

# Public Document Pack

## **Supplementary information for 13 September 2013 Joint Health Overview and Scrutiny Committee (Yorkshire and the Humber)**

Pages 1-18: Agenda item 8 – supplementary information in relation to the new review of congenital heart services in England

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## **Notes from the meeting with Geoff Alltimes (Local Government Association) and Tim Gilling (Centre for Public Scrutiny), 27 August 2013**

The following points were raised in the discussion:

- Early engagement with OSCs is appropriate because their role is both overview and scrutiny. It would be for each OSC to manage any potential conflict raised by involvement.
- Concerns were raised that John Holden's blog seemed to suggest that the engagement with local authorities is an 'afterthought' when it prioritised engagement with clinicians and patients. This was not appropriate: local authorities represent patients or potential patients.
- OSCs, although important, are only one part of local government. Engaging with councils therefore needs to be wider than just OSCs and should also include leaders, cabinet, lead members, health and wellbeing boards, executives.
- It is helpful to agree the principles in any proposed health service change before moving on to the detail.
- The NHS has not been good at selling the benefits even when these have been demonstrably achieved – changes to stroke and major trauma services were cited as examples. The benefits of any proposed changes would need to be carefully articulated, ideally by specialist clinicians.
- NHS England considers it important to develop solutions within a year because services are vulnerable having been in 'limbo' for a long time. Any decisions will be developed working closely with the stakeholders.
- NHS England will need to ensure that the stakeholders have trust in the process used to reach the decision and that the decision is strongly supported by those that will be affected by it.
- NHS England agreed that it should seek to engage with local government early in the process. NHS England will want them to have a strong role in designing services as well as in scrutinising them.
- The potential for establishing a single joint scrutiny committee was discussed (as envisaged in the relevant directions on overview and scrutiny). This seemed to offer advantages to the NHS in giving a single point of engagement and the opportunity for a more in depth approach. It was considered by CfPS that it was unlikely that a single national committee would be formed because of the practical challenges involved in doing so.
- NHS England set out the considerable challenge of engaging effectively with every council across England and sought to explore possible approaches.
- It was agreed that not all local councils, OSCs and Health and Wellbeing Boards would be interested in the review to the same extent. NHS England should make sure that some types of information will be sent to all councils but there will be some who will be interested in additional in-depth briefings.
- NHS England will also organise a meeting with all concerned local authorities and Health and Wellbeing Boards to explain the issues and ensure there is a national perspective. NHS England will also brief all OSCs, Council leaders and HWBBs in writing about the Review.
- NHS England will continue to ask CfPS for advice regarding engagement with the OSCs. CfPS suggested that NHS England organise a meeting with the OSCs to

explore how they want to be engaged with. The OSCs will be approached through their regional networks.

Email address: [bruce.keogh@nhs.net](mailto:bruce.keogh@nhs.net)

30 August 2013

Dear Tony,

Thank you for the work that you have been doing to ensure that we have a comprehensive set of standards for the provision of care for children with congenital heart disease. I am aware that you have been in this for the long haul and I want to assure you that your work remains vital for the new review.

I have asked Professor Deirdre Kelly to oversee the process of bringing to a conclusion the work on additional standards for children's congenital heart services and working with the ACHD standards group to make a joint recommendation on a single combined set of standards.

I would like to take the opportunity to highlight three points that have been raised with us as important, and ask that in your work you take them into account:

Firstly, the scope of the new review – although yet to be finalised – is different from any previous work in that it is comprehensive and includes the whole patient pathway:

- Fetal diagnosis of congenital heart disease
- Pre-natal care (including care of women whose unborn child has suspected or confirmed congenital heart disease)
- Care for children and young people
- Transition from children's services to adult services
- Care for adults
- End of life care
- Care and support for families suffering bereavement

It is important therefore that the standards we set now, building on those developed by the Safe and Sustainable process, cover the whole pathway. I would be grateful if you would work with John Deanfield who has been leading the group developing adult standards to ensure that there is a comprehensive and consistent set of standards covering the whole pathway. We are still considering the full scope of the review, including its relationship to other heart disease in children, ECMO and transplant services. If there is any expansion of scope this will be agreed by the advisory group which I am establishing, and which you have been invited to join, so you will be able to consider whether this will require any further work on standards.

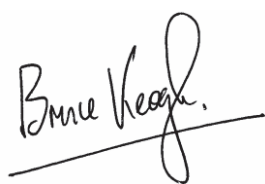
*High quality care for all, now and for future generations*

Secondly, I wanted to pick up on a concern that has been voiced by a number of people in the listening events that we have organised. It has been said on more than one occasion that some of the standards previously developed were 'fudged', that is to say that they took too much account of whether existing providers were already meeting them or would be able to meet them in the future. Examples would be the definition of and requirements for co-location. My colleague Bill McCarthy set out NHS England's position clearly in the paper discussed by our board on 18 July 2013. The aim of the new review is to ensure that services achieve the highest possible quality within the available resources, now and for future generations. It is important therefore that the standards set out what is needed to achieve this. If that means that some aspects of the Safe and Sustainable standards have to be reconsidered or revised then please provide me with advice to that effect. As we are seeking to improve services it is quite likely that there will be some standards that are very challenging for existing providers. But it is important that your group sets standards that represent the ideal. If it transpires that one or more provider is unable to meet some of the standards this is a process that will be managed by commissioners and does not need to be taken into account by you in setting the standards.

