers that this is desirable and should be encouraged. To ensure safe services of the highest possible quality for patients, this issue requires on-going and active monitoring, collaboration and management at a national level."*

Comment

This cycle will not benefit patients to the fullest extent without referrals being confidently and collaboratively made and accepted when they are in the best interests of the patient.

Recommendation

R8 Regulatory bodies should consider including evidence of robust referral protocols and their effective use as markers of quality services.

Complaints

9.35 The rapid review identified that Leeds' handling of formal complaints needed improvement and evidence shows this happened.

9.36 The bigger issue is about how other bodies deal with the concerns they receive about the care and treatment given to a patient.

9.37 The main reasons for suspending surgery, apart from the incomplete NICOR data, were the concerns raised by families and by Newcastle. These concerns included specific allegations of poor practice and allegations of serious professional misconduct.

9.38 Families began reporting their concerns to the CQC and CHF at the end of 2012.

9.39 Some of these families may have had their concerns looked at by the rapid review team in April 2013 but were not involved in that process and did not know of its conclusions.

9.40 The CQC, the Safe and Sustainable team and charities are not the usual first contact for complaints about a patient's hospital care. The orthodox route for dealing with complaints is for the complainant to complain directly to the trust and then to the Health Service Ombudsman if they are not satisfied with the way their complaint was dealt with by the trust.

9.41 A total of 23 families had their children's cases included in the Newcastle dossier, or gave evidence to Professor Cantrill, or both. We know that five families made formal complaints to Leeds in February and April 2013, because their children are included in the Newcastle dossier and we have seen their complaints. They have had responses from Leeds and so are aware of Leeds' view of their concerns. The families of the other children in the Newcastle dossier did not make complaints, nor did they raise concerns with the CQC.

9.42 Not everyone who spoke to Professor Cantrill or whose child was included in the Newcastle dossier has raised concerns.

9.43 We know that the parents of at least one of the Newcastle 14 did not raise concerns or make any complaint; their child is included because Newcastle contacted them at the beginning of the Easter weekend in March 2013, to ask their permission to do so.

9.44 We have also been told by a Leeds cardiologist that one of her paediatric colleagues at another hospital told her of a conversation with a patient in September 2013. This patient's child had died at Leeds some years before. The Leeds cardiologist made a note of the conversation with her colleague which read:

> *“She explained that she had had no concerns about her [child’s] death at the time but had recently been contacted by [a woman whose child was being treated at Newcastle and who is active in the Newcastle parents’ support group] who had rung her and encouraged her to complain about Leeds and ‘re-open the case’. She was sent an email with ‘forms to fill in to get the case re-opened’. She has since spoken to Pat Cantrill for the report”*

Comment

Presumably this contact was made as part of NHS England’s request to charities that they should ‘consider sharing the NHS England letter of invitation to be part of the review with any families they felt may wish to take part’.

9.45 The way in which these complaints and concerns by parents and professionals have been dealt with shows that some families at least have been getting rather mixed messages.

9.46 Before sending the Newcastle dossier to Dr Mike Bewick in April 2013, Newcastle obtained the consent of families, some of whom had already raised concerns elsewhere. We consider that they were entitled to believe that Newcastle accepted the accuracy and completeness of their concerns. The reality is, however, that if they have not also made formal complaints to Leeds, they have not had a formal response to their concerns.

9.47 Families who raised concerns with Jeremy Hunt, the CQC, Safe and Sustainable and charities and also spoke to Professor Cantrill did not have their concerns investigated in that process. Professor Cantrill made recommendations based on what she had been told, which were described as ‘findings’. However, the terms of reference of her review did not allow her to obtain a response from Leeds to allegations made about Leeds staff, so assertions of poor professional conduct justifying regulatory investigation were published without the possibility of challenge. It would not be surprising if the families who were quoted in the report assumed that their experiences had been officially accepted by Professor Cantrill.

9.48 The terms of reference in our review of the 14 cases allowed us to receive evidence from more sources than Professor Cantrill could. We found significant factual inaccuracies in some of the complaints and concerns of families, such that we disagree with their views about what happened.

9.49 This lack of consistency is unfair on the families affected.

9.50 All the concerns should have been looked at promptly. Leeds should have been asked to respond in the normal way to all the matters reported to CQC, CHF, the Safe and Sustainable team and anyone else contacted by families. The similarities and discrepancies between the families' recollections and the contemporaneous records and correspondence would then have provided a clearer picture of events.

9.51 The failure to do this not only left clinicians at Leeds dealing for many months with the burden of unproven allegations of serious professional misconduct, but it also left families in the unsatisfactory position of not having a detailed response to their concerns.

9.52 Some of the families raising concerns may have been campaigners wishing to influence the future of the service at Leeds and may not have expected detailed investigations. This is their right, and does not diminish the validity of their concerns, but we think those receiving the concerns and acting on them should have distinguished between concerns to which parents wanted answers and those being communicated for political purposes.

Recommendation

R9 Where families raise concerns other than by way of complaint to the relevant provider trust, those receiving the concerns should establish whether the families are looking for answers or raising quality concerns. If the former the concern should be investigated as a complaint. If the latter the family should be invited to raise concerns with the appropriate regulator and if they are willing to do so with the relevant trust.

Managing consultation on major reconfiguration

Minimising the effects of consultation about reconfiguration on patients and families

9.53 The Safe and Sustainable review created rivalry between Leeds and Newcastle which set up anxieties in local families.

9.54 For instance, as long ago as June 2011, a Leeds psychologist working with the mother of one of the children in the Newcastle dossier wrote to the child's cardiologist:

> *"I got a sense of complete mistrust of all clinicians caring for [the child] which has been intensified by the Safe and Sustainable Review which is going on. They worry that Leeds are not interested in treating [the child] because [the child] is too complex and it would look bad for the unit so have arranged to see someone in Newcastle…for a second opinion. Equally they are also concerned that Newcastle could take [the child's] case to score points against Leeds."*

9.55 This theme recurs in letters from families and the charities supporting them, and although we found no evidence to support it, we have no reason to doubt it was a genuine concern that they had.

9.56 Parents having to make life and death, or life-altering, decisions about their children need to be sure that they are being given impartial advice on the options and their possible consequences. This is particularly important in a specialism such as children's congenital heart surgery, where the data on long-term outcomes are still insufficient to provide detailed guidance.

9.57 It is difficult to deal with someone's fear of raising concerns, but nonetheless the attempt must be made. Parents of seriously ill children know how dependent their children are on the skill, dedication and commitment of the specialists treating their child, and are often reluctant to do anything they fear might jeopardise that commitment. Trusts, and staff, must provide an environment in which families feel comfortable in raising any concern or anxiety, including about the conduct or expertise of staff at every level. Parents should be encouraged by staff to do this informally, and should receive a friendly, sympathetic and detailed response.

9.58 Some staff already provide this environment for the patients but it must be overt, well published and closely monitored across the trust. There should be an assumption that a formal complaint is an indication that the informal system has failed, and this should be part of the investigation into the complaint. Where a formal complaint is raised without any previous concerns being expressed, or identified, the reasons for this should be investigated.

Recommendations

R10 Any review that leads patients or their families to reasonably believe that clinical advice from a doctor could be coloured by his or her self-interest is not well structured. We recommend those setting the terms of reference of such reviews should be alert to this risk.

R11 Where such anxiety by parents is expressed or is likely, staff at both hospitals affected by the review have a duty to minimise it. They should anticipate the possibility of such fears and offer convincing reassurance that all advice is given simply in the interests of the child. Leaders in the organisation should anticipate such problems and prepare for them.

