Update on the New Congenital Heart Review process

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Executive Summary

Context

This paper provides the Trust Board with an update on the campaign to retain the East Midlands Congenital Heart Centre, (EMCHC) at UHL. The paper also invites the Board to comment on and ultimately, endorse our proposed response to the NHS England consultation. (Appendix A)

Questions

1. What has been happening in the campaign since the purdah period for the General Election has finished?
2. What are the next steps in relation to the consultation process?
3. What are the key points and the next steps for the Trust's formal response to the consultation?

Conclusion

1. The Purdah period relating to the General Election ended on the 9th June 2017. Since then EMCHC colleagues have attended public consultation meetings in Lincoln and Nottingham, and the Leicester, Leicestershire & Rutland Health Overview &Scrutiny Committee meeting, all of which were also attended by NHS England. The draft consultation response from the Trust has been prepared, reviewed by the clinical and legal teams and is being presented for comment and endorsement at this Trust Board.
2. Meetings are planned for parents and patients to meet NHS England on 1st July at Glenfield Hospital and the East Midlands cross party MPs on 4th July in London. A visit to Glenfield is planned by the Shadow Health Secretary, Jon Ashworth on the 7th July. John Adler has extended an invitation to John Stewart, Director of Specialist Commissioning NHS England to visit the Trust before the end of the consultation, to discuss the growth plan submitted on 3rd May 2017, and to meet staff. A final effort to encourage all stakeholders to complete the consultation questions is being supported internally and through local media.
3. The draft Trust formal response to the consultation questions is attached for Trust Board review. The overall summary of the Trust's position, and our proposals as to a way forward is;
    - The evidence shows that, like other centres, we currently deliver high quality care to our patients
    - We accept NHS England's overall approach i.e. standards-based commissioning, although we have concerns about the interpretation of some of these standards

- We welcome the fact that for UHL NHS England has confirmed that there is only one outstanding standard about which it has concerns i.e. case numbers
- To address these concerns, during the consultation period we have submitted a more comprehensive and updated growth plan demonstrating how we can meet the case numbers standard
- We would like NHS England to accept this plan and support us in further developing our regional network
- We would ask NHS England to accept that supporting this approach carries significantly less risk in terms of destabilisation than does the decommissioning of our centre.
- We would ask NHS England to acknowledge that the decommissioning of our centre would substantially reduce choice for the population of the East Midlands and therefore an alternative viable approach to achieving the objective of compliance with the standards is preferable.

4. Once approved, the response will be sent to the NHS England consultation hub and also sent in hard copy to NHS England. The consultation deadline is the 17th July 2017. We have no firm timeline for the decision making process once the consultation has finished.

Input Sought

We would welcome the Board's review and endorsement of the Trust's draft response to the consultation questions.

For Reference

Edit as appropriate:

1. The following **objectives** were considered when preparing this report:

Safe, high quality, patient centred healthcare	[Yes]
Effective, integrated emergency care	[Yes]
Consistently meeting national access standards	[Yes]
Integrated care in partnership with others	[Yes]
Enhanced delivery in research, innovation & ed'	[Yes]
A caring, professional, engaged workforce	[Yes]
Clinically sustainable services with excellent facilities	[Yes]
Financially sustainable NHS organisation	[Yes]
Enabled by excellent IM&T	[Yes]

2. This matter relates to the following **governance** initiatives:

a. Organisational Risk Register [Yes]

If YES please give details of risk ID, risk title and current / target risk ratings.

Datix Risk ID	Operational Risk Title(s) – add new line for each operational risk	Current Rating	Target Rating	CMG
2940	There is a risk that paediatric cardiac surgery will cease to be commissioned in Leicester with consequences for intensive care and other specialist paediatric services	15	0	Women's and Children

If NO, why not? Eg. Current Risk Rating is LOW

b. Board Assurance Framework [No]

If YES please give details of risk No., risk title and current / target risk ratings.

Principal Risk	Principal Risk Title	Current Rating	Target Rating
No.	…		

3. Related **Patient and Public Involvement** actions taken, or to be taken: [Insert here]
4. Results of any **Equality Impact Assessment**, relating to this matter: [Insert here]
5. Scheduled date for the **next paper** on this topic: August 2017
6. Executive Summaries should not exceed **1 page**. [My paper does not comply]
7. Papers should not exceed **7 pages.** [My paper does not comply]

University Hospitals of Leicester NHS

NHS Trust

University Hospitals of Leicester NHS Trust - Response to the NHS England Public Consultation on;

Proposals to implement standards for congenital heart disease services for children and adults in England

Consultation Questions

Meeting the standards

1. **In what capacity are you responding to the consultation?**

   NHS provider organisation - University Hospitals of Leicester NHS Trust

2. **In which region are you based?**

   Midlands and East - East Midlands

3. **NHS England proposes that in future Congenital Heart Disease services will only be commissioned from hospitals that are able to meet the full set of standards within set timeframes. To what extent do you support or oppose this proposal?**

We agree that the standards are appropriate; however we disagree with the proposed approach to how these standards are applied; particularly in respect to timeframes. We feel that there should be equity across all providers in the way that they are supported to meet the standards and over what time period.

