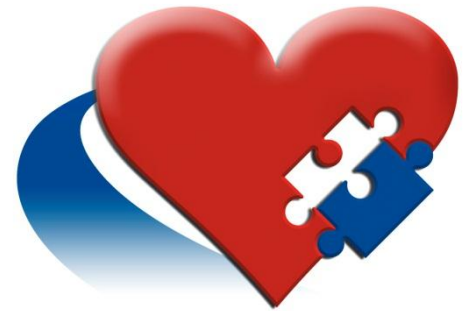


Letter 1

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Little Hearts Matter

Half a heart...not half a life

Our Ref: SH/TR

17th April 2013

Sir Bruce Keogh
Medical Director of NHS England

Dear Sir Bruce

Re: Stage Two of the Inquiry into Congenital Cardiac services at Leeds General Infirmary,
NHS England and the Care quality Commission

“We need to enable individual surgical teams to maximise their experience on particular complex and rare conditions. The only way we can do this is by increasing the number of cases to which they are exposed. This cannot be achieved by simply tinkering at the edges of local services.”

Sir Bruce Keogh

Over the past three years Little Hearts Matter has striven to achieve the changes needed within the Congenital Cardiac service that would allow every patient with only one functioning ventricle a chance at the best quality of life possible, no matter where they were born. The promise that the reorganisation of cardiac services would at last remove the risk of low skilled teams offering inexperienced treatment, or no treatment at all, gained our support and so we have patiently waited for the change promised, but the children can wait no longer.

As the national charity with a specialist view on the diagnosis, treatment and lifestyle care of children and young adults with these complex, non correctable conditions, we have had the responsibility of ensuring that their voice has been heard in the mêlée of discord. It is clear from parental and patient comment and the evidence within the CCAD and NICOR documentation that the service for children with complex hearts hangs in the balance. We are also aware that the data, yet to be fully collected for the year 2012/13 will highlight a series of deaths related to our group of patients.

Our concerns are wide spread but in three distinct sections.

- The current service for children treated at the Leeds General Infirmary. *See detailed list of concerns attached.*
- The national care of children receiving surgery for single ventricle disorders is varied and in some areas barely mediocre. The CCAD information and the risk adjusted information on expected deaths relate in the main to patients with complex conditions namely Hypoplastic Left Heart Syndrome or other Fontan circulation conditions. The evidence that units have come close to referral for deaths during or following treatment for single ventricle conditions is very concerning. The fact that we have no indicators for the short or long term outcome for these patients is even more disquieting as death is not the only bad outcome for these children.
- The inertia that is currently delaying the reconfiguration of services is causing the service to seriously crumble. Lack of unit investment, low staffing levels, long waiting lists and localism preventing patient case discussion and timely referral.

As the medical director of the NHS England we urge you to take action on behalf of this very vulnerable group of children.

Having taken our Leeds based concerns to the Care Quality Commission they have directed us to NHS England as it is you that is conducting the stage two assessment of patient notes which should clearly indicate the treatment pathways for these complex children. All of our concerns are set out in the documentation attached.

On the broader issue of Fontan care we again raise the need to restrict the number of units offering Norwood and Fontan care. Had the reconfiguration of congenital cardiac services gone ahead as planned the final number of units should have been able to create, with education and scrutiny, a service that every child with a complex heart deserves, but with every day of delay their care becomes poorer, their lives are put at risk and their chances of achieving even half the potential of their peers is reduced. It is time for action.

The current political and media frenzy surrounding the need for change is creating a smoke screen that is masking true risks for children with congenital heart disease. The whole premise for the need for change set out by Kennedy over 12 years ago, is more evident today than it was then. We should not have to wait for more deaths before someone takes the important step forward on behalf of these complex children.

Yours Sincerely

Suzie Hutchinson RGN; RSCN
Chief Executive

Peter Turner
Chair

Enclosed with letter 1

NHS England and The Care Quality Commission

Little Hearts Matter is a national organisation that offers support and information to children, and their families, affected by a diagnosis of single ventricle heart disease. The charity supplies all of the UK units with Information Standards Certificated information on the diagnosis, treatment and lifestyle information needed by families as they learn about the treatment pathway planned for their child. The charity receives direct referral from many of the UK units at antenatal diagnosis and works as an added source of lifestyle information for clinical teams throughout the country. The charity sits on the Implementation Standards team and the Congenital cardiac Clinical Reference Group as well as working to highlight the needs of this complex group of children and young adults within arenas for change, medical, educational, social service and governmental.

Little Hearts Matter Concerns

1. Types of surgery undertaken at Leeds, outcomes not mortality but morbidity.
2. Timing of surgery – evidence that operations are undertaken later than the nation average. Glen and Fontan.
3. Surgery that Leeds admit that they should not undertake. – Norwood's.
4. Referral for complex care beyond local units.
5. Patients/Parents access to second opinions or a transfer of care.
6. Antenatal diagnosis, termination rates, treatment plans and referrals.
7. Potential miss diagnosis.
8. The critical condition of many of the children once they are received by a referral unit.