Minimising the effects of consultation on working relationships between services

9.59 Paediatric heart surgery is a tiny speciality, with about 30 consultant paediatric cardiac surgeons in the NHS. They all know each other or of each other, trained or were trained by each other, share information on new techniques and offer each other help when asked for a second opinion or to take on a case where they have greater expertise. They are all working in a specialised area of medicine in which innovation has led to huge gains for patients, and they all know that they depend on each other to ensure the best results for their patients.

9.60 Any disagreements and personality clashes should be in a context of mutual respect, but this is not the case at Leeds and Newcastle, where we found evidence of a strained relationship between clinicians.

9.61 Some of this clearly followed Newcastle's intervention in March and April 2013, but some seems to pre-date those events and to have arisen from the Safe and Sustainable process.

9.62 For instance, we met most of the Newcastle clinicians and the chief executive in January 2014 and they told us about a rally in Leeds in 2012 in which they claimed uniformed Leeds nurses were carrying a placard suggesting that Newcastle was the 'Road to Death.' They had seen newspaper pictures of this. We considered that this was a serious allegation and asked Newcastle to provide us with the evidence. We were provided with a link to a video clip.[1]

9.63 We do not consider that this clip bears out what Newcastle told us. The rally was in support of surgery remaining at Leeds. Most of the placards did not mention Newcastle and were carried by members of the public. Speeches and interviews that mentioned Newcastle made no criticism of it. They referred to the distance sick children would have to travel in an emergency and the risk that they would not survive the journey.

9.64 The video showed one hand-made placard saying 'Leeds-Newcastle-Death Row' which appeared not to be held by a nurse and, in the context of all the other comments, probably referred to the length of the journey to Newcastle rather than to the quality of the treatment there.

9.65 We were told about this 16 months after the rally, but the fact that we were told at all indicates a high level of upset by Newcastle professionals about Leeds professionals at the time.

9.66 The judicial review, challenging the decision to concentrate surgery at Newcastle and not Leeds, was another cause of tension.

9.67 Save our Surgery made its case based in part on a long witness statement from the then senior surgeon at Leeds, Mr Kevin Watterson. Newcastle told us that the statement was so inaccurate that the trust asked to be joined to the judicial review as an interested party, so that they could rebut what they saw as unfair criticism of their services and standards.

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[1] http://www.yorkshireeveningpost.co.uk/news/latest-news/top-stories/video-thousands-march-through-leeds-in-children-s-heart-unit-protest-1-4766403

The written evidence for their case was contained in a long statement by the senior surgeon at Newcastle, Mr Hasan.

9.68 In litigation evidence is provided by those best placed to provide information in support of the case being put forward, so it is not surprising that the senior surgeons at Leeds and Newcastle were called upon in this way. This seems to have resulted in making the legal challenge and defence of the decision to choose Newcastle instead of Leeds to be seen as detailed, personal, and public criticism by each of these senior surgeons about the children's cardiac services provided by the other's hospital.

9.69 The depth of antipathy was also evident when we spoke to a group of Newcastle consultants and the chief executive of the trust, Sir Leonard Fenwick. One told us, without challenge from colleagues that if it came to choosing between what parents had told Newcastle and what the Leeds notes revealed, he would doubt the accuracy of the Leeds notes.

9.70 This consultant also felt that, in discussing cases with us, Leeds would provide after-the-event justification for their actions or inactions that would not accurately reflect why they had made decisions at the time.

9.71 Leeds, for their part, were sceptical of the 'whistleblowing' motives of Newcastle in raising the 14 cases, pointing out that such concerns would have normally been raised with them directly and that some were old.

9.72 We were told about a better way of dealing with some of the anxieties the Safe and Sustainable review provoked. In London there are three paediatric cardiac centres, one of which was identified by the Safe and Sustainable team for closure. Its trust challenged the decision through a judicial review.

9.73 The London Steering Group for Children's Congenital Heart Services was originally established to provide oversight and strategic direction to the implementation in London of the Safe and Sustainable team decisions on children's congenital heart services. Its role changed during 2012-13, while the legal challenges to the Safe and Sustainable team decisions were underway.

9.74 During that period of uncertainty, the London Steering Group gave strategic leadership in London to ensure that services were not adversely affected and that the three service providers and their commissioners continued to work together to improve services for the benefit of patients and their relatives.

9.75 The London Steering Group's membership included the chief executives and medical directors of the three provider trusts – the Royal Brompton, Great Ormond Street and Guys and St. Thomas' NHS Foundation Trusts, the medical director of NHS London (from April 2013, NHS England – London Region) and the London head of specialised commissioning. It was chaired initially by a Primary Care Trust chief executive, then by an independent person.

9.76 Arising from discussions at the London Steering Group, the chief executives of the three trusts agreed a joint statement (appendix H), which was issued on 6 December 2012, placed onto each of their websites and made available to relatives of patients and to staff in the services. It stressed that standards, and safety of services would be maintained, families and referrers would be involved and staff would be valued, involved, protected and made aware that their skills and expertise would continue to be needed by the London network.

Recommendations

R12 Those making decisions where reconfiguration is being considered have a responsibility to ensure that relationships between medical and nursing staff at 'competing' trusts are not damaged. This should be built into the systems and processes.

R13 Managers at affected trusts also have a responsibility to ensure that strong, respectful relationships are maintained between staff at 'competing' trusts.

The effects on staff need to be taken into consideration when planning reconfiguration

9.77 Individuals charged with planning reconfiguration must look at the bigger picture. Where the purpose of reconfiguration is to improve services rather than to save money, the individual circumstances of the highly skilled professionals likely to be affected are part of the bigger picture and must be taken into account.

9.78 The rapid review found that Leeds was suffering from a form of planning blight. It had been unable to recruit surgeons to substantive posts because of the threat of closure of surgical services. The consequent reliance on locums was one of the triggers for the suspension of surgery. The rapid review found that locum surgeons at Leeds were competent and held the appropriate qualifications

9.79 The IRP report also found the unwillingness or inability of skilled staff to move from one centre to another was an important issue in ensuring high-quality, safe services.

9.80 Those we met in both Leeds and Newcastle were anxious about their future in a reconfigured service.

Recommendation

R14 During the course of any review, consultation or implementation of reconfiguration a trust's management must give a high priority to minimising the understandable anxiety in staff likely to be affected.

9.81 Maintaining staff morale while radical change is being considered is an obvious element of maintaining quality while improvement is being planned.

9.82 The potential disruption to careers and lives must be acknowledged and addressed and staff should know that contingency planning, looking at their legitimate expectations as well as those of patients, is taking place.

Whistleblowing

9.83 Newcastle were clear to us that they felt they were acting as a whistleblower in raising the concerns. They told us the details of the 14 cases and explained*:*

> *"These were the reasons why the issues were raised with NHS England at a very politically sensitive time for us. We had discussed this thoroughly between myself, [cardiologist] and with Sir Leonard as it would have been convenient not to raise issues which might be taken in a political context. We felt that patients' safety was paramount and that prompted us to raise our concerns."*

9.84 However, the evidence was inconsistent.

9.85 The information provided by the Newcastle paediatric heart surgeon Mr Hasan to Sir Bruce Keogh on 26 March 2013 was an important element of the decision to suspend surgery at Leeds.

