

VERITA

IMPROVEMENT THROUGH INVESTIGATION

Leeds Teaching Hospitals NHS Trust

Overarching report about paediatric cardiac surgery

A report for
NHS England

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Authors:

Lucy Scott-Moncrieff

Barry Morris

Jess Martin

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

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

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

1. Mortality data released by staff from the National Institute for Cardiovascular Outcomes Research (NICOR) in March 2013.
2. Complaints and concerns of families of children treated in the unit and reported to the care quality commission (CQC); Sir Bruce Keogh, medical director at the Department of Health¹; the Safe and Sustainable Review² Team: Heartline; Children's Heart Federation (CHF) and Little Heart Matters (LHM).
3. Concerns about patient care that other NHS professionals passed to Sir Bruce Keogh.

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

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

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

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

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

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

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

Approach and structure of the report

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

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

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

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

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

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

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

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

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

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

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

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

2. Executive summary

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

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

2.3 A rapid review of the LTHT children's cardiac unit was carried out between 5 and 7 April and found *"no immediate significant safety concerns in terms of clinical governance, staffing or in the management of the patient pathway for surgical care in the Unit or for referral to other Units"*.

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

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

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

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

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

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

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

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

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

2.13 Statistical information on outcomes and research conclusions offer very limited assistance in making these decisions. One reason for this is that numbers are too low to provide robust data. Another is that many advances in treatment are so recent that reliable long term outcomes are not yet available. Another difficulty is that variations in the

physiology of each child means that average outcomes may have little relevance in reaching a particular decision for a particular child.

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

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

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

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

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

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

Recommendations

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

Data submission and record keeping

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

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

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

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

Communications and complaints

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

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

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

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

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

Managing consultations on major reconfiguration

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

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

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

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

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

Restoring trust and confidence

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

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

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

R17 NHS England should act to dispel the “almost morbid sense of spectatorship and foreboding that hangs over these services”, ensuring that all stakeholders, service-users and their families are involved.’ This could be done during, and as a part of the New Review¹.

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

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

3. Chronology

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 April 2013 NHS England is created.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4. Congenital heart disease and delivery of services

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

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

4.3 *There are two main types of CHD:*

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

Caring for children with CHD

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

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

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

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

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

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

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

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

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

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

5. Political background

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

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

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

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

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

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

“The phrase ‘waiting for the next Bristol’¹ captures the almost morbid sense of spectatorship and foreboding that hangs over these services.The nature of the

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

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

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

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

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

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

6. Suspending surgery

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

6.2 We asked Sir Bruce Keogh how the meeting had come about. He told us that on 26 March he had received a call from Bill Brawn, who he described as "*a well-respected cardiac surgeon, probably number one in this country*". Sir Bruce told us that Mr Bill Brawn was concerned that one consultant paediatric cardiac surgeon at Leeds had been suspended¹; two of the remaining three consultants were relatively junior and were locums; the long Easter weekend was coming up; and the senior surgeon, Mr Watterson, was away. He felt that this was not a safe situation.

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

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

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

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

6(a) Family concerns

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

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

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

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

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

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

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

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

Comment

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

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

6(b) NICOR data

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

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

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

6.14 NICOR told us that its records show that:

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

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

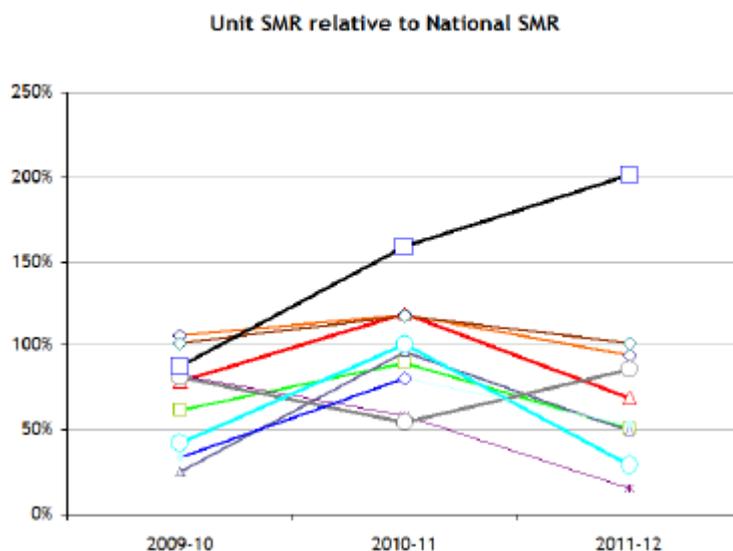
6.16 NICOR told us that there was a trend since 2006-2007 showing that all other centres except Leeds had improved their data quality with regards to weight.

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

“I think he has done more for heart disease... in this country than anybody else; an outstanding individual.”

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

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



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

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

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

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

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

6.24 Dr Bewick told us:

“It was put down as a pause and not a cessation. In other words, we’re saying we just want to take stock and do that as quickly as possible. We were trying to give the benefit of the doubt to the organisation in many ways that we weren’t shutting it. It wasn’t as if CQC had been in and had basically said ‘this is unsafe, we’re stopping it today’. We advised the trust to do that and, therefore, they had a choice... Most fire engines go to false alarms and not to fires, but we’re very glad they go and that’s how I would portray it.

The fact that we could put in another plan fairly rapidly to deal, particularly with children, and we didn’t stop them completely operating.... We have tried to minimise disruption to families and to minimise the effects and maintain resilience in the system. Actually this has taught us that you can maintain resilience because there’s a whole host of reasons why a unit might have to shut temporarily and we live in that world as it is...had we not acted and that following Tuesday a child had gone under the anaesthetic for whatever reason and the public knew that we had

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

Comment

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

6(c) Other concerns

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

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

6.27 Dr Bewick explained to us:

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

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

Comment

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

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

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

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

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

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

“Last Tuesday you called me in confidence, to express your grave concerns regarding the quality of advice families were receiving from colleagues in Leeds. You asked me to intervene as a matter of urgency.

I have done so, based on your concerns and those of others.

I was clear you would need to back up your assertions, given that in my position I would have no alternative but to act”

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

6(d) The decision to suspend surgery

6.33 Dr Riley told us:

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

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

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

“...it is not at all surprising that given the legal position that opponents of the [Safe and Sustainable] decision believed that this was an attempt to...subvert other processes.

Equally we were faced...with serious concerns that we were bound to act upon and that the failure to act upon those concerns could itself have been the subject of subsequent very serious criticism... What do you do? Well, you think through very carefully what the right thing to do is in the interests of securing safe service delivery in the interests of patients and act accordingly. Then you have to deal with fallout from that if there is fallout, which there was.”

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

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

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

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

6.39 The context was:

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

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

6.40 The evidence was:

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

Comment

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

7. Lifting the suspension of surgery

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

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

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

- **Phase 1** would be a rapid review of the Leeds’ clinical standards, patient pathway management and clinical governance. An externally led team of investigators would undertake this.
- **Phase 2** would cover:
 - a detailed mortality case review of the deaths identified by NICOR by an externally-led team of specialist clinicians
 - detailed interviews and investigations of parental concerns
 - investigation of the concerns raised by other professionals.