4 Please explain your response to question 3.

Statements from NHS England colleagues have made clear that that the only standard with which EMCHC does not now fully comply, and which would form the only basis against which not to continue to commission our service, is the case volume standard. It should be noted that at the point of submitting this consultation response we have had no response to the growth plan which was submitted to NHS England on 3rd May 2017 and which we believe clearly shows that EMCHC can reach the case volume numbers. In any event, we believe that the rigid application of the volume standard against our centre is inequitable as it is clear that there is leeway for this standard to be applied with some flexibility to at least one other centre. We do agree with the basic proposition that at least up to a certain threshold, larger centres are more likely to achieve better results than smaller centres (despite the paucity of evidence for a suitable definition of 'large') but we would point out that all of the present UK centres except for Manchester and Bart's are 'large' by most internationally accepted professional definitions and standards.

Before responding to the specific questions in the consultation document, we want to make a number of observations which we consider to be material to any decision that the NHSE Board makes about the future of CHD services in England.

An overall summary of UHL's position on the review, and our proposals as to a way forward, is:

- The evidence shows that, like other centres, we currently deliver high quality care to our patients.
- We accept NHS England's overall approach i.e. standards-based commissioning, although we have concerns about the interpretation of some of these standards

- We welcome the fact that for UHL NHS England has confirmed that there is only one outstanding standard about which it has concerns i.e. case numbers
- To address these concerns, during the consultation period we have submitted a more comprehensive and updated growth plan demonstrating how we can meet the case numbers standard
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1.1 Introduction

This review follows the series of previous reviews after the problems in Bristol 25 years ago. However, today, there is recognition, on the basis of rigorous audit, that there is no excessive mortality in any centre and the smallest of the current mainstream centres, Newcastle and EMCHC, are both doing multiples of the historical Bristol caseload figures. Furthermore, we would assert that whilst there is nothing wrong with the standards per se, they were never designed to decide which centres should be closed. We believe that the standards are being used in a fashion for which they were not designed, to confront issues that no longer exist, and are in fact irrelevant to the main problems faced by CHD services in this country over the next 5-10 years.

1.2 The *current* issues with CHD services

Normally, the process designed to review a service like Congenital Heart Disease (CHD) would begin by identifying the long term problems faced by the service. That is what the NHS does in any other area: It looks for problems and then solves them. That is what happened for example when Regional Trauma Centres or Hyper-Acute Stroke Units or the Percutaneous Primary Angioplasty services were established: there was agreed to be a problem with the existing service; a remedy for that specific problem was agreed and it was then applied to the service.

In the case of CHD, NHS England did not adopt this approach not least because it was generally agreed that there was little wrong with the quality of existing services as measured by mortality and clinical outcomes. So, rather than identifying a problem, the review started from a concept of perfection and then decided which units would be able to meet that concept.

These are the issues which we think are really facing providers of CHD services in England:

1) *Lack of staff* –
   Every hospital in the country is challenged by a shortage of staff, as a result of which resources are being diverted to pay for more expensive agency staff. In this field we depend upon the dedication of highly specialised staff, people who are in very short supply. This process of endless scrutiny and threatened reorganisation over 20 years has had a damaging impact on the training of young CHD surgeons,[1] and

[1] Last year there were 70 applicants for 14 places for cardiac surgical training, an over-supply of 500%. Yet when they came to sub-specialise, only one trainee applied for three PCCS places so that two were unfilled. This year there has been no applicant for PCCS training.

raised major concerns about the training of paediatric cardiologists.[2] However, it is the shortage of cardiac PICU nurses that is *most threatening* to the day-to-day delivery of the service. Today, patients are routinely finding beds only as a result of regular telephone conferences between staff in different centres who come together to share priorities.