9.86 Sir Bruce Keogh said in an email to Mr Buck on 27 March 2013 that neither Mr Brawn nor Mr Hasan was "*alarmist or meddlers by nature, so I would take their concerns very seriously."* Shortly after this email was sent one of recipients[1] who had been copied into Mr Buck's email responded *"The two phone calls very clearly add considerably to what we already know. I think they definitely tip the balance towards the need for some sort of assurance exercise."*

9.87 Sir Bruce Keogh wrote to Mr Hasan on 31 March 2013 confirming their conversation and requesting evidence in support, which needed to be "*sound."*

9.88 Mr Hasan responded the same day:

> *"I am delighted that you have taken a prompt and courageous decision to investigate the concerns raised by myself and others relating to Leeds cardiac services. I spoke to you after considerable deliberations between me and my colleagues, these refer to a barrage of clinical problems we have had to deal with in the last few months emanating from patients in the Leeds area."*

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[1] Name redacted in the email we have seen.

9.89 Sir Bruce Keogh wrote to Dr Damien Riley and others that evening, referring to the phone call and saying he had told Mr Hasan he was making a serious accusation that he could not ignore. He went on to say that Mr Hasan confirmed that the difference of opinion between Newcastle and Leeds was serious rather than normal and that he had evidence to back up what he was saying. He concluded "*In many senses this is the most serious issue.*"

9.90 Dr Bewick met staff at Newcastle on 3 April 2013 to hear more about the concerns, and reported in an email to Sir Bruce Keogh on 4 April:

> *"Newcastle have 14 cases where significant criticisms of the care at LTHT have been recognised over the last 12 months. Common themes are: late referral; inappropriate and premature use of the palliative care pathway; lack of counselling for intra-uterine diagnosis; inappropriate or incompetent surgery (small number)."*

9.91 When we first visited Newcastle, before we had seen the dossier, we met the chief executive and senior staff, including consultant surgeons and a consultant cardiologist. One of them described the genesis of the dossier:

> *"There has been a background over the last few years, of what we can best describe as rather bizarre routes of referral of patients from the Leeds catchment area, which on an individual case didn't really raise any concerns, but the pattern began to emerge…*
>
> *The other bit of background is that within the whole area of congenital heart disease, in paediatrics in particular with the spotlight being on it, there is a concern as to what happens to high risk cases and how units respond and how vulnerable units feel when they have to take on high risk cases.*
>
> *There has been a pattern of high risk cases emanating from Leeds, sometimes through this rather bizarre referral pathway.*
>
> *The index case describes an individual case where the patient arrived here in a very poor clinical condition... The family gave a heart-wrenching story to us describing how the family ended up at our unit. We are aware that sometimes the family description of events is not completely accurate but this particular case stood out. When we looked at that case, when we came together, we felt we had to highlight*

> *some of the things that that case brought forward, in terms of communication, the wider network and we were aware that this child could have come to serious harm. As it happened, Mr Hasan was able to do an operation, semi-acutely, the child has done well.*
>
> *That is the index case, and when we brought that to the attention of the wider organisation (NHS), we were then asked 'Were there any wider issues?' which is how we began to look at the cases that I have been previously alluding to ie the unusual referral route, the poor communication and some high risk cases. They have all come together in this, what has been called, dossier."*

9.92 The 14 cases arrived at Newcastle between 2005 and 2013. Mr Hasan reported on 31 March 2013 *"a barrage of clinical problems we have had to deal with in the last few months."* When Dr Bewick reported his meeting with Newcastle on 3 April in his email of 4 April, he referred to Newcastle having 14 cases where significant criticisms of the care at Leeds had been recognised in the last year.

9.93 These statements seem to describe different things. The records show that in the last six months (our interpretation of the "last few months") before making this comment, one child had received conventional open heart surgery having been referred for a unconventional procedure the previous year; one baby with a congenital heart defect was born after the mother chose to give birth in Newcastle; one child had a minor operation after being referred for possible complex surgery by Leeds and one had a serious operation several days after the mother asked for an immediate referral of the child to Newcastle.

9.94 The 14 cases discussed with Dr Bewick included one referred to Newcastle in April 2013 and so clearly not in Mr Hasan's mind at the time of his email on 31 March. Three children were referred from Leeds to Newcastle in the year before Mr Hasan's email and one pregnant mother referred herself. All the other referrals were at least a year earlier, and sometimes many years earlier.

9.95 The description of the genesis of the dossier in the quote above also gives a different perspective to the concerns expressed by Newcastle; the description in Mr Hasan's 31 March email of a "*barrage of clinical problems…in the last few months*" becomes a single troubling event which led to earlier cases being reconsidered at the request of the NHS.

9.96 The evidence shows that in March 2013, despite what Newcastle said and recalled having done, they compressed the period of their concerns in a way that put Leeds in an unfairly poor light, even if all the concerns had been substantiated.

9.97 We asked Newcastle why they had not dealt with these concerns in a more orthodox way, for instance by contacting their colleagues in Leeds, or reporting them to the relevant regulators.

9.98 They told us that they were so busy getting on with work that this was not at the forefront of their minds. Also that the problem was systemic rather than individual.

> *"It is a systemic organisational issue. All the medium-sized units in the country are under pressure, this includes Alder Hey, Bristol, Southampton, Leeds and ourselves. The problem is that the units are not big enough. The clinicians cannot just take all the blame they are caught between a rock and a hard place. The cardiologists are also caught up amongst this problem especially in a unit who does not do quite a few operations…*
>
> *The cardiologists are caught in the same situation especially if an operation is not being undertaken by their own surgical colleagues. It is difficult then to assign a mortality to these patients. This is endemic of the systemic failure… It is imperative that this crumbling service is resurrected; this can only happen with reconfiguration in to larger sized units. In the meantime what is happening will continue to happen. I can give you several examples where I think the patients have come to real harm."*

Comment

This is a troubling statement. If Newcastle thought that patients had come to real harm at Leeds they should have taken action as their concerns crystallised, rather than collecting evidence for later reporting.

9.99 Newcastle's certainty about the issues they had raised in March and April 2013 shifted between then and April 2014.

9.100 When Mr Hasan spoke to Sir Bruce Keogh on 26 March 2013, and when he and others met Dr Bewick on 3 April, they were understood to be expressing their own concerns about Leeds, not simply passing on the complaints of parents.

9.101 This impression is not dispelled by the introduction to the dossier:

> *"This dossier has been formulated following discussion of cases within the Newcastle multidisciplinary team and summarises the experience with patients and families from the Yorkshire population catchment area and concerns raised directly with us. Some of these patients have already been treated and others are waiting for treatment at the Freeman Hospital in Newcastle upon Tyne (the Freeman)."*

9.102 Sir Leonard Fenwick's letters to Dr Mike Bewick on the 12 and 18 April outline what are described as Newcastle's concerns about Leeds paediatric cardiac unit.

9.103 Furthermore, when Newcastle spoke to us in January 2014, they gave no indication they were repeating the concerns of others.

9.104 However, when we visited Newcastle for a second time in April 2014 and queried some of the assertions in the dossier, they clarified that the entries in the dossiers reflected what they had been told, not necessarily what they knew as fact.

> *"At the beginning of the case studies the introduction states that the document summarises our experience with patients and families from the Leeds area and the concerns raised by them with us"*

9.105 They also made clear to us that their approach was to assume that what parents were saying to them was true.

9.106 We mentioned the case of one patient where the dossier entry had asserted that the patient had had to wait too long for surgery in Leeds and that when the patient's mother asked for a transfer to Newcastle this was refused, and the operation was carried out in Leeds. Subsequently the patient's mother lost confidence in Leeds and transferred to Newcastle.