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

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

7.6 The NICOR report concluded:

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

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

7.7 It also commented:

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

7.8 The report of the rapid review¹ was finalised on 9 April. Its remit was:

“With regard to the safety of surgery performed in Leeds on children up to and including 16 years of age for congenital cardiac conditions to review and advise upon

- *the clinical governance systems and processes in place to deliver safe and effective care*
- *the ability of the Unit to undertake proposed surgical procedures*
- *the existing service and comment on overall safety, with reference to current best practice”*

7.9 Its objectives were:

“With regard to Governance Process

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

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

With regard to Staffing and Unit Capability

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

With regard to patient management and patient experience

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

7.10 The summary of its findings included:

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

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

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

7.11 It concluded:

“Data Management internally in the Unit and by Leeds for internal audit, routine care, routine morbidity and mortality audit processes was found to be adequate, but there were lapses in data uploading and export to national reporting databases, in particular to CCAD. The team has identified this as an area for improvement, in addition to recommending improvements in complaint handling, the format of multidisciplinary case discussions and the information conveyed in some clinic letters to patients.

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

Comment

- 1.** *We were not asked to comment on the conclusions of the rapid review and updated NICOR data, and as far as we know neither has been challenged. We therefore proceeded on the basis that their findings can be relied upon.*
- 2.** *We consider that the decision to resume surgery before the specific concerns raised by families and Newcastle had been investigated was reasonable. Some of these concerns related to alleged failures of good practice rather than of safety. Safety had*

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

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

8. The three reports

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

8 (a) Mortality review

8.2 This was carried out by a group of clinicians and was jointly commissioned by Leeds and NHS England¹. It was published on 11 March 2014 at the same time as the Patient Experience report. Its purpose was to review the 24 deaths NICOR included in their comparative 2009-2012 analysis and to review the 11 cases known to Leeds where a patient had died in the 30 days after a primary surgical procedure in 2012-2013.

8.3 Its methodology was:

“The expert external review team consisted of a congenital cardiac surgeon, a children’s congenital cardiologist, and a paediatric intensivist, was established. They declared no conflict of interest. The review team were joined by the NHS England (West Yorkshire) Medical Director and the LTHT Medical Director (Quality and Governance) in undertaking the review process who declared no conflict other than their role in their employing organisations.

... the team reviewed the clinical case notes, relevant imaging, minutes of discussions at multidisciplinary case conferences and details from the presentations and conclusions at the LTHT unit’s clinical governance meetings

Interviews were also held with the lead surgeon and lead cardiologist.”

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

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

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

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

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

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

Comment

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

8(b) Family Experience report

8.7 This review was undertaken by Professor Pat Cantrill.

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

Comment

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

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

“contacted key patient support groups serving families and children with congenital cardiac conditions. These groups included:

- The Children’s Heart Foundation*
- The Downs Heart Group*
- Little Heart Matters support group*
- Leeds Children’s Heart Surgery Fund*
- Fragile Hearts group.*

Each of the above groups were contacted directly and asked to consider sharing the NHS England letter of invitation (see appendix G) to be part of the review with any families they felt may wish to take part. In this way the families contacted were self-selecting. The families were provided with the aims of the review and asked to consent in writing to participating.”

Comment

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

8.10 The work involved:

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

Comment

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

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

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

8.12 It concludes:

“Those families who wished their experiences views and concerns to be heard have been listened to. Their stories were all heartfelt, moving and sincere. All the families were saddened to find themselves in a position where they had lost confidence in the care provided for their children and for them as a family. They want the services for children with congenital heart conditions both nationally and locally to learn from their experience. They want services for children and their families to improve.

The experiences, views and concerns identified by the families have been used to establish a number of recommendations for NHS England, Leeds Teaching Hospitals NHS Trust and other heart units to assess the quality of services provided for children with congenital heart conditions and families.

It is likely that there will be other families with different stories about their experiences of children’s heart services in Leeds, including some with completely positive stories. However this must not be allowed to stand in the way of hearing and acting upon the stories that underpin this report. It is imperative that our focus remains on improving health outcomes for children with congenital heart abnormalities and their families.

We have learned throughout 2013 as a result of the Francis report of the great importance and value of listening to patients, their carers, and their families. This report is yet another opportunity to do so.”

Comment

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

The report has obvious limitations:

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

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

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

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

1. Investigate the governance and communication processes around the care of children at the unit in Leeds, with particular reference to transfers to other trusts
2. Undertake specific clinical reviews of the 14 cases identified in Sir Leonard Fenwick's letter (unless the review team consider they have been adequately covered by previous phases)
3. Determine the actions necessary to secure and assure the safe and effective management of paediatric cardiac services at Leeds
4. Agree how the work of the review will be communicated to patients and public, including the conduct of any necessary patient recall exercises

8.14 After the start of the work the review team agreed with Dr Bewick, on behalf of the regional Quality Surveillance Group, that the report on the 14 cases Newcastle identified should focus on systems and processes and not on individual clinical decision-making, except

insofar as such decisions provided evidence relating to systems and processes. It would also identify any examples of good practice.

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

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

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

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

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

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

9. Conclusions, lessons and recommendations

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

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

9.2 Each of these is explained below.

Data submission and record keeping

The importance of full and accurate data

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

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

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

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

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

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

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

Recommendation

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

Comprehensive record-keeping

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

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

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

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

Recommendation

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

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

9.12 For instance, in the case of one patient¹ the operation risk quoted by the surgeon was higher than the cardiologist expected and caused the patient's parents such distress and anxiety that they sought a second opinion at Newcastle. This discrepancy between the surgeon's view and that of the cardiologist was more likely to have been identified and sorted out before the surgeon met the patient's parents if an agreed process had been followed and recorded.

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

Recommendation

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

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

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

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

Recommendation

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

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

Communication and complaints

The importance of good communication between a service and its users

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

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

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

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

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

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

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

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

9.25 An advantage of communicating online is that the parent and the professional have a written record of what was discussed. The parent can go back to it, ask for clarification or raise other issues, and the whole dialogue remains for reference. Online communication also gives the professional an opportunity to provide links to useful sites, and to provide

generic information about care pathways for different conditions, information on how to raise concerns and how they will be responded to.

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

Recommendation

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

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

The importance of good communication between services

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

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

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

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

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

Recommendation

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

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

Recommendation

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

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

“saw evidence of a shift away from the historical pattern of certain rare and complex procedures being undertaken in only a few centres... The Panel is mindful of the fact that the definition of what is a ‘complex’ procedure changes over time as clinical practice develops....

Rather than expecting every centre to be undertaking every type of procedure, the more likely pattern to be observed over time is a cycle of innovation, dissemination and some sub-specialisation. The Panel considers that this is desirable and should be encouraged. To ensure safe services of the highest possible quality for patients, this issue requires on-going and active monitoring, collaboration and management at a national level.”

Comment

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

Recommendation

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

Complaints

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

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

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

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

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

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

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

9.42 Not everyone who spoke to Professor Cantrill or whose child was included in the Newcastle dossier has raised concerns.