Little Hearts Matter would like these concerns highlighted during the case note review planned as part of the second stage of review into the Leeds surgical service.

Information sources.

- Individual Little Hearts Matter membership concerns.
- Members seeking a clearer understanding of the surgical process for their child.
- CCAD and NICOR data.
- Research on optimal surgical care for children with complex single ventricle disorders

Types of Surgery Undertaken at Leeds

Concerns that complex procedures, Fontan, are being undertaken in a unit with poor outcomes. See CCAD data.

Number of Glen/Cavo Pulmonary Connections done in relationship to the number of Fontan procedures. If they are not having Fontan's what is being done for these patients?

- Are they being transferred to other units?
- Is their surgery being delayed?
- Are they dying?

There are signs of slow post operative recovery, long periods of time spent in ITU, HDU, Ward. Re-operation rates for complications. Long term outcome appears poor but currently unmeasured.

A number of patients with complex conditions are being seen in OPD 2 monthly, continually, why.

HES and CCAD data does not give a clear view of this sort of outcome experience because it only reports mortality.

There is also an issue with the developmental issues experienced by a number of children.

Is outcome explained correctly? Are parents being given all the right information to make choices about surgery? Parents will not know about outcomes unless they are told. They have full faith in their cardiac team.

Timing of Surgery

Evidence from LHM members that surgery is done far later than in other units.

Glen Shunts done at age 2 or 3 years sometimes as late as 6 years old. (Nationally recognises timing between 3 and 9 months - deciding factor cyanosis, increased heart failure and reduction in growth)

Fontans done in late childhood. (Most units offer this surgery between 3 and 6 years - deciding factors, tailing off in growth, increased heart failure, and increased cyanosis)

Delays in setting out treatment plans have caused a marked deterioration in outcome.

Confirmation of types of surgery not undertaken at Leeds

Leeds agreed some years ago to stop offering the Norwood procedure for complex cases (because of poor outcomes), LHM would like to understand the criteria for other complex cases being referred away or not. It is clear that some single ventricle heart conditions are being treated at Leeds. National experts recommend a minimum of 20 Norwood's and 20 Fontans to maintain the expertise needed for these complex cases. (This is still to be agreed by the medical profession but is one submission to the IRP)

Referrals for complex care beyond Leeds

Having confirmed that some patients require a referral to a unit beyond Leeds the referral pattern does not appear to be clear and certainly does not meet Leeds own requirement for patients to be treated as close to home as possible.

Many patients are being referred to London when the Newcastle or Birmingham Units would be closer.

Patient/Parent access to a second opinion

Patient choice is clearly set down as the right of anyone being treated by the NHS.

It is clear that a number of families, when seeking either a second opinion or to transfer their care, are meeting with resistance and in some cases a clear NO to the request. (One mother was even tainted with the diagnosis of Munchausen's by proxy).

Delays in referral and mis-information or no information following the patient to another unit have delayed emergency treatment to the point where their condition has deteriorated markedly potentially affecting outcome.

Medical consultation about complex cases is not as forth coming as it used to be.

Antenatal diagnosis, termination rates, treatment plans and referrals

Expectant parents are being given mixed messages about diagnosis and very mixed messages about the referral plans for treatment if treatment is offered at all.

Many families feel that they are being pushed to termination. It is important to note that any expectant family being told that their child has an incurable condition may only hear that termination is recommended and not hear that there are other options but some families report being told that their child had a completely inoperable condition when another unit was able to offer surgery.

There are no clear referral pathways, no clear delivery information and no referral to other organisations who would be able to offer support and parent lead information.

Potential miss diagnosis.

Antenatal diagnosis of congenital heart disease is a highly skilled area of medical care. Often patients have to undergo a series of scans before a final diagnosis is confirmed.

Expectant parents will be offered, in most cases of complex disease, a series of treatment pathways. One of which will be termination of pregnancy.

It is rare, but not impossible, for the malformation within the heart to be so extensive that there can be no treatment offered but that diagnosis would be reached after a series of scans allowing for growth of the baby to allow for change.

Sometimes at birth a diagnosis will be changed because scanning the baby's heart directly is easier than scanning through the mother.

Following a series of scans there should be a clear diagnosis and a pathway of care set out.

The critical condition of many of the children once they are received by a referral unit.

The timing of the referral of a child for expert treatment at another centre is paramount to the surgical outcome for that child. Not just their survival but also their neurological and developmental outcome.

The pathway from diagnosis, through treatment planning into referral needs to be swift and clear (where possible). Parents, and the child themselves, need to be fully included in the planning and decision making.

Skilful judgement about optimal referral time is essential.