9.107 We went through with them the discussions between Leeds clinicians and the patient's mother, which were detailed and lengthy and provided a different account from that in the dossier.

9.108 The Newcastle consultant who had taken on the patient's care told us:

> "*My involvement with [the patient] has been after the operation. I have heard the story from Mum, which you also have. The referral to us post operatively was through [Leeds cardiologist] who telephoned me and referred by letter….When we get a referral from outside then we take it unless the review is inappropriate. In terms of the pre-operative events I wasn't involved.*"

9.109 The referral letter explained the patient's clinical and operational history and explained that the patient's mother had decided 10 months after the operation to transfer to Newcastle because the cardiologist had raised official concerns that the patient's mother seemed to be convinced that her child needed invasive treatment that the Leeds team thought unnecessary and undesirable.

9.110 A Newcastle liaison nurse told us:

> "[*The patient's] mother requested to come over and have a look, a visit, to Freeman to see if she liked the unit and would be able to get on and manage at Freeman. We went round... She quite clearly had found it difficult to talk to people in Leeds. She wanted to come to Newcastle, but I did actively encourage her, if she had been given the surgical date in Leeds, to stay in Leeds, because she did have family – she is a single mum…and that it would be easier for her to manage in Leeds. She specifically said that she had not lost faith in the surgeon in Leeds. She went back to Leeds and the next thing we know is [the patient] had had the operation.*"

Conclusions

1. Reporting the unchecked allegations of others is not whistleblowing, and Newcastle should have made the status of their concerns clearer when they reported them.

2. We consider that anyone reading Sir Leonard Fenwick's letter to Dr Mike Bewick of 18 April would believe that he was expressing the concerns of clinicians, not of families.

3. The entry in the dossier about the patient referred to in paragraphs 9.106-110 seems to have been prepared only on the basis of the patient's mother's story, despite the evidence from the liaison nurse of the mother's ambivalence and that she had encouraged the mother to let the patient have the operation in Leeds, and despite the cardiologist's knowledge of the difficult circumstances surrounding the transfer to Newcastle, about which the Leeds cardiologist was perfectly open.

9.111 Some of the families of the 14 children in the Newcastle dossier were campaigning for surgery to be permanently closed at Leeds as part of the Safe and Sustainable process. Their views about the care their children had received at Leeds compared to Newcastle committed them to the Newcastle camp and to doing their best to support Newcastle when Leeds challenged the decision of 4 July 2012 to end the provision of surgery at Leeds and transfer it to Liverpool and Newcastle.

9.112 The mother of the patient referred to above did not make a complaint to Leeds about how she claims she was treated. She was a signatory to the letter to Jeremy Hunt of 25 March. She also went public about her concerns when surgery was suspended. She did not respond to our invitation to discuss the issues in the dossier. However, the matters mentioned at the beginning of this paragraph strongly suggest that she was a campaigner for services in Newcastle to prevail over services in Leeds.

9.113 In a highly charged political atmosphere, such as that which existed in early 2013 in Leeds and Newcastle, professionals raising the concerns of parents need to be very clear whether parents are complaining, whistleblowing or campaigning, even if the parents are not.

9.114 In his letter of 18 April, Sir Leonard states that Newcastle were aware that patient's families had "*either individually or as a group raised their most fundamental concerns with the Care Quality Commission (CQC) and also the Independent Reconfiguration Panel*". This shows that Newcastle clinicians were aware of the campaigning of some of the patient's families, which should have alerted them to the need for caution in this regard.

9.115 Newcastle explained to us in detail their awareness of how families deal with information about the risks, options and outcomes for their children. What they said revealed that they knew about the possibility that families could take some time and several attempts to get a full understanding of their child's diagnosis and the risks and options associated with it. We are thus surprised at their willingness to put their reputation behind the parental concerns by transmitting them to commissioners without even elementary checking.

9.116 Newcastle should have carried out basic checks before they passed on the stories of these families, whether or not they knew that some families were campaigning on their behalf.

9.117 For instance, in the 'index case' (referred to by Newcastle in the quote above in paragraph 9.91), Newcastle could easily have contacted health care colleagues (not working at Leeds) to get their account of what had happened before the patient reached Newcastle. This would have given them valuable information to help put into perspective the *"heartwrenching"* and no doubt heartfelt story the family told.

Recommendation

R15 Professionals should make clear when they pass on concerns about other professionals whether those concerns are their own or those of patients or families.

Before professionals pass on the concerns of patients or families, they should establish whether the patient or family has complained formally to the trust concerned. If the families have complained, the professionals should include any response from the trust when they pass on concerns. If they have not complained, the professionals should find out why, and provide that information when passing on the concern.

Restoring trust and confidence

9.118 We became aware that the anxiety and fearfulness in evidence in Leeds and Newcastle were also felt elsewhere in the larger network of paediatric cardiac services. We were told at Leeds that experienced surgeons had moved abroad and there was an impression that younger surgeons were hesitant about choosing paediatric heart surgery as a specialism. The IRP report contains this comment:

> *"The phrase 'waiting for the next Bristol' captures the almost morbid sense of spectatorship and foreboding that hangs over these services"*

9.119 This should have been a wake-up call to all those who commission, regulate, provide and use paediatric heart services.

9.120 Paediatric heart surgery is one of the great modern successes of modern medicine. Once inoperable conditions are now routinely treated successfully, children are living now who once would not have survived their babyhood, and adults who once would not have survived childhood have normal life expectancy. Many of them are relatively unaffected by their heart condition in their daily lives.

9.121 Survival rates following surgery, although very important, are not the only measure of quality. Timely surgery; minimising disability; improving quality of life; and providing good patient (and parental) experiences are all important markers of quality.

9.122 However, reliable and comprehensive measurements of these quality markers are not yet in place so as to allow comparisons between units. The IRP report recognises the importance of collecting such data and recommends that this should be given a high priority, but currently we can only rely on the mortality data.

9.123 The IRP report commented that:

> *"The proposals for change have not been argued on the grounds that current services are unsafe. For several years, standard data have been collected about each intervention and summary comparative analysis is publicly available on the NICOR website. The Panel were consistently told that the quality of the outcome data and the range of robust, publicly available data on paediatric cardiac surgery in the UK is the envy of the rest of the world. Published mortality rates are uniformly around two percent or less for primary surgical procedures in all the current surgical centres, and as such comparable with the best equivalent services internationally…*

> *In this context, the Panel were troubled to hear some people assert that there were known and significant differences between the outcomes achieved by the existing centres. The Panel sought the evidence behind these assertions without receiving anything conclusive. At the end of the review, the Panel asked the JCPCT, as commissioners, whether there existed any further information about the safety or performance of the current centres that would help inform the Panel's advice to the Secretary of State. The JCPCT confirmed that there did not…"*

9.124 The advances in treatment have occurred through the dedicated professionalism of surgeons, cardiologists, specialist nurses and all those in the teams who treat and care for these children.

9.125 Sometimes things will go wrong, and sometimes this will be the result of human error. Anything that goes wrong must be identified and scrutinised openly, not only so that families can be sure that they have all relevant information but also so that the chance of a recurrence is minimised and public confidence is maintained. Equally importantly, evidence of problems and difficulties must be dealt with proportionately, so that what is good or excellent about the service is not harmed.

9.126 The reconfiguration proposed in the Kennedy report of 2001 has still not taken place. This is a problem for the service. The recommendation was intended to ensure that all surgeons carried out enough operations to maintain their expertise. The failure to bring about reconfiguration has left the impression that some centres or surgeons are unsafe because they do not reach the required volume. The decision in July 2012 to remove surgery from Leeds can only have added to this impression there.