9.43 We know that the parents of at least one of the Newcastle 14 did not raise concerns or make any complaint; their child is included because Newcastle contacted them at the beginning of the Easter weekend in March 2013, to ask their permission to do so.

9.44 We have also been told by a Leeds cardiologist that one of her paediatric colleagues at another hospital told her of a conversation with a patient in September 2013. This patient's child had died at Leeds some years before. The Leeds cardiologist made a note of the conversation with her colleague which read:

“She explained that she had had no concerns about her [child’s] death at the time but had recently been contacted by [a woman whose child was being treated at Newcastle and who is active in the Newcastle parents’ support group] who had rung her and encouraged her to complain about Leeds and ‘re-open the case’. She was sent an email with ‘forms to fill in to get the case re-opened’. She has since spoken to Pat Cantrill for the report”

Comment

Presumably this contact was made as part of NHS England’s request to charities that they should ‘consider sharing the NHS England letter of invitation to be part of the review with any families they felt may wish to take part’.

9.45 The way in which these complaints and concerns by parents and professionals have been dealt with shows that some families at least have been getting rather mixed messages.

9.46 Before sending the Newcastle dossier to Dr Mike Bewick in April 2013, Newcastle obtained the consent of families, some of whom had already raised concerns elsewhere. We consider that they were entitled to believe that Newcastle accepted the accuracy and completeness of their concerns. The reality is, however, that if they have not also made formal complaints to Leeds, they have not had a formal response to their concerns.

9.47 Families who raised concerns with Jeremy Hunt, the CQC, Safe and Sustainable and charities and also spoke to Professor Cantrill did not have their concerns investigated in that process. Professor Cantrill made recommendations based on what she had been told, which were described as ‘findings’. However, the terms of reference of her review did not allow her to obtain a response from Leeds to allegations made about Leeds staff, so assertions of poor professional conduct justifying regulatory investigation were published without the possibility of challenge. It would not be surprising if the families who were quoted in the report assumed that their experiences had been officially accepted by Professor Cantrill.

9.48 The terms of reference in our review of the 14 cases allowed us to receive evidence from more sources than Professor Cantrill could. We found significant factual inaccuracies

in some of the complaints and concerns of families, such that we disagree with their views about what happened.

9.49 This lack of consistency is unfair on the families affected.

9.50 All the concerns should have been looked at promptly. Leeds should have been asked to respond in the normal way to all the matters reported to CQC, CHF, the Safe and Sustainable team and anyone else contacted by families. The similarities and discrepancies between the families' recollections and the contemporaneous records and correspondence would then have provided a clearer picture of events.

9.51 The failure to do this not only left clinicians at Leeds dealing for many months with the burden of unproven allegations of serious professional misconduct, but it also left families in the unsatisfactory position of not having a detailed response to their concerns.

9.52 Some of the families raising concerns may have been campaigners wishing to influence the future of the service at Leeds and may not have expected detailed investigations. This is their right, and does not diminish the validity of their concerns, but we think those receiving the concerns and acting on them should have distinguished between concerns to which parents wanted answers and those being communicated for political purposes.

Recommendation

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

Managing consultation on major reconfiguration

Minimising the effects of consultation about reconfiguration on patients and families

9.53 The Safe and Sustainable review created rivalry between Leeds and Newcastle which set up anxieties in local families.

9.54 For instance, as long ago as June 2011, a Leeds psychologist working with the mother of one of the children in the Newcastle dossier wrote to the child's cardiologist:

"I got a sense of complete mistrust of all clinicians caring for [the child] which has been intensified by the Safe and Sustainable Review which is going on. They worry that Leeds are not interested in treating [the child] because [the child] is too complex and it would look bad for the unit so have arranged to see someone in Newcastle...for a second opinion. Equally they are also concerned that Newcastle could take [the child's] case to score points against Leeds."

9.55 This theme recurs in letters from families and the charities supporting them, and although we found no evidence to support it, we have no reason to doubt it was a genuine concern that they had.

9.56 Parents having to make life and death, or life-altering, decisions about their children need to be sure that they are being given impartial advice on the options and their possible consequences. This is particularly important in a specialism such as children's congenital heart surgery, where the data on long-term outcomes are still insufficient to provide detailed guidance.

9.57 It is difficult to deal with someone's fear of raising concerns, but nonetheless the attempt must be made. Parents of seriously ill children know how dependent their children are on the skill, dedication and commitment of the specialists treating their child, and are often reluctant to do anything they fear might jeopardise that commitment. Trusts, and staff, must provide an environment in which families feel comfortable in raising any concern or anxiety, including about the conduct or expertise of staff at every level. Parents should be encouraged by staff to do this informally, and should receive a friendly, sympathetic and detailed response.

9.58 Some staff already provide this environment for the patients but it must be overt, well published and closely monitored across the trust. There should be an assumption that a formal complaint is an indication that the informal system has failed, and this should be part of the investigation into the complaint. Where a formal complaint is raised without any previous concerns being expressed, or identified, the reasons for this should be investigated.

Recommendations

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

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

Minimising the effects of consultation on working relationships between services

9.59 Paediatric heart surgery is a tiny speciality, with about 30 consultant paediatric cardiac surgeons in the NHS. They all know each other or of each other, trained or were trained by each other, share information on new techniques and offer each other help when asked for a second opinion or to take on a case where they have greater expertise. They are all working in a specialised area of medicine in which innovation has led to huge gains for patients, and they all know that they depend on each other to ensure the best results for their patients.

9.60 Any disagreements and personality clashes should be in a context of mutual respect, but this is not the case at Leeds and Newcastle, where we found evidence of a strained relationship between clinicians.

9.61 Some of this clearly followed Newcastle's intervention in March and April 2013, but some seems to pre-date those events and to have arisen from the Safe and Sustainable process.

9.62 For instance, we met most of the Newcastle clinicians and the chief executive in January 2014 and they told us about a rally in Leeds in 2012 in which they claimed uniformed Leeds nurses were carrying a placard suggesting that Newcastle was the 'Road to Death.' They had seen newspaper pictures of this. We considered that this was a serious allegation and asked Newcastle to provide us with the evidence. We were provided with a link to a video clip.¹

9.63 We do not consider that this clip bears out what Newcastle told us. The rally was in support of surgery remaining at Leeds. Most of the placards did not mention Newcastle and were carried by members of the public. Speeches and interviews that mentioned Newcastle made no criticism of it. They referred to the distance sick children would have to travel in an emergency and the risk that they would not survive the journey.

9.64 The video showed one hand-made placard saying 'Leeds-Newcastle-Death Row' which appeared not to be held by a nurse and, in the context of all the other comments, probably referred to the length of the journey to Newcastle rather than to the quality of the treatment there.

9.65 We were told about this 16 months after the rally, but the fact that we were told at all indicates a high level of upset by Newcastle professionals about Leeds professionals at the time.

9.66 The judicial review, challenging the decision to concentrate surgery at Newcastle and not Leeds, was another cause of tension.

9.67 Save our Surgery made its case based in part on a long witness statement from the then senior surgeon at Leeds, Mr Kevin Watterson. Newcastle told us that the statement was so inaccurate that the trust asked to be joined to the judicial review as an interested party, so that they could rebut what they saw as unfair criticism of their services and standards.

