



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

Authors:

Lucy Scott-Moncrieff

Barry Morris

Jess Martin

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Verita

53 Frith St

London W1D 4SN

Telephone **020 7494 5670**

Fax **020 7734 9325**

E-mail enquiries@verita.net

Website www.verita.net

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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 Health¹, 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.

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 LTH. 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 review¹ 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.

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 serviceI'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.

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

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

A handwritten signature in black ink, appearing to read 'L Fenwick', followed by a small dot.

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/carers 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 rationalise 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

A handwritten signature in black ink, appearing to read 'L Fenwick', followed by a small dot.

Sir Leonard Fenwick CBE
Chief Executive

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

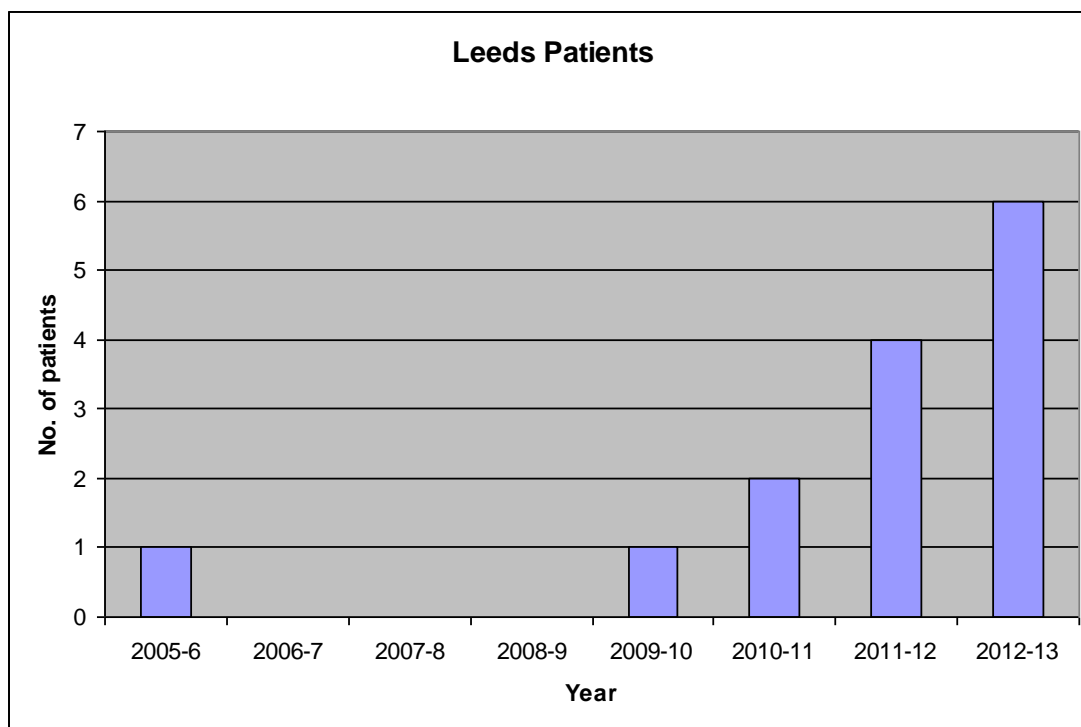
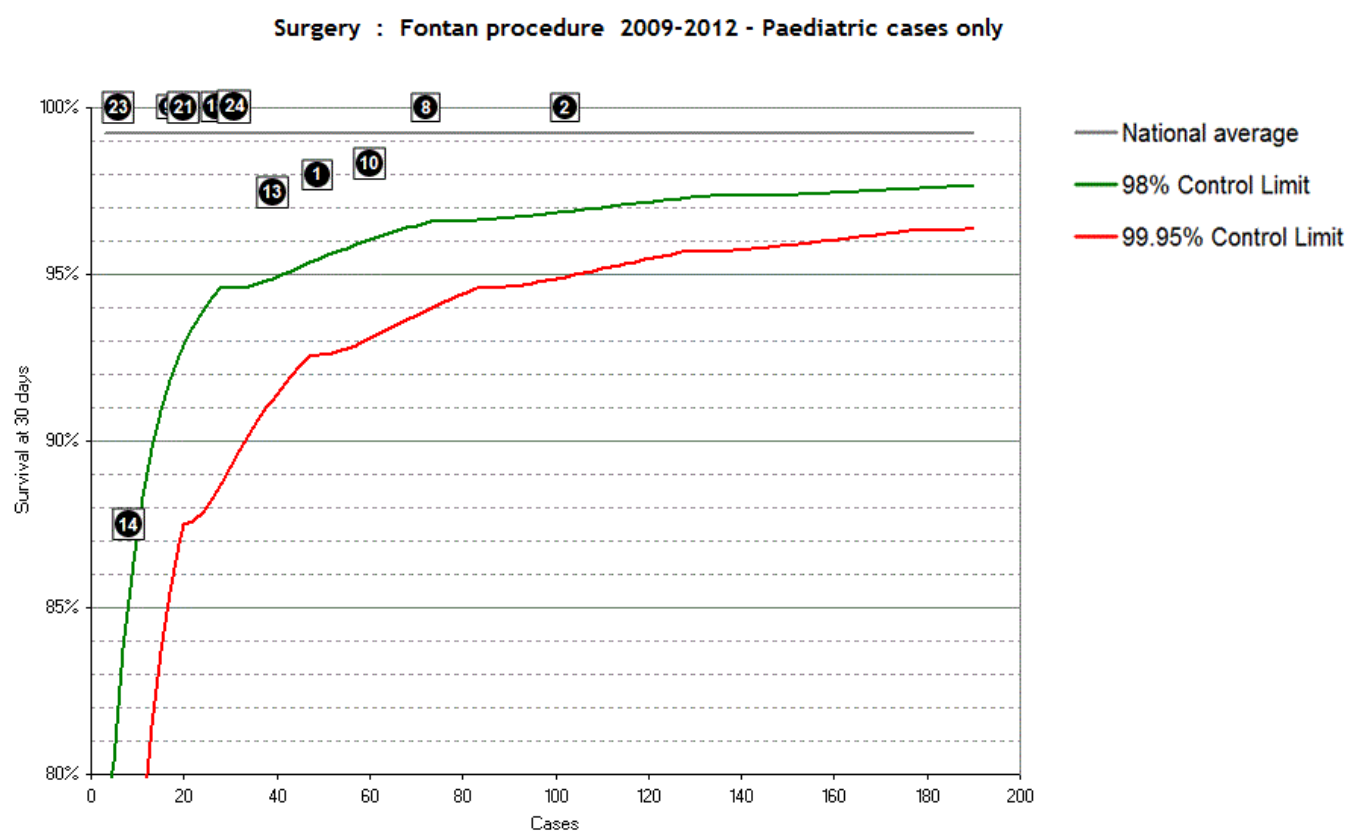


Exhibit 2: CCAD Fontan Data



		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%

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

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 appear 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	
<p>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.</p> <p>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.</p>	

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

Documents reviewed

Clinical notes

- LTH 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

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

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.