9.127 The IRP report does much to challenge this view. It noted that the Safe and Sustainable review had asserted that a minimum of 400 to 500 operations in a surgical centre is associated with better outcomes. It reviewed the NHS evidence in the Safe and Sustainable review and found that:

> *"… the thresholds for minimum critical mass recommended by the Kennedy Report, Munro Report and European Association for Cardio-Thoracic Surgery were substantially lower than 400-500 cases per surgical centre. The Kennedy Report*

> *suggested that paediatric congenital heart surgeons should perform a minimum of between 40 and 50 open heart operations a year."*

9.128 It also noted that the Munro Report[1] recommended that centres should have at least three surgeons undertaking at least 300 paediatric surgical procedures a year, and that the European Association for Cardio-Thoracic Surgery Report[2] recommended that each centre should operate on more than 250 patients a year; each surgeon should perform 125 cardiac surgical procedures on adults or children each year.

9.129 Leeds reaches the recommended thresholds in the Munro and EACTS reports.

9.130 The IRP report concluded:

> *"There are no data in the scientific literature of an exact cut-off point between what is a too small, adequate or optimal case load and indeed it seems impossible to ensure such points as so much of medical service is dependent on the local culture and circumstances."*

Recommendation

R16 NHS England should publicise the fact that all cardiac units in the UK undertake sufficient numbers of operations for safety, as currently measured. This should help reassure families that their children are not being treated in units with sub-optimal numbers.

9.131 The New Review is currently underway at the time of writing this report. It takes on board many of the IRP report's criticisms, and is an opportunity to restore trust and confidence in the service nationally. This trust needs not only to be between parents of patients and those treating them but also between clinicians in different centres. However desirable it is for all centres to be capable of undertaking all operations, referral to another centre is sometimes in a patient's interests. Clinicians need to feel sure that they can make such referrals without the risk of criticism.

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[1] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/175391/Munro-Review.pdf

[2] http://www.westyorkshireobservatory.org/resource/view?resourceId=2939

Recommendation

R17 NHS England should act to dispel the “almost morbid sense of spectatorship and foreboding that hangs over these services”, ensuring that all stakeholders, service-users and their families are involved.’ This could be done during, and as a part of the New Review.

The leaders of trusts containing these services also have an important role in providing accessible information about the safety and quality of their service. We recommend that they work together on this, to avoid any element of competition that would give rise to the very worries they should all be trying to dispel.

Appendix A

Terms of reference

Review into the Concerns about Paediatric Cardiac Surgery at Leeds Teaching Hospitals NHS Trust (LTHT)

Overview:

Sir Bruce Keogh has asked Deputy Medical Director Mike Bewick to undertake a review into concerns about paediatric cardiac surgery at LTHT. The external consultancy Verita has now been appointed to investigate the governance processes around the care of children at LTHT, and the specific cases detailed in the letter from Sir Leonard Fenwick. Work will start imminently and should be completed by January 2014.

Background:

During 2013 concerns were raised in relation to the quality of care offered to patients undergoing surgery for congenital cardiac conditions at Leeds Teaching Hospitals NHS Trust.

The concerns arose from 3 sources:

1. Mortality data released by staff from the National Institute for Cardiovascular Outcomes Research ("NICOR") in March 2013. The data gave a partially risk-adjusted analysis of patients who died in the 30 days after a surgical procedure and who were operated on in the years 2009 to 2012.

2. Complaints and concerns expressed by families of children treated in the Unit and reported to the Care Quality Commission or to NHS England.

3. Concerns relating to patient care expressed to NHS England from another NHS Trust.

The initial data released by NICOR staff, appeared to show that LTHT children's cardiac surgery unit had a mortality rate much higher than other comparable units. This led to a temporary cessation of surgery commencing 28th March 2013. Following a Risk Summit convened by NHS England on 4th April 2013, it was agreed that investigation of the concerns relating to the LTHT Unit would be undertaken in two phases.

Phase 1 would be a rapid review of the LTHT Unit clinical standards, patient pathway management, and clinical governance. This was undertaken by an externally-led team of investigators and is now complete.

Phase 2 would have the following components:

(a) a detailed mortality case review of the deaths identified by NICOR by an externally-led team of specialist clinicians. This is now complete.

(b) detailed interviews and investigations of parental concerns; the interviews for this phase are complete and a report imminent.

(c) investigation of the concerns raised by other professionals.

These ToR relate to Phase 2c) above. The review team will ensure that they do not duplicate any of the work previously undertaken in the earlier phases.

Aims of the Review:

The aims of the review are to

1. Investigate the governance and communication processes around the care of children at the unit in LTHT, with particular reference to transfers to other trusts

2. Undertake specific clinical reviews of the 14 cases identified in Sir Leonard Fenwick's letter (unless the review team consider they have been adequately covered by previous phases)

3. Determine the actions necessary to secure and assure the safe and effective management of paediatric cardiac services at Leeds

4. Agree how the work of the review will be communicated to patients and public, including the conduct of any necessary patient recall exercises

Governance

The review team will report directly to Dr Mike Bewick, Deputy Medical Director, NHS England, and to senior members of the regional and area teams.

All members of the review team will coordinate actions and take no significant action without the knowledge and/or agreement of other team members as appropriate.

The review team will maintain a log of all decisions, timescales and actions completed and outstanding.

Outcomes of the Review

- A report setting out
    - the lessons to be learnt (or already learnt) from the management of the 14 cases
    - what (if any) aspects of best practice have been identified

  - recommendations for any further actions that could be taken to improve patient management and patient pathways, inter-unit referrals, professional relationships and communications
  - any potential wider implications identified for other parts of the NHS

Communication and Administration

The review team will communicate weekly initially, by telephone with Dr Mike Bewick and the administration support.

The review will be administered by Verita, with support from NHS England

Appendix B

Team biographies

Lucy Scott-Moncrieff CBE

Mental health and human rights lawyer, Lucy Scott-Moncrieff is a long-term associate of Verita. She is a former president of the Law Society of England and Wales, and chairs its Equality and Diversity Committee. She is a Commissioner with the Judicial Appointments Commission and a part time judge for the Mental Health Tribunal. She is co-chair of the International Bar Association's Access to Justice and Legal Aid Committee.

Her voluntary work includes being a trustee of LawWorks and of the Howard League for Penal reform and a member of the Prime Minister's Dementia Challenge Group.

Lucy has written and broadcast regularly on legal issues over the years.

For Verita she has carried out a number of complex and high profile reviews including the death of a patient during routine day surgery, the action of a SHA in relation to the dismissal of a trust chief executive, and the care and treatment of serial killer Daniel Gonzales.

Barry Morris

Barry joined Verita soon after it started in 2002. He previously worked as a consultant in financial and general management where he specialised in working with companies and charities in the areas of finance, change management and organisational development. He is a trustee of PAC, a charity working in the field of adoption. Barry has a wide range of experience gained over the last 10 years in investigations and reviews. He is currently leading the sampling team supporting Kate Lampard in her oversight of the NHS investigations into matters relating to Jimmy Savile.

Jessica Martin

Jess Martin has worked at Verita since 2011. As a consultant she has worked on a number of high-profile cases. She is a member of the team providing national oversight and assurance to investigations into allegations about sexual abuse by Jimmy Savile in healthcare, educational and social care settings. Other cases include a review of a specialist paediatric service in the north of England, a governance review of a leading private healthcare provider, an investigation into allegations of misreporting of A&E performance figures and a review of GP performance issues. Jess has recently completed the John Hopkins University Science of Safety in Healthcare course.