¹ <http://www.yorkshireeveningpost.co.uk/news/latest-news/top-stories/video-thousands-march-through-leeds-in-children-s-heart-unit-protest-1-4766403>

The written evidence for their case was contained in a long statement by the senior surgeon at Newcastle, Mr Hasan.

9.68 In litigation evidence is provided by those best placed to provide information in support of the case being put forward, so it is not surprising that the senior surgeons at Leeds and Newcastle were called upon in this way. This seems to have resulted in making the legal challenge and defence of the decision to choose Newcastle instead of Leeds to be seen as detailed, personal, and public criticism by each of these senior surgeons about the children's cardiac services provided by the other's hospital.

9.69 The depth of antipathy was also evident when we spoke to a group of Newcastle consultants and the chief executive of the trust, Sir Leonard Fenwick. One told us, without challenge from colleagues that if it came to choosing between what parents had told Newcastle and what the Leeds notes revealed, he would doubt the accuracy of the Leeds notes.

9.70 This consultant also felt that, in discussing cases with us, Leeds would provide after-the-event justification for their actions or inactions that would not accurately reflect why they had made decisions at the time.

9.71 Leeds, for their part, were sceptical of the 'whistleblowing' motives of Newcastle in raising the 14 cases, pointing out that such concerns would have normally been raised with them directly and that some were old.

9.72 We were told about a better way of dealing with some of the anxieties the Safe and Sustainable review provoked. In London there are three paediatric cardiac centres, one of which was identified by the Safe and Sustainable team for closure. Its trust challenged the decision through a judicial review.

9.73 The London Steering Group for Children's Congenital Heart Services was originally established to provide oversight and strategic direction to the implementation in London of the Safe and Sustainable team decisions on children's congenital heart services. Its role changed during 2012-13, while the legal challenges to the Safe and Sustainable team decisions were underway.

9.74 During that period of uncertainty, the London Steering Group gave strategic leadership in London to ensure that services were not adversely affected and that the three service providers and their commissioners continued to work together to improve services for the benefit of patients and their relatives.

9.75 The London Steering Group's membership included the chief executives and medical directors of the three provider trusts - the Royal Brompton, Great Ormond Street and Guys and St. Thomas' NHS Foundation Trusts, the medical director of NHS London (from April 2013, NHS England - London Region) and the London head of specialised commissioning. It was chaired initially by a Primary Care Trust chief executive, then by an independent person.

9.76 Arising from discussions at the London Steering Group, the chief executives of the three trusts agreed a joint statement (appendix H), which was issued on 6 December 2012, placed onto each of their websites and made available to relatives of patients and to staff in the services. It stressed that standards, and safety of services would be maintained, families and referrers would be involved and staff would be valued, involved, protected and made aware that their skills and expertise would continue to be needed by the London network.

Recommendations

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

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

The effects on staff need to be taken into consideration when planning reconfiguration

9.77 Individuals charged with planning reconfiguration must look at the bigger picture. Where the purpose of reconfiguration is to improve services rather than to save money, the

individual circumstances of the highly skilled professionals likely to be affected are part of the bigger picture and must be taken into account.

9.78 The rapid review found that Leeds was suffering from a form of planning blight. It had been unable to recruit surgeons to substantive posts because of the threat of closure of surgical services. The consequent reliance on locums was one of the triggers for the suspension of surgery. The rapid review found that locum surgeons at Leeds were competent and held the appropriate qualifications

9.79 The IRP report also found the unwillingness or inability of skilled staff to move from one centre to another was an important issue in ensuring high-quality, safe services.

9.80 Those we met in both Leeds and Newcastle were anxious about their future in a reconfigured service.

Recommendation

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

9.81 Maintaining staff morale while radical change is being considered is an obvious element of maintaining quality while improvement is being planned.

9.82 The potential disruption to careers and lives must be acknowledged and addressed and staff should know that contingency planning, looking at their legitimate expectations as well as those of patients, is taking place.

Whistleblowing

9.83 Newcastle were clear to us that they felt they were acting as a whistleblower in raising the concerns. They told us the details of the 14 cases and explained:

“These were the reasons why the issues were raised with NHS England at a very politically sensitive time for us. We had discussed this thoroughly between myself, [cardiologist] and with Sir Leonard as it would have been convenient not to raise issues which might be taken in a political context. We felt that patients’ safety was paramount and that prompted us to raise our concerns.”

9.84 However, the evidence was inconsistent.

9.85 The information provided by the Newcastle paediatric heart surgeon Mr Hasan to Sir Bruce Keogh on 26 March 2013 was an important element of the decision to suspend surgery at Leeds.

9.86 Sir Bruce Keogh said in an email to Mr Buck on 27 March 2013 that neither Mr Brawn nor Mr Hasan was *“alarmist or meddlers by nature, so I would take their concerns very seriously.”* Shortly after this email was sent one of recipients¹ who had been copied into Mr Buck’s email responded *“The two phone calls very clearly add considerably to what we already know. I think they definitely tip the balance towards the need for some sort of assurance exercise.”*

9.87 Sir Bruce Keogh wrote to Mr Hasan on 31 March 2013 confirming their conversation and requesting evidence in support, which needed to be *“sound.”*

9.88 Mr Hasan responded the same day:

“I am delighted that you have taken a prompt and courageous decision to investigate the concerns raised by myself and others relating to Leeds cardiac services. I spoke to you after considerable deliberations between me and my colleagues, these refer to a barrage of clinical problems we have had to deal with in the last few months emanating from patients in the Leeds area.”

¹ Name redacted in the email we have seen.

9.89 Sir Bruce Keogh wrote to Dr Damien Riley and others that evening, referring to the phone call and saying he had told Mr Hasan he was making a serious accusation that he could not ignore. He went on to say that Mr Hasan confirmed that the difference of opinion between Newcastle and Leeds was serious rather than normal and that he had evidence to back up what he was saying. He concluded *“In many senses this is the most serious issue.”*

9.90 Dr Bewick met staff at Newcastle on 3 April 2013 to hear more about the concerns, and reported in an email to Sir Bruce Keogh on 4 April:

“Newcastle have 14 cases where significant criticisms of the care at LTHT have been recognised over the last 12 months. Common themes are: late referral; inappropriate and premature use of the palliative care pathway; lack of counselling for intra-uterine diagnosis; inappropriate or incompetent surgery (small number).”

9.91 When we first visited Newcastle, before we had seen the dossier, we met the chief executive and senior staff, including consultant surgeons and a consultant cardiologist. One of them described the genesis of the dossier:

“There has been a background over the last few years, of what we can best describe as rather bizarre routes of referral of patients from the Leeds catchment area, which on an individual case didn’t really raise any concerns, but the pattern began to emerge...”

The other bit of background is that within the whole area of congenital heart disease, in paediatrics in particular with the spotlight being on it, there is a concern as to what happens to high risk cases and how units respond and how vulnerable units feel when they have to take on high risk cases.

There has been a pattern of high risk cases emanating from Leeds, sometimes through this rather bizarre referral pathway.