Thirdly, NHS England has set out principles for the new review that include transparency and evidence. We have said that we will be clear about the nature and limitations of the available evidence and about any intention to rely on expert opinion in the absence of evidence. I would be grateful therefore if you could consider how this can be achieved for the standards that you have been developing.

Finally, let me once again thank you, and through you those who have worked as part of your group, for the hard work that you have already put in and for your continued commitment to see the task through.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Bruce Keogh', with a long horizontal stroke extending from the bottom of the signature.

**Professor Sir Bruce Keogh**  
**National Medical Director, NHS England**

Cc: Professor John Deanfield  
Professor Deirdre Kelly

Email address: [bruce.keogh@nhs.net](mailto:bruce.keogh@nhs.net)

30 August 2013

Dear John,

Thank you for the work that you have done to develop standards for adults with congenital heart disease. I am aware that you have been in this for the long haul and I want to assure you that your work remains vital for the new review.

I have asked Professor Deirdre Kelly who was leading the clinical work on how to implement the Safe and Sustainable model with her Clinical Implementation Advisory Group to oversee the process of bringing to a conclusion the work on additional standards for children's congenital heart services and I would be grateful if you would work with her to make a joint recommendation on a single combined set of standards.

I would like to take the opportunity to highlight three points that have been raised with us as important, and ask that in your work you take them into account:

Firstly, the scope of the new review – although yet to be finalised – is different from any previous work in that it is comprehensive and includes the whole patient pathway:

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- Care for adults
- End of life care
- Care and support for families suffering bereavement

It is important therefore that the standards we set now, building on those developed by the Safe and Sustainable process, cover the whole pathway. I would be grateful if you would work with Tony Salmon who has been leading the group developing standards for children to ensure that there is a comprehensive and consistent set of standards covering the whole pathway. We are still considering the full scope of the review, including its relationship to other heart disease in children, ECMO and transplant services. If there is any expansion of scope this will be agreed by the

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advisory group which I am establishing, and which you have been invited to join, so you will be able to consider whether this will require any further work on standards.

Secondly, I wanted to pick up on a concern that has been voiced by a number of people in the listening events that we have organised. It has been said on more than one occasion that some of the standards previously developed were 'fudged', that is to say that they took too much account of whether existing providers were already meeting them or would be able to meet them in the future. Examples would be the definition of and requirements for co-location. My colleague Bill McCarthy set out NHS England's position clearly in the paper discussed by our board on 18 July 2013. The aim of the new review is to ensure that services achieve the highest possible quality, within the available resources, now and for future generations. It is important therefore that the standards set out what is needed to achieve this. As we are seeking to improve services it is quite likely that there will be some standards that are very challenging for existing providers. It is important that the standards we set represent the ideal. If it transpires that one or more provider is unable to meet some of the standards this is a process that will be managed by commissioners and does not need to be taken into account in setting the standards. This may not have been stated so clearly at the time your group were developing the ACHD standards so I would be grateful if you would consider whether they are aligned with this approach, and if not what further work needs to be done.

Thirdly, NHS England has set out principles for the new review that include transparency and evidence. We have said that we will be clear about the nature and limitations of the available evidence and about any intention to rely on expert opinion in the absence of evidence. I would be grateful therefore if you could consider how this applies to the standards you have developed and advise me accordingly.

Finally, let me once again thank you, and through you those who have worked as part of your group, for the hard work that you have already put in and for your continued commitment to see the task through.

Yours sincerely,

A handwritten signature in black ink, reading 'Bruce Keogh' with a stylized flourish at the end.

**Professor Sir Bruce Keogh**  
**National Medical Director, NHS England**

Cc: Dr Tony Salmon  
Professor Deirdre Kelly

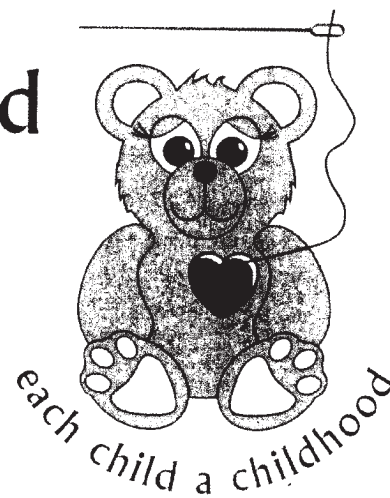


# Children's Heart Surgery Fund

RUN 70725

September 12<sup>th</sup>, 2013

Bill McCarthy  
National Director for Policy  
NHS England  
Quarry House  
Quarry Hill  
Leeds  
LS2 7UE



Dear Bill

Thank you for inviting comments on the new Congenital Heart Disease (CHD) Review from interested groups. I feel obliged to raise some strong concerns I have regarding appointments to the Congenital Heart Disease Clinical Reference Group (CRG), including Anne Keatley-Clarke, Chief Executive of the Children's Heart Federation; Suzie Hutchinson, lead support for Little Hearts Matter; and Samantha Lloyd, a parent and carer representative. I am deeply concerned about the impact which these appointments will have on the new CHD Review.