Appendix C

Documents reviewed

Policies and procedures

- Embrace Yorkshire & Humber Infant and Children’s Transport Service, Call Coordination Form
- Embrace Yorkshire & Humber Infant and Children’s Transport Service, Planned Transfer Booking Form
- Embrace Yorkshire & Humber Infant and Children’s Transport Service, Parent Information Leaflet
- Leeds Teaching Hospitals NHS Trust Parent Information leaflet on second opinions, 2010 (updated 2013)
- Leeds Teaching Hospitals NHS Trust Procedure for second opinions, December 2013
- Leeds Teaching Hospital NHS Trust Process for External Referrals, April 2013
- Leeds Teaching Hospitals NHS Trust, complex single ventricle pathway
- University Hospitals Bristol NHS Foundation Trust Paediatric Congenital Joint Cardiac Conference Operating Protocol, 10 August 2011
- University Hospitals Bristol NHS Foundation Trust Fetal Cardiology Referral form, February 2011
- University Hospitals Bristol NHS Foundation Trust Fetal Cardiology Service Clinical Guideline, March 2012
- University Hospitals Bristol NHS Foundation Trust Fetal Cardiology Handbook, June 2012
- University Hospitals Bristol NHS Foundation Trust CNS role in cardiac patient journey
- University Hospitals Bristol NHS Foundation Trust Bereavement Pathway Guideline (Non-clinical), Version 1.1
- University Hospitals Bristol NHS Foundation Trust Examples of Information given to Families

Reports

- Report of the External Review of CCCS service at Leeds by D Riley, April 2013

- Safe and Sustainable, Review of Childern's Congenital Cardiac Services in England, Decision Making Business Case, July 2012
- Independent Reconfiguration Panel (IRP) Advice on Safe and Sustainable Proposals for Children's Congenital Heart Services, April 2013
- Sheffield Children's NHS Foundation Trust Embrace Annual Report 2011/12
- Children's Congenital Cardiac Surgery Services at Leeds Teaching Hospitals NHS Trust, Mortality Case Review for the period 2009-2013 Overview Report, March 2014
- Family Experience Report, A thematic analysis of the experience, views and concerns of some of the parents whose children received care from Leeds Teaching Hospitals NHS Trust Children's Cardiac Services between 2009-2013, Pat Cantrill, March 2014

Miscellaneous

- Newcastle upon Tyne Hospitals NHS Foundation Trust, Children's Heart Surgery, Summary of 14 Cases, April 2013
- Leeds's view on 14 cases from Newcastle, March 2014
- High Court judicial review decision on children's heart surgery services, Case No: CO/10505/2012, 07 March 2013
- Newcastle upon Tyne Hospitals NHS Foundation Trust, Press statement following the High Court judicial review on children's heart surgery services, 07 March 2013
- Statement on Safe and Sustainable by the Secretary of State for Health (Mr Jeremy Hunt)
- IRP press release on publishing the IRP report on the Safe and Sustainable review, June 2013
- Family statements and responses from NHS England
- Minutes from the Joint Committee of Primary Care Trusts, July 2012
- *Trends in Fontan surgery and risk factors for early adverse outcomes after Fontan surgery: The Australia and New Zealand Fontan Registry experience Journal of Thoracic and Cardiovascular Surgery*, Ajay H. Iyengar, et al., 2013
- Newcastle's response to cardiac centre questions, February 2014
- Alder Hey response to cardiac centre questions, February 2014
- University Hospitals Bristol NHS Foundation Trust's response to cardiac centre questions, February 2014

Correspondence

- Letters from Sir Leonard Fenwick to Dr Mike Bewick regarding Newcastle's concerns dated 12 and 18 April 2013
- Correspondence between families in regards to referrals

Clinical notes

- Leeds clinical notes and nurse liaison notes
- Newcastle clinical notes

List of interviewees

NHS England:

- Sir Bruce Keogh, medical director, NHS England
- Dr Mike Bewick, deputy medical director, NHS England
- Dr Damian Riley, acting medical director, NHS England North
- Andy Buck, director, West Yorkshire
- Gill Harris, chief nurse, NHS England North
- Carol Wilby, head of office national medical director, NHS England

Leeds:

- Julian Hartley, chief executive
- Dr Yvette Oade, chief medical officer
- Dr Bryan Gill, medical director, quality and governance
- Miss Carin Van Doorn, head of congenital surgery
- Dr Elspeth Brown, lead clinician for Congenital Heart Disease Services and consultant paediatric cardiologist
- Dr Michael Blackburn, paediatric cardiologist (two interviews)
- Dr John Thomson, paediatric cardiologist
- Dr Fiona Willcoxson, paediatric cardiologist (two interviews)
- Dr Alex Perez, paediatric cardiologist (locum)
- Dr Helen Michael, paediatric cardiologist (locum)
- Dr Shuba Barwick, paediatric cardiologist (two interviews)
- Dr Dominic Hares, paediatric cardiologist
- Dr Kate English, adult congenital cardiologist
- Dr George Ballard, adult congenital cardiologist
- Mr Stefano Congiu, congenital cardiac surgeon
- Dr John Gibbs, retired congenital cardiologist
- Mr Nihal Weerasena, congenital cardiac surgeon

Newcastle:

- Sir Leonard Fenwick, chief executive

- Liz Bailey, directorate manager, cardiothoracic services
- Mr Asif Hasan, consultant paediatric cardiothoracic surgeon
- Dr John O'Sullivan, consultant paediatric cardiologist
- Dr Lee Ferguson, consultant in paediatric intensive care medicine and anaesthesia
- Sister Paddy Walsh, children's specialist cardiac sister
- Dr Milind Chaudhari, consultant paediatric cardiologist
- Dr David Crossland, consultant paediatric cardiologist
- Dr Richard Kirk, consultant paediatric cardiologist
- Angie Johnson, matron

District General Hospital:

- Dr Gary Savill, consultant paediatrician
- Dr Matthew Babirecki, consultant paediatrician

Families:

- Six families

NICOR:

- John Deanfield, director
- Julie Sanders, chief operating officer

Other:

- Mr Bill Brawn, former paediatric cardiac surgeon at Birmingham Children's Hopsital
- Sir Roger Boyle, former co-director of NICOR
- Terry Hanafin

Appendix E

Report abbreviations

CCAD - Congenital Cardiac Audit Database

CHD - Congenital Heart Disease

CHF - Children’s Heart Federation

CQC - Care Quality Commission

DoH – Department of Health

DQI - Date Quality Index

IRP - Independent Reconfiguration Panel (see also glossary)

JCPCT - Joint Committee of Primary Care Trusts

LGI – Leeds General Infirmary

LHM - Little Heart Matters

LTHT – Leeds Teaching Hospitals NHS Trust

MDT – Multi-Disciplinary Team

NICE – National Institute for Health and Care Excellence

NICOR - National Institute for Cardiovascular Outcomes Research

NSCG - NHS National Specialist Commissioning Group

PRAiS - Partial Risk Adjustment in Surgery (see also glossary)

TDA - NHS Trust Development Authority

SMR - Standardised Mortality Rate

Glossary

Fontan procedure

The Fontan procedure, is a palliative surgical procedure used in children with complex congenital heart defects, including hypoplastic left heart syndrome. It involves diverting the venous blood from the right atrium to the pulmonary arteries without passing through the morphologic right ventricle.