The index case describes an individual case where the patient arrived here in a very poor clinical condition... The family gave a heart-wrenching story to us describing how the family ended up at our unit. We are aware that sometimes the family description of events is not completely accurate but this particular case stood out. When we looked at that case, when we came together, we felt we had to highlight

some of the things that that case brought forward, in terms of communication, the wider network and we were aware that this child could have come to serious harm. As it happened, Mr Hasan was able to do an operation, semi-acutely, the child has done well.

That is the index case, and when we brought that to the attention of the wider organisation (NHS), we were then asked ‘Were there any wider issues?’ which is how we began to look at the cases that I have been previously alluding to ie the unusual referral route, the poor communication and some high risk cases. They have all come together in this, what has been called, dossier.”

9.92 The 14 cases arrived at Newcastle between 2005 and 2013. Mr Hasan reported on 31 March 2013 “a barrage of clinical problems we have had to deal with in the last few months.” When Dr Bewick reported his meeting with Newcastle on 3 April in his email of 4 April, he referred to Newcastle having 14 cases where significant criticisms of the care at Leeds had been recognised in the last year.

9.93 These statements seem to describe different things. The records show that in the last six months (our interpretation of the “last few months”) before making this comment, one child had received conventional open heart surgery having been referred for a unconventional procedure the previous year; one baby with a congenital heart defect was born after the mother chose to give birth in Newcastle; one child had a minor operation after being referred for possible complex surgery by Leeds and one had a serious operation several days after the mother asked for an immediate referral of the child to Newcastle.

9.94 The 14 cases discussed with Dr Bewick included one referred to Newcastle in April 2013 and so clearly not in Mr Hasan’s mind at the time of his email on 31 March. Three children were referred from Leeds to Newcastle in the year before Mr Hasan’s email and one pregnant mother referred herself. All the other referrals were at least a year earlier, and sometimes many years earlier.

9.95 The description of the genesis of the dossier in the quote above also gives a different perspective to the concerns expressed by Newcastle; the description in Mr Hasan’s 31 March email of a “barrage of clinical problems...in the last few months” becomes a single troubling event which led to earlier cases being reconsidered at the request of the NHS.

9.96 The evidence shows that in March 2013, despite what Newcastle said and recalled having done, they compressed the period of their concerns in a way that put Leeds in an unfairly poor light, even if all the concerns had been substantiated.

9.97 We asked Newcastle why they had not dealt with these concerns in a more orthodox way, for instance by contacting their colleagues in Leeds, or reporting them to the relevant regulators.

9.98 They told us that they were so busy getting on with work that this was not at the forefront of their minds. Also that the problem was systemic rather than individual.

“It is a systemic organisational issue. All the medium-sized units in the country are under pressure, this includes Alder Hey, Bristol, Southampton, Leeds and ourselves. The problem is that the units are not big enough. The clinicians cannot just take all the blame they are caught between a rock and a hard place. The cardiologists are also caught up amongst this problem especially in a unit who does not do quite a few operations...”

The cardiologists are caught in the same situation especially if an operation is not being undertaken by their own surgical colleagues. It is difficult then to assign a mortality to these patients. This is endemic of the systemic failure... It is imperative that this crumbling service is resurrected; this can only happen with reconfiguration in to larger sized units. In the meantime what is happening will continue to happen. I can give you several examples where I think the patients have come to real harm.”

Comment

This is a troubling statement. If Newcastle thought that patients had come to real harm at Leeds they should have taken action as their concerns crystallised, rather than collecting evidence for later reporting.

9.99 Newcastle’s certainty about the issues they had raised in March and April 2013 shifted between then and April 2014.

9.100 When Mr Hasan spoke to Sir Bruce Keogh on 26 March 2013, and when he and others met Dr Bewick on 3 April, they were understood to be expressing their own concerns about Leeds, not simply passing on the complaints of parents.

9.101 This impression is not dispelled by the introduction to the dossier:

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

9.102 Sir Leonard Fenwick’s letters to Dr Mike Bewick on the 12 and 18 April outline what are described as Newcastle’s concerns about Leeds paediatric cardiac unit.

9.103 Furthermore, when Newcastle spoke to us in January 2014, they gave no indication they were repeating the concerns of others.

9.104 However, when we visited Newcastle for a second time in April 2014 and queried some of the assertions in the dossier, they clarified that the entries in the dossiers reflected what they had been told, not necessarily what they knew as fact.

“At the beginning of the case studies the introduction states that the document summarises our experience with patients and families from the Leeds area and the concerns raised by them with us”

9.105 They also made clear to us that their approach was to assume that what parents were saying to them was true.

9.106 We mentioned the case of one patient where the dossier entry had asserted that the patient had had to wait too long for surgery in Leeds and that when the patient’s mother asked for a transfer to Newcastle this was refused, and the operation was carried out in Leeds. Subsequently the patient’s mother lost confidence in Leeds and transferred to Newcastle.

9.107 We went through with them the discussions between Leeds clinicians and the patient's mother, which were detailed and lengthy and provided a different account from that in the dossier.

9.108 The Newcastle consultant who had taken on the patient's care told us:

“My involvement with [the patient] has been after the operation. I have heard the story from Mum, which you also have. The referral to us post operatively was through [Leeds cardiologist] who telephoned me and referred by letter....When we get a referral from outside then we take it unless the review is inappropriate. In terms of the pre-operative events I wasn't involved.”

9.109 The referral letter explained the patient's clinical and operational history and explained that the patient's mother had decided 10 months after the operation to transfer to Newcastle because the cardiologist had raised official concerns that the patient's mother seemed to be convinced that her child needed invasive treatment that the Leeds team thought unnecessary and undesirable.

9.110 A Newcastle liaison nurse told us:

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

Conclusions

1. Reporting the unchecked allegations of others is not whistleblowing, and Newcastle should have made the status of their concerns clearer when they reported them.

2. *We consider that anyone reading Sir Leonard Fenwick's letter to Dr Mike Bewick of 18 April would believe that he was expressing the concerns of clinicians, not of families.*

3. *The entry in the dossier about the patient referred to in paragraphs 9.106-110 seems to have been prepared only on the basis of the patient's mother's story, despite the evidence from the liaison nurse of the mother's ambivalence and that she had encouraged the mother to let the patient have the operation in Leeds, and despite the cardiologist's knowledge of the difficult circumstances surrounding the transfer to Newcastle, about which the Leeds cardiologist was perfectly open.*

9.111 Some of the families of the 14 children in the Newcastle dossier were campaigning for surgery to be permanently closed at Leeds as part of the Safe and Sustainable process. Their views about the care their children had received at Leeds compared to Newcastle committed them to the Newcastle camp and to doing their best to support Newcastle when Leeds challenged the decision of 4 July 2012 to end the provision of surgery at Leeds and transfer it to Liverpool and Newcastle.

9.112 The mother of the patient referred to above did not make a complaint to Leeds about how she claims she was treated. She was a signatory to the letter to Jeremy Hunt of 25 March. She also went public about her concerns when surgery was suspended. She did not respond to our invitation to discuss the issues in the dossier. However, the matters mentioned at the beginning of this paragraph strongly suggest that she was a campaigner for services in Newcastle to prevail over services in Leeds.