You will recall that the Independent Reconfiguration Panel (IRP) criticised the role of the Children's Heart Federation in the Safe and Sustainable Review. The IRP reported that "*a number of parents and some charities raised concerns about the role played in the process by the CHF in undertaking surveys that influenced the weighting given to the access criterion and the fact that this organisation was the sole voice for children and parents inside the process. For many parents who spoke to the Panel this arrangement become more problematic after the CHF itself issued public statements critical of those challenging the proposals.*" It concluded that the Charity's role in the Review was as "*a source of unhelpful divisiveness that undermined achieving the necessary engagement rather than delivering it*" and said that it "*found some of the media statements issued by the CHF... were seen to be combative in style, serving to polarise the debate and unnecessarily antagonize those raising their concerns.*" Whilst I of course do not object to CHF contributing to the new Review, the same as any other organisation, I do believe that to afford a specially created place (affiliate membership without voting rights) to Ms Keatley-Clarke who as Chief Executive was primarily responsible for CHF's behaviour during the Safe and Sustainable Review, is hugely inappropriate and risks discrediting the new Review in much the same way as its predecessor.

Ms Keatley-Clarke's appointment is especially alarming in the light of the fact that in January 2010, she co-signed a controversial statement in which she pre-determined the outcome of the Safe and Sustainable Review by setting out which children's heart surgery units should remain open (see enclosed). This was also signed by Suzie Hutchinson, another Patient Experience appointee to the CRG, who wrote to Professor Sir Bruce Keogh as recently as April 17<sup>th</sup> this year, making allegations against the Leeds Unit on specific medical cases which she is neither qualified nor informed to comment upon. I was dismayed that she chose to raise her concerns in this way, without taking

t: 0113 392 5742

x: 0113 392 8174

mail: [ch.sf@leedsth.nhs.uk](mailto:ch.sf@leedsth.nhs.uk)

web: [www.chsf.org.uk](http://www.chsf.org.uk)

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them up with staff at the Unit or going through the appropriate channels at the Hospital, and as a result her actions inflicted maximum damage on the Leeds Unit. Surely this demonstrates a bias against Leeds which is incompatible with occupying an important role on a neutral body? I was especially dismayed because at a meeting in the spring attended by Ms Hutchinson, myself and several clinicians, she did not raise the concerns which she then detailed in her letter (**enclosed**) to Sir Bruce shortly afterwards.

On August 7<sup>th</sup>, Samantha Lloyd attended the meeting which was arranged for local and regional charities and organisations to contribute to the CHD Review as spokesperson for Newcastle-based Children's Heart Unit Fund (CHUF). Ms Lloyd has pursued an active campaign against the Leeds Unit and publicly repeated her desire to see the Unit close. I **enclose** screenshots of her pronouncements on Facebook, where she is listed as a member of the Fragile Hearts and 'Support the closure of the children's heart unit at LGI', as examples of this.

The Children's Heart Surgery Fund (CHSF) wants the new Review to be a success for the sake of the patients and families we represent. We welcome the efforts you and your team have made to be open and transparent and to ensure stakeholders, including regional charities such as ours, are included in discussions. You will, however, appreciate that we are profoundly concerned by the appointment of individuals with a record of campaigning against the Leeds Unit on to a body which will presumably play a prominent role in the CHD Review. I hope you will also appreciate that this goes completely against the assurance given by NHSE at the August 7<sup>th</sup> meeting that it "*will seek assurance that the patient representation [on the CRGs] is broad enough to capture the full range of views.*"

I should therefore be grateful for clarification on the precise role which the Clinical Reference Groups will play in the new Review, whether as advisers or decision-makers, and for your assurance that none of these individuals will have a special position in the Review.

I look forward to hearing from you.

Yours sincerely



Sharon Cheng  
Director

Copied to:  
Jeremy Hunt MP, Health Secretary  
Graham Stuart, Chairman of the Congenital Heart Services CRG  
Mike Bewick, NHSE Deputy Medical Director for Northern England  
Andy Buck, NHSE Director (West Yorkshire)  
Cllr John Illingworth, Chairman of the Yorkshire and Humber JHOSC

**Letter 1**

11 Greenfield Crescent, Edgbaston  
Birmingham, B15 3AU, United Kingdom

Telephone: 0121 455 8982

Facsimile: 0121 455 8983

[info@lhm.org.uk](mailto:info@lhm.org.uk)

[www.lhm.org.uk](http://www.lhm.org.uk)



Our Ref: SH/TR

17<sup>th</sup> 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.

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