Alternatively treatment for hypoplastic left heart syndrome requires either a three-step surgical procedure called staged palliation or a heart transplant. Staged palliation is considered one of the major achievements of congenital heart surgery in recent years. The survival rate for children at age 5 is about 70 percent and most of these children have normal growth and development. This three-step surgery procedure is designed to create normal blood flow in and out of the heart, allowing the body to receive the oxygenated blood it needs.

The three steps consist of the following procedures:

Norwood procedure

This procedure is performed shortly after birth. It converts the right ventricle into the main ventricle pumping blood to both the lungs and the body. The main pulmonary artery and the aorta are connected and the main pulmonary artery is cut off from the two branching pulmonary arteries that direct blood to each side of the lungs. Instead, a connection called a shunt is placed between the pulmonary arteries and the aorta to supply blood to the lungs.

Bi-directional Glenn operation

This operation usually is performed about six months after the Norwood to divert half of the blood to the lungs when circulation through the lungs no longer needs as much pressure from the ventricle. The shunt to the pulmonary arteries is disconnected and the right pulmonary artery is connected directly to the superior vena cava, the vein that brings deoxygenated blood from the upper part of the body to the heart. This sends half of the deoxygenated blood directly to the lungs without going through the ventricle.

Fontan operation

This is the third stage, usually performed about 18 to 36 months after the Glenn. It connects the inferior vena cava, the blood vessel that drains deoxygenated blood from the lower part of the body into the heart, to the pulmonary artery by creating a channel through or just outside the heart to direct blood to the pulmonary artery. At this stage, all deoxygenated blood flows passively through the lungs.

Independent Reconfiguration Panel

The Independent Reconfiguration Panel is the independent expert on NHS service change. It was established in 2003 to provide advice to the Secretary of State for Health on contested proposals for health service change in England. It also offers ongoing support and advice to the NHS and other interested bodies on successful service changes.

Independent Reconfiguration Panel terms of reference are as follows:

> *"A1. To provide expert advice on:*
>
> - *proposed NHS reconfigurations or significant service change;*
> - *options for NHS reconfigurations or significant service change;*
>
> *referred to the Panel by Ministers.*
>
> *A2. In providing advice, the Panel will consider whether the proposals will provide safe, sustainable and accessible services for the local population, taking account of:*
>
> i. *clinical and service quality*
>
> ii. *the current or likely impact of patients' choices and the rigour of public involvement and consultation processes*
>
> iii. *the views and future referral needs of local GPs who commission services, the wider configuration of the NHS and other services locally, including likely future plans*
>
> iv. *other national policies, including guidance on NHS service change*

v. any other issues Ministers direct in relation to service reconfigurations generally or specific reconfigurations in particular

A3. The advice will normally be developed by groups of experts not personally involved in the proposed reconfiguration or service change, the membership of which will be agreed formally with the Panel beforehand.

A4. The advice will be delivered within timescales agreed with the Panel by Ministers with a view to minimising delay and preventing disruption to services at local level.

B1. To offer pre-formal consultation generic advice and support to NHS and other interested bodies on the development of local proposals for reconfiguration or significant service change - including advice and support on methods for public engagement and formal public consultation.

C1. The effectiveness and operation of the Panel will be reviewed annually."

http://www.irpanel.org.uk

Quality Surveillance Groups

Quality Surveillance Groups (QSGs) operate at a local and regional level. There are 27 local QSGs aligned to same geographical areas as the NHS Local Area Teams (LATs). There are four regional teams; North of England, South of England, London and Midlands and East. These are aligned to the NHS Commissioning Board (NHSCB), Care Quality Commission (CQC), Monitor, Public Health England (PHE) and the NHS Trust Development Authority's (NHS TDA) four regional teams.

The membership of the local QSG includes NHSCB area team, Clinical Commissioning Group (CCG) leads, Local Authority representatives, Local Healthwatch, CQC, Monitor, NHS TDA, Local education and training boards and public health centre.

The membership of the regional QSG includes NHSCB Regional office, NHSCB Area Team, CQC, Monitor, NHS Trust Development Authority, Local Authority Representative(s), Local Healthwatch representative(s), Health Education England, Health Service Ombudsman, Professional Regulators (GMC, NMC) and Public Health England.

QSGs act "*as a virtual team across a health economy, bringing together organisations and their respective information and intelligence gathered through performance monitoring, commissioning, and regulatory activities. By collectively considering and triangulating information and intelligence, QSGs will work to safeguard the quality of care that people receive…*

…They engage in surveillance of quality at a local level by those closest to the detail and most aware of concerns. They will not only consider information and intelligence but also be able to work together to take coordinated action to mitigate quality failure.

Regional QSGs provide an escalation mechanism for Local QSGs. They assimilate risks and concerns from local QSGs, identifying common or recurring issues that would merit a regional or national response."

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/216996/Establishing-Quality-Surveillance-Groups.pdf

New Review

NHS England have established a new review that is considering the whole lifetime pathway of care for people with congenital heart disease.

"The ambition of this review is to ensure that services for people with CHD are provided in a way that achieves the highest possible quality within the available resources:

- *the best outcomes for all patients, not just lowest mortality but reduced disability and an improved opportunity for survivors to lead better lives.*
- *tackling variation so that services across the country consistently meet demanding performance standards and are able to offer resilient 24/7 care*
- *great patient experience, which includes how information is provided to patients and their families, considerations of access and support for families when they have to be away from home"*

www.england.nhs.uk/wp-content/uploads/2013/07/180713-item13.pd

Appendix G

Letter of invitation to participate in the Cantrill review

NHS England

Dear

Our Ref: SC/2907Cardiac

West Yorkshire Area Team
3 Leeds City Office Park
Meadow Lane
Leeds
LS11 5BD

Email: susan.cannon4@nhs.net

9th September 2013

Leeds Paediatric Children’s Cardiac Care

Firstly we would like to take this opportunity to thank you for the contribution you have already made to us gaining a better understanding of the care received by children and their parents at the Children's Heart Unit at Leeds General Infirmary. We do not underestimate the demands that having to tell us about your experience places on you and we are very grateful because without you we cannot identify the lessons that need to be learned.

We have spent some time considering how we should take your concerns forward and have decided to ask Professor Pat Cantrill to undertake an independent review.

Pat has led a number of important reviews across social services, education, NHS and voluntary organisations. She has significant experience of undertaking and managing complex investigations which have required a systematic review of leadership, practice and clinical governance.

Pat will be commencing the work in August and it is anticipated that her findings will be available in the autumn.

Aim of the work

The overall aim of the work we have commissioned is to review the effectiveness of the support given by Leeds Teaching Hospitals NHS Trust to parents and children receiving cardiac care.

The work will involve:

- Reviewing written information already obtained from parents and from other key individuals.
- Undertaking one to one or group interviews, telephone conversations or a listening event with parents to identify key issues. The method used will be based on individual parental preference.
- Reviewing and analysing information gained from listening to parents to identify issues and patterns associated with the support that parents and children have received.

It is anticipated that the result of this work will be a report which identifies key issues and patterns related to parental concerns. This will be used to inform future changes to services and to identify areas of further investigation and/or development.

Your involvement

We are therefore asking for your agreement to being involved in the review.

Firstly we would like your agreement that any information you have provided to date either in writing to the CQC or discussions at the meetings we have held can be made available to Pat.