9.113 In a highly charged political atmosphere, such as that which existed in early 2013 in Leeds and Newcastle, professionals raising the concerns of parents need to be very clear whether parents are complaining, whistleblowing or campaigning, even if the parents are not.

9.114 In his letter of 18 April, Sir Leonard states that Newcastle were aware that patient's families had *"either individually or as a group raised their most fundamental concerns with the Care Quality Commission (CQC) and also the Independent Reconfiguration Panel"*. This shows that Newcastle clinicians were aware of the campaigning of some of the patient's families, which should have alerted them to the need for caution in this regard.

9.115 Newcastle explained to us in detail their awareness of how families deal with information about the risks, options and outcomes for their children. What they said revealed that they knew about the possibility that families could take some time and several attempts to get a full understanding of their child's diagnosis and the risks and options associated with it. We are thus surprised at their willingness to put their reputation behind the parental concerns by transmitting them to commissioners without even elementary checking.

9.116 Newcastle should have carried out basic checks before they passed on the stories of these families, whether or not they knew that some families were campaigning on their behalf.

9.117 For instance, in the 'index case' (referred to by Newcastle in the quote above in paragraph 9.91), Newcastle could easily have contacted health care colleagues (not working at Leeds) to get their account of what had happened before the patient reached Newcastle. This would have given them valuable information to help put into perspective the "*heartwrenching*" and no doubt heartfelt story the family told.

Recommendation

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

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

Restoring trust and confidence

9.118 We became aware that the anxiety and fearfulness in evidence in Leeds and Newcastle were also felt elsewhere in the larger network of paediatric cardiac services. We

were told at Leeds that experienced surgeons had moved abroad and there was an impression that younger surgeons were hesitant about choosing paediatric heart surgery as a specialism. The IRP report contains this comment:

“The phrase ‘waiting for the next Bristol’ captures the almost morbid sense of spectatorship and foreboding that hangs over these services”

9.119 This should have been a wake-up call to all those who commission, regulate, provide and use paediatric heart services.

9.120 Paediatric heart surgery is one of the great modern successes of modern medicine. Once inoperable conditions are now routinely treated successfully, children are living now who once would not have survived their babyhood, and adults who once would not have survived childhood have normal life expectancy. Many of them are relatively unaffected by their heart condition in their daily lives.

9.121 Survival rates following surgery, although very important, are not the only measure of quality. Timely surgery; minimising disability; improving quality of life; and providing good patient (and parental) experiences are all important markers of quality.

9.122 However, reliable and comprehensive measurements of these quality markers are not yet in place so as to allow comparisons between units. The IRP report recognises the importance of collecting such data and recommends that this should be given a high priority, but currently we can only rely on the mortality data.

9.123 The IRP report commented that:

“The proposals for change have not been argued on the grounds that current services are unsafe. For several years, standard data have been collected about each intervention and summary comparative analysis is publicly available on the NICOR website. The Panel were consistently told that the quality of the outcome data and the range of robust, publicly available data on paediatric cardiac surgery in the UK is the envy of the rest of the world. Published mortality rates are uniformly around two percent or less for primary surgical procedures in all the current surgical centres, and as such comparable with the best equivalent services internationally...”

In this context, the Panel were troubled to hear some people assert that there were known and significant differences between the outcomes achieved by the existing centres. The Panel sought the evidence behind these assertions without receiving anything conclusive. At the end of the review, the Panel asked the JCPCT, as commissioners, whether there existed any further information about the safety or performance of the current centres that would help inform the Panel's advice to the Secretary of State. The JCPCT confirmed that there did not..."

9.124 The advances in treatment have occurred through the dedicated professionalism of surgeons, cardiologists, specialist nurses and all those in the teams who treat and care for these children.

9.125 Sometimes things will go wrong, and sometimes this will be the result of human error. Anything that goes wrong must be identified and scrutinised openly, not only so that families can be sure that they have all relevant information but also so that the chance of a recurrence is minimised and public confidence is maintained. Equally importantly, evidence of problems and difficulties must be dealt with proportionately, so that what is good or excellent about the service is not harmed.

9.126 The reconfiguration proposed in the Kennedy report of 2001 has still not taken place. This is a problem for the service. The recommendation was intended to ensure that all surgeons carried out enough operations to maintain their expertise. The failure to bring about reconfiguration has left the impression that some centres or surgeons are unsafe because they do not reach the required volume. The decision in July 2012 to remove surgery from Leeds can only have added to this impression there.

9.127 The IRP report does much to challenge this view. It noted that the Safe and Sustainable review had asserted that a minimum of 400 to 500 operations in a surgical centre is associated with better outcomes. It reviewed the NHS evidence in the Safe and Sustainable review and found that:

"... the thresholds for minimum critical mass recommended by the Kennedy Report, Munro Report and European Association for Cardio-Thoracic Surgery were substantially lower than 400-500 cases per surgical centre. The Kennedy Report

suggested that paediatric congenital heart surgeons should perform a minimum of between 40 and 50 open heart operations a year.”

9.128 It also noted that the Munro Report¹ recommended that centres should have at least three surgeons undertaking at least 300 paediatric surgical procedures a year, and that the European Association for Cardio-Thoracic Surgery Report² recommended that each centre should operate on more than 250 patients a year; each surgeon should perform 125 cardiac surgical procedures on adults or children each year.

9.129 Leeds reaches the recommended thresholds in the Munro and EACTS reports.

9.130 The IRP report concluded:

“There are no data in the scientific literature of an exact cut-off point between what is a too small, adequate or optimal case load and indeed it seems impossible to ensure such points as so much of medical service is dependent on the local culture and circumstances.”

Recommendation

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

9.131 The New Review is currently underway at the time of writing this report. It takes on board many of the IRP report’s criticisms, and is an opportunity to restore trust and confidence in the service nationally. This trust needs not only to be between parents of patients and those treating them but also between clinicians in different centres. However desirable it is for all centres to be capable of undertaking all operations, referral to another centre is sometimes in a patient’s interests. Clinicians need to feel sure that they can make such referrals without the risk of criticism.

¹ https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/175391/Munro-Review.pdf

² <http://www.westyorkshireobservatory.org/resource/view?resourceId=2939>

Recommendation

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

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

Terms of reference

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

Overview:

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

Background:

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

The concerns arose from 3 sources:

1. Mortality data released by staff from the National Institute for Cardiovascular Outcomes Research ("NICOR") in March 2013. The data gave a partially risk-adjusted analysis of patients who died in the 30 days after a surgical procedure and who were operated on in the years 2009 to 2012.
2. Complaints and concerns expressed by families of children treated in the Unit and reported to the Care Quality Commission or to NHS England.
3. Concerns relating to patient care expressed to NHS England from another NHS Trust.

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

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

Phase 2 would have the following components:

- (a) a detailed mortality case review of the deaths identified by NICOR by an externally-led team of specialist clinicians. This is now complete.
- (b) detailed interviews and investigations of parental concerns; the interviews for this phase are complete and a report imminent.
- (c) investigation of the concerns raised by other professionals.