We know that NHS England are proposing to review this problem in a parallel review of PICU services, but it is misguided to suppose that centres can be closed without making this problem worse, especially at a time when the funding challenges and Brexit are coming together to restrict the supply of nurses. As NHS England will be aware, these nurses are not particularly mobile, (they have families), and here in Leicester we have carried out a review of our staff, which shows that most of them will be lost to PCCS services because they will not be willing or able to move with the work they have been trained to do over years. This matches a similar survey result at the time of Safe and Sustainable five years ago.

Whilst the parallel review of PICUs is welcomed, (albeit too late to inform the consultation), in the present state of NHS resources and training it is unlikely that there will be any effective solution unless there is a radical realignment of resources within the NHS.

2) *Transition* –

We know that over the last 20 years, EMCHC has built a good service with excellent outcomes. Indeed, NHS England has repeatedly acknowledged this in meetings with staff and stakeholders. However, like most other systems in Europe and North America that depend mainly upon treating children in children's hospitals, nationally we have seen a failure to manage the problems of transition to adult services. Enormous efforts have been made, and in some places the achievements are marvellous, but still we know that unacceptable numbers of patients do badly as a result of poor transition in the years after they graduate from children's services. To ask them to move to another hospital is undesirable for a number of reasons: they have to get used to a new and strange environment which some find challenging; they have to make an abrupt transition, moving from one set of doctors and nurses who they have known all their lives, at a time that may not turn out to be appropriate. Our transition patients come to the same clinics and can revert to seeing the same doctors if they prefer. When they need investigations they are carried out in the same place by teams they have known for years. In our centre there is good evidence that the existing set-up works.

We believe the changes NHS England proposes either exacerbate or fail to address these two issues, the real challenges faced by CHD services. The current approach could be justified when dealing with a service in trouble, one that is manifestly failing to meet the needs of its patients, but that is not the case for the CHD service. As NHS England colleagues will know and Knowles and Bull et al reported:

> **"Death rates attributable to CHDs have fallen dramatically with advances in Paediatric cardiac surgery and intensive care, largely due to decreased mortality in infants aged under 1 year. Initially, mortality in later childhood rose as infant deaths fell, suggesting death was delayed beyond infancy. Children born within the last 20 years experienced lower mortality throughout childhood……**

[2] See the letter from Alan Magee, Chair of SAC Paediatric Cardiology to Will Huxter, 10 11 2016.

….Crucially, the decline in CHD-related mortality in children and young adults born in the most recent decade shows no signs of stabilising….”[3]

In other words nationally and locally CHD services are continuing to improve from a point that already compares favourably with other parts of the world. As such despite the real problems around staff and transition, nationally ours is a success story and we therefore think that the NHS is consulting on a solution that is looking for a problem which no longer exists.

1.3 What the new CHD Review originally set out to do

Before considering the consultation questions in more detail we want to briefly reflect on what the Consultation Document on the Standards[4] said were the eight core aspirations:

1. *Disruption*
   NHS England noted that confidence in the service has been disrupted by many years of repeated reviewing. We agree, however how another review can be seen as the solution to this is something we do not understand.

   The major *avoidable* problem is disruption due to the threats to close centres. The threat of closure makes it harder to recruit staff; it destroys training; and it diverts the energies of those clinicians who have to explain, once more, why their service is a valuable asset to the NHS.

   One announcement from NHS England could resolve this overnight.

   Moreover the growth plan submitted by UHL on the 3rd of May 2017 is in part dependent on the removal of the uncertainty and disruption caused by the current process. Without this, the likelihood of the new referral pathways agreed by our network partners actually materialising is diminished. A responsible consultant needing to refer a patient for a lifetime of treatment, will struggle to establish new referral pathways to UHL with the current uncertainty - however much they agree the service should remain within the East Midlands.

2. *Fetal Medicine*
   NHS England rightly said that better detection rates in utero would improve outcomes – and that NICOR reports that only 35% were diagnosed in utero. We agree, but there is no reason to suppose that closing one of the most successful fetal medicine services in the country could improve things. The NICOR website tells us:

   “Overall antenatal detection rates continue to improve (Figure 1) although there are differences between countries and regions within the UK (Figure 2 and 3). Antenatal diagnosis rates are higher in the UK than in the US between 2006 and 2012, although the gap has narrowed in recent years (Figure 4).[5]”

[3] http://adc.bmj.com/content/97/10/*861Mortality with congenital heart defects in England and Wales, 1959–2009: exploring technological change through period and birth cohort analysis*
[4] Proposed Congenital Heart Disease Standards and Service Specifications 15 September 2014 Executive Summary
[5] https://nicor4.nicor.org.uk/CHD/an_paeds.nsf/vwContent/Antenatal%20Diagnosis?Opendocument

In other words, this is another area in which England does better than other countries and is continuing to improve. The London area is shown to have a better than 50% detection rate and East Midlands better than 35%, so both are better than the national average.