We also would like your agreement for Pat to contact you to agree a one to one meeting, a telephone conversation or if you prefer to meet as a member of a group of parents. It is difficult to say how long such a meeting will take as it will be very much led by you but Pat estimates that on average it should take no longer than two hours.

To indicate your willingness to be involved would you please contact us :

- Email to laura.irwin@nhs.net
- Or complete the tear off slip below and return to Laura Irwin, NHS England West Yorkshire Area Team, 3 Leeds City Office Park, Holbeck, Leeds, LS11 5BD

If we do not hear from you before 17th September 2013, we will understand that you do not wish to be involved in the review.

Finally once again thank you for all your help so far in what has been and continues to be very difficult circumstances.

Yours sincerely

Sue Cannon
Director of Nursing and Quality (West Yorkshire)

NHS England

Name ------------------------

I/we are prepared to be involved in the review	Yes/ No
I/we consent to information being shared with Professor Cantrill	Yes/ No
I/we would prefer to see Professor Cantrill on my/our own	Yes/ No
I/ we would prefer a telephone conversation	Yes/ No
I/we would prefer to see Professor Cantrill as members of a group	Yes/ No

Appendix H

Joint statement on behalf of Guy's and St Thomas', Great Ormond Street Hospital and Royal Brompton & Harefield NHS Foundation Trusts

Royal Brompton & Harefield NHS
NHS Foundation Trust

Great Ormond Street Hospital for Children NHS
NHS Trust

Guy's and St Thomas' NHS
NHS Foundation Trust

Joint Statement on behalf of Guy's & St Thomas', Great Ormond Street Hospital and Royal Brompton & Harefield NHS Foundation Trusts

Changes to Services for Children with Congenital Heart Conditions

Our three NHS Foundation Trusts are collectively committed to ensuring that current services for patients continue as normal while discussions begin to determine how the 4th July 2012 recommendation of the Joint Committee of Primary Care Trusts, that London should have two NHS child heart surgery centres from 2014, is safely and effectively implemented. As leaders of our respective organisations, we acknowledge a collective responsibility to work together and to provide direction and support for the families and staff affected. They, and colleagues at hospitals in London and the South East, should be confident that future services will build upon and enhance the undoubted quality of existing services, and that the transition to the new arrangements will be planned carefully and sensitively.

In particular, we will:

- develop a shared overall implementation plan for London, including joint monitoring mechanisms to give confidence that standards and safety are maintained throughout the period of transition;
- ensure that other services for children and adults are not adversely affected by plans to reconfigure children's congenital heart services;
- communicate consistently with families, staff and referrers, and actively seek their involvement as we develop our implementation plans;
- ensure that staff facing change and uncertainty feel valued and protected and understand that their skills and expertise will continue to be needed by the London networks;
- work collaboratively together to maintain a good outcome for London overall.

Robert J. Bell
Chief Executive, Royal Brompton & Harefield NHS Foundation Trust

Jan Filochowski.

Jan Filochowski
Chief Executive, Great Ormond Street NHS Foundation Trust

Sir Ron Kerr, CBE
Chief Executive, Guy's & St Thomas NHS Foundation Trust

6 December 2012

Leeds
CITY COUNCIL

Report author: Steven Courtney
Tel: 24 74707

Report of the Head of Scrutiny and Member Development

Report to the Joint Health Overview and Scrutiny Committee (Yorkshire and the Humber)

Date: 25 November 2014

Subject: NHS England's Review of Children's Heart Surgery Services at Leeds Teaching Hospitals NHS Trust – Next Steps

Are specific electoral Wards affected? If relevant, name(s) of Ward(s):	☐ Yes	☒ No
Are there implications for equality and diversity and cohesion and integration?	☐ Yes	☒ No
Is the decision eligible for Call-In?	☐ Yes	☒ No
Does the report contain confidential or exempt information? If relevant, Access to Information Procedure Rule number: Not applicable Appendix number: Not applicable	☐ Yes	☒ No

Purpose

1. The purpose of this report is to allow the Joint Health Overview and Scrutiny Committee (JHOSC) for Yorkshire and the Humber to identify and agree any further scrutiny activity associated with NHS England's review of quality of children's heart surgery services at Leeds Teaching Hospitals NHS Trust (LTHT).

Background

2. It has been reported that during 2013 a number of concerns were raised regarding the quality of Children's Heart Surgery Services provided at Leeds Teaching Hospitals NHS Trust (LTHT). These concerns led to the temporary closure of services on 28 March 2013, pending an investigation.

3. A Quality Surveillance Group (QSG) was convened by NHS England on 2 April 2013 to oversee the investigation process and at a subsequent Risk Summit meeting (held on 4 April 2013), it was agreed that a two-phase review would be carried out.

<u>Phase 1</u>

4. The first phase of investigation consisted of a 'rapid review', which found no significant or immediate safety concerns and surgery re-commenced on 10 April 2013, while the second phase of investigation took place.

5. It should be noted that, while no immediate safety concerns were identified, the rapid review highlighted a number of recommendations and areas for improvement. Some details of LTHT's actions and progress have previously been reported to the JHOSC.

Phase 2

6. It has previously been confirmed that the second phase of investigation would consist of three specific workstreams, namely:
   - A case note review of the child deaths that had occurred in the period from 2009 to 2012 which was the time period used in the collection of NICOR data (*Mortality Case Review*).
   - An investigation of the experiences, views and concerns of parents and families (*The Family Experience Review*).
   - An investigation of concerns raised by other clinicians in relation to inter-unit transfers and patient pathways *(The Independent Review of Concerns about Paediatric Cardiac Surgery at LTHT)*.

7. It was subsequently confirmed that an 'Overarching Report' would also be produced, drawing together the outcomes and key themes from each of the three specific workstreams.

8. The reports, findings and recommendations from the Mortality Case Review and the Family Experience Report were published by NHS England in March 2014 and were subsequently considered by the JHOSC in April 2010.

9. Both these reports highlighted a number of recommendations and areas for improvement. While the JHOSC received a verbal address on proposed actions against the recommendations, the joint committee has not considered a formal written response and/or progress report against the identified areas for improvement.

Main issues and considerations

10. Following the areas for improvement and recommendations identified from the 'rapid review', the JHOSC has sought assurance regarding the implementation of those recommendations and associated reporting arrangements.

11. Actions against the findings and recommendations from the Mortality Case Review and the Family Experience Report have not been formally reported (i.e. by way of a written report) to the JHOSC.

12. Furthermore, and elsewhere on the agenda, the joint committee considered the following information:
    - The Independent Review of Concerns about Paediatric Cardiac Surgery at LTHT (presented as Appendix 1); and,
    - Leeds Teaching Hospitals NHS Trust: Overarching Report about Paediatric Cardiac Surgery (presented at Appendix 2).

13. The joint committee also considered input from senior representatives from NHS England, Verita and Leeds Teaching Hospitals NHS Trust, alongside input from other interested.

14. One of the main considerations for the joint committee is whether sufficient information has been provided and made available to the joint committee or, should further information be requested and/or made available. For example, members may wish to seek a written report/ progress update against all the various identified areas for

improvement and recommendations. Alternatively, the joint committee may wish to produce a report based on the information made available to date.

15. The JHOSC may wish to seek further verbal assurance against the identified areas for improvement and recommendations.

Recommendations

16. That, along with the details outlined at the meeting, the joint committee considers the details presented in this report and identifies any specific actions and/or additional scrutiny.

Background documents[1]

17. None used

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[1] The background documents listed in this section are available to download from the Council's website, unless they contain confidential or exempt information. The list of background documents does not include published works.