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

Aims of the Review:

The aims of the review are to

1. Investigate the governance and communication processes around the care of children at the unit in LTHT, with particular reference to transfers to other trusts
2. Undertake specific clinical reviews of the 14 cases identified in Sir Leonard Fenwick's letter (unless the review team consider they have been adequately covered by previous phases)
3. Determine the actions necessary to secure and assure the safe and effective management of paediatric cardiac services at Leeds
4. Agree how the work of the review will be communicated to patients and public, including the conduct of any necessary patient recall exercises

Governance

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

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

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

Outcomes of the Review

- A report setting out
 - the lessons to be learnt (or already learnt) from the management of the 14 cases
 - what (if any) aspects of best practice have been identified

- recommendations for any further actions that could be taken to improve patient management and patient pathways, inter-unit referrals, professional relationships and communications
- any potential wider implications identified for other parts of the NHS

Communication and Administration

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

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

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.

Documents reviewed

Policies and procedures

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

Reports

- Report of the External Review of CCCS service at Leeds by D Riley, April 2013

- Safe and Sustainable, Review of Children's Congenital Cardiac Services in England, Decision Making Business Case, July 2012
- Independent Reconfiguration Panel (IRP) Advice on Safe and Sustainable Proposals for Children's Congenital Heart Services, April 2013
- Sheffield Children's NHS Foundation Trust Embrace Annual Report 2011/12
- Children's Congenital Cardiac Surgery Services at Leeds Teaching Hospitals NHS Trust, Mortality Case Review for the period 2009-2013 Overview Report, March 2014
- Family Experience Report, A thematic analysis of the experience, views and concerns of some of the parents whose children received care from Leeds Teaching Hospitals NHS Trust Children's Cardiac Services between 2009-2013, Pat Cantrill, March 2014

Miscellaneous

- Newcastle upon Tyne Hospitals NHS Foundation Trust, Children's Heart Surgery, Summary of 14 Cases, April 2013
- Leeds's view on 14 cases from Newcastle, March 2014
- High Court judicial review decision on children's heart surgery services, Case No: CO/10505/2012, 07 March 2013
- Newcastle upon Tyne Hospitals NHS Foundation Trust, Press statement following the High Court judicial review on children's heart surgery services, 07 March 2013
- Statement on Safe and Sustainable by the Secretary of State for Health (Mr Jeremy Hunt)
- IRP press release on publishing the IRP report on the Safe and Sustainable review, June 2013
- Family statements and responses from NHS England
- Minutes from the Joint Committee of Primary Care Trusts, July 2012
- *Trends in Fontan surgery and risk factors for early adverse outcomes after Fontan surgery: The Australia and New Zealand Fontan Registry experience Journal of Thoracic and Cardiovascular Surgery*, Ajay H. Iyengar, et al., 2013
- Newcastle's response to cardiac centre questions, February 2014
- Alder Hey response to cardiac centre questions, February 2014
- University Hospitals Bristol NHS Foundation Trust's response to cardiac centre questions, February 2014

Correspondence

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

Clinical notes

- Leeds clinical notes and nurse liaison notes
- Newcastle clinical notes

List of interviewees

NHS England:

- Sir Bruce Keogh, medical director, NHS England
- Dr Mike Bewick, deputy medical director, NHS England
- Dr Damian Riley, acting medical director, NHS England North
- Andy Buck, director, West Yorkshire
- Gill Harris, chief nurse, NHS England North
- Carol Wilby, head of office national medical director, NHS England

Leeds:

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

Newcastle:

- Sir Leonard Fenwick, chief executive

- Liz Bailey, directorate manager, cardiothoracic services
- Mr Asif Hasan, consultant paediatric cardiothoracic surgeon
- Dr John O’Sullivan, consultant paediatric cardiologist
- Dr Lee Ferguson, consultant in paediatric intensive care medicine and anaesthesia
- Sister Paddy Walsh, children’s specialist cardiac sister
- Dr Milind Chaudhari, consultant paediatric cardiologist
- Dr David Crossland, consultant paediatric cardiologist
- Dr Richard Kirk, consultant paediatric cardiologist
- Angie Johnson, matron

District General Hospital:

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

Families:

- Six families

NICOR:

- John Deanfield, director
- Julie Sanders, chief operating officer

Other:

- Mr Bill Brawn, former paediatric cardiac surgeon at Birmingham Children’s Hospital
- Sir Roger Boyle, former co-director of NICOR
- Terry Hanafin

Report abbreviations

CCAD - Congenital Cardiac Audit Database

CHD - Congenital Heart Disease

CHF - Children's Heart Federation

CQC - Care Quality Commission

DoH - Department of Health

DQI - Data Quality Index

IRP - Independent Reconfiguration Panel (see also glossary)

JCPCT - Joint Committee of Primary Care Trusts

LGI - Leeds General Infirmary

LHM - Little Heart Matters

LTHT - Leeds Teaching Hospitals NHS Trust

MDT - Multi-Disciplinary Team

NICE - National Institute for Health and Care Excellence

NICOR - National Institute for Cardiovascular Outcomes Research

NSCG - NHS National Specialist Commissioning Group

PRAiS - Partial Risk Adjustment in Surgery (see also glossary)

TDA - NHS Trust Development Authority

SMR - Standardised Mortality Rate

Glossary

Fontan procedure

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

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

The three steps consist of the following procedures:

Norwood procedure

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

Bi-directional Glenn operation

This operation usually is performed about six months after the Norwood to divert half of the blood to the lungs when circulation through the lungs no longer needs as much pressure from the ventricle. The shunt to the pulmonary arteries is disconnected and the right pulmonary artery is connected directly to the superior vena cava, the vein that brings

deoxygenated blood from the upper part of the body to the heart. This sends half of the deoxygenated blood directly to the lungs without going through the ventricle.

Fontan operation

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

Independent Reconfiguration Panel

The Independent Reconfiguration Panel is the independent expert on NHS service change. It was established in 2003 to provide advice to the Secretary of State for Health on contested proposals for health service change in England. It also offers ongoing support and advice to the NHS and other interested bodies on successful service changes.

Independent Reconfiguration Panel terms of reference are as follows:

“A1. To provide expert advice on:

- proposed NHS reconfigurations or significant service change;*
- options for NHS reconfigurations or significant service change;*

referred to the Panel by Ministers.

A2. In providing advice, the Panel will consider whether the proposals will provide safe, sustainable and accessible services for the local population, taking account of:

- i. clinical and service quality*
- ii. the current or likely impact of patients' choices and the rigour of public involvement and consultation processes*
- iii. the views and future referral needs of local GPs who commission services, the wider configuration of the NHS and other services locally, including likely future plans*
- iv. other national policies, including guidance on NHS service change*

- v. *any other issues Ministers direct in relation to service reconfigurations generally or specific reconfigurations in particular*
- A3. The advice will normally be developed by groups of experts not personally involved in the proposed reconfiguration or service change, the membership of which will be agreed formally with the Panel beforehand.*
- A4. The advice will be delivered within timescales agreed with the Panel by Ministers with a view to minimising delay and preventing disruption to services at local level.*
- B1. To offer pre-formal consultation generic advice and support to NHS and other interested bodies on the development of local proposals for reconfiguration or significant service change - including advice and support on methods for public engagement and formal public consultation.*
- C1. The effectiveness and operation of the Panel will be reviewed annually.”*

<http://www.irpanel.org.uk>

Quality Surveillance Groups

Quality Surveillance Groups (QSGs) operate at a local and regional level. There are 27 local QSGs aligned to same geographical areas as the NHS Local Area Teams (LATs). There are four regional teams; North of England, South of England, London and Midlands and East. These are aligned to the NHS Commissioning Board (NHSCB), Care Quality Commission (CQC), Monitor, Public Health England (PHE) and the NHS Trust Development Authority's (NHS TDA) four regional teams.

The membership of the local QSG includes NHSCB area team, Clinical Commissioning Group (CCG) leads, Local Authority representatives, Local Healthwatch, CQC, Monitor, NHS TDA, Local education and training boards and public health centre.

The membership of the regional QSG includes NHSCB Regional office, NHSCB Area Team, CQC, Monitor, NHS Trust Development Authority, Local Authority Representative(s), Local Healthwatch representative(s), Health Education England, Health Service Ombudsman, Professional Regulators (GMC, NMC) and Public Health England.

QSGs act “as a virtual team across a health economy, bringing together organisations and their respective information and intelligence gathered through performance monitoring, commissioning, and regulatory activities. By collectively considering and triangulating information and intelligence, QSGs will work to safeguard the quality of care that people receive...

...They engage in surveillance of quality at a local level by those closest to the detail and most aware of concerns. They will not only consider information and intelligence but also be able to work together to take coordinated action to mitigate quality failure.

Regional QSGs provide an escalation mechanism for Local QSGs. They assimilate risks and concerns from local QSGs, identifying common or recurring issues that would merit a regional or national response.”

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/216996/Establishing-Quality-Surveillance-Groups.pdf

New Review

NHS England have established a new review that is considering the whole lifetime pathway of care for people with congenital heart disease.

“The ambition of this review is to ensure that services for people with CHD are provided in a way that achieves the highest possible quality within the available resources:

- the best outcomes for all patients, not just lowest mortality but reduced disability and an improved opportunity for survivors to lead better lives.
- tackling variation so that services across the country consistently meet demanding performance standards and are able to offer resilient 24/7 care
- great patient experience, which includes how information is provided to patients and their families, considerations of access and support for families when they have to be away from home”

www.england.nhs.uk/wp-content/uploads/2013/07/180713-item13.pdf

Letter of invitation to participate in the Cantrill review



Dear

Our Ref: SC/2907Cardiac

West Yorkshire Area Team

3 Leeds City Office Park

Meadow Lane

Leeds

LS11 5BD

Email: susan.cannon4@nhs.net

9th September 2013

Leeds Paediatric Children's Cardiac Care

Firstly we would like to take this opportunity to thank you for the contribution you have already made to us gaining a better understanding of the care received by children and their parents at the Children's Heart Unit at Leeds General Infirmary. We do not underestimate the demands that having to tell us about your experience places on you and we are very grateful because without you we cannot identify the lessons that need to be learned.

We have spent some time considering how we should take your concerns forward and have decided to ask Professor Pat Cantrill to undertake an independent review.

Pat has led a number of important reviews across social services, education, NHS and voluntary organisations. She has significant experience of undertaking and managing complex investigations which have required a systematic review of leadership, practice and clinical governance.

Pat will be commencing the work in August and it is anticipated that her findings will be available in the autumn.

Aim of the work

The overall aim of the work we have commissioned is to review the effectiveness of the support given by Leeds Teaching Hospitals NHS Trust to parents and children receiving cardiac care.

The work will involve:

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

It is anticipated that the result of this work will be a report which identifies key issues and patterns related to parental concerns. This will be used to inform future changes to services and to identify areas of further investigation and/or development.

Your involvement

We are therefore asking for your agreement to being involved in the review.

Firstly we would like your agreement that any information you have provided to date either in writing to the CQC or discussions at the meetings we have held can be made available to Pat.

We also would like your agreement for Pat to contact you to agree a one to one meeting, a telephone conversation or if you prefer to meet as a member of a group of parents. It is difficult to say how long such a meeting will take as it will be very much led by you but Pat estimates that on average it should take no longer than two hours.

To indicate your willingness to be involved would you please contact us :

- Email to laura.irwin@nhs.net
- Or complete the tear off slip below and return to Laura Irwin, NHS England West Yorkshire Area Team, 3 Leeds City Office Park, Holbeck, Leeds, LS11 5BD

If we do not hear from you before 17th September 2013, we will understand that you do not wish to be involved in the review.

Finally once again thank you for all your help so far in what has been and continues to be very difficult circumstances.

Yours sincerely



Sue Cannon
Director of Nursing and Quality (West Yorkshire)
NHS England

Name -----

I/we are prepared to be involved in the review	Yes/ No
I/we consent to information being shared with Professor Cantrill	Yes/ No
I/we would prefer to see Professor Cantrill on my/our own	Yes/ No
I/ we would prefer a telephone conversation	Yes/ No
I/we would prefer to see Professor Cantrill as members of a group	Yes/ No

Joint statement on behalf of Guy's and St Thomas', Great Ormond Street Hospital and Royal Brompton & Harefield NHS Foundation Trusts

Royal Brompton & Harefield 
NHS Foundation Trust

Great Ormond Street 
Hospital for Children
NHS Trust

Guy's and St Thomas' 
NHS Foundation Trust

Joint Statement on behalf of Guy's & St Thomas', Great Ormond Street Hospital and Royal Brompton & Harefield NHS Foundation Trusts

Changes to Services for Children with Congenital Heart Conditions

Our three NHS Foundation Trusts are collectively committed to ensuring that current services for patients continue as normal while discussions begin to determine how the 4th July 2012 recommendation of the Joint Committee of Primary Care Trusts, that London should have two NHS child heart surgery centres from 2014, is safely and effectively implemented. As leaders of our respective organisations, we acknowledge a collective responsibility to work together and to provide direction and support for the families and staff affected. They, and colleagues at hospitals in London and the South East, should be confident that future services will build upon and enhance the undoubted quality of existing services, and that the transition to the new arrangements will be planned carefully and sensitively.

In particular, we will:

- develop a shared overall implementation plan for London, including joint monitoring mechanisms to give confidence that standards and safety are maintained throughout the period of transition;
- ensure that other services for children and adults are not adversely affected by plans to reconfigure children's congenital heart services;
- communicate consistently with families, staff and referrers, and actively seek their involvement as we develop our implementation plans;
- ensure that staff facing change and uncertainty feel valued and protected and understand that their skills and expertise will continue to be needed by the London networks;
- work collaboratively together to maintain a good outcome for London overall.



Robert J. Bell
Chief Executive, Royal Brompton & Harefield NHS Foundation Trust



Jan Filochowski
Chief Executive, Great Ormond Street NHS Foundation Trust



Sir Ron Kerr, CBE
Chief Executive, Guy's & St Thomas NHS Foundation Trust

6 December 2012