3. *More Consistency*

The third aim of the standards was to eliminate the variation in the way that different providers deliver services. However, since there has been no attempt to compare the outcomes achieved by different hospitals, it is impossible to differentiate patterns of delivery as either better or worse.

4. *Improving Outcomes*

NHS England's fourth aim was to "Maintain and Improve Outcomes". The review noted that the 30 day survival of 98.2% in 2012/2013[6] was "very good". We would contend therefore that in the context of steadily improving outcomes for all centres NHS England should recognise that there is more scope for making things worse than improving them if this process continues.

There is also a contradiction between the 'normal' approach to commissioning for outcomes (as set out in NHS England's *Commissioning Outcomes Framework: Engagement document)* and the approach being used in the CHD review:

> ***"Liberating the NHS"* set out a vision of an NHS that achieves health outcomes that are among the best in the world. To achieve this, it outlined two major shifts:**
>
> **• a move away from centrally driven process targets which get in the way of patient care; and**
> **• a relentless focus on delivering the outcomes that matter most to people.**
>
> **The purpose of the reforms is to put patients at the heart of everything the NHS does. Patients will have more choice and control, helped by easy access to the information they need about local health services. Success will be measured, not through process targets, but against results that matter to patients – such as improving cancer and stroke survival rates and patient experience of NHS care**.[7]"

The document then says:

> **"All the indicators in the Commissioning Outcomes Framework will measure progress in improving outcomes. Some indicators will measure outcomes directly, such as morbidity or mortality, patient reported outcome measures and patient reported experience measures. Other outcomes, however, may not be sufficiently attributable to the influence of CCGs as commissioners, for instance because of size of population, or there may be long time-lags before the outcomes are achieved. The Framework will also, therefore, need to include some proxy indicators of outcomes that are nonetheless good predictors of improvement. These could be 'intermediate' outcome indicators or healthcare processes that are shown to have a strong link to outcomes. "**

The discrepancy between the approach set out above and what is actually being done in this review is puzzling.

5. *Patient–Centred Care*

[6] In fact he NICOR Database shows that figure has been revised. In 2012/2013 the survival rate for the 10,407 procedures was 98%, however the improvement has been continued and in 2015/16 98.% of the 12,327 total procedures.
[7] https://www.england.nhs.uk/wp-content/uploads/2011/11/COF-final1.pdf

NHS England's fifth assertion does support the proposals. They said:

> **"We have been told that sometimes it can take too long to get the help of other teams, and that sometimes the different teams of doctors do not work closely together."**

And this is something of which all current centres will be mindful.

6. *ACHD*

The standards consultation document then said that ACHD services were problematic. However, patient transition to ACHD services was not mentioned in the Executive Summary at all. Nowhere in the body of the report is it acknowledged that this is an area where patients are badly served.[8] ACHD services at UHL have not, so far as we are aware, been criticised, and we believe our transition is second to none.

7. *Other Services*

The next proposition was that Quality of Care is not just about surgical skills. We agreed, (The Phase of Care Mortality Analysis (POCMA) data suggests that more patients may die as a result of events in ITU or pre-operative administrative delays than as a result of avoidable events in theatre) and we recognise that survival now depends not just on the skills of the surgeon, but on the whole MDT and the ability to get the patient to the hospital quickly when necessary. However, the document elided over that aspect and instead chose to concentrate on communication – Patient Liaison Nurses and Psychologists. We do acknowledge the importance of these people but we question these words:

> **"Our proposals will make sure there are enough specialist nurses to provide support for patients of all ages."**

This raises the question how will the NHS improve the supply of specialist nurses by closing the centres where they work? Most will be lost to the service through retirement or a choice to do other types of nursing. Even if the NHS thinks it can mitigate the damage in some way that we have not foreseen, the proposal to close Leicester will, of itself, reduce the supply of specialist nurses.

8. *Costs*

Finally, NHS England suggested that it could deal with the cost of the resources needed to build new hospital facilities because:

> "**Our analysis shows that if recent trends continue we can expect that activity will increase whether or not new standards are introduced. So spending on these services by commissioners can be expected to increase. Our assessment of the financial impact of introducing the standards indicates that the higher costs of providing the service to the new standards will be met from the additional funding hospitals will receive as activity levels increase."**

In our view that proposition is flawed.

1 The individual trusts may earn more tariff payments, but out of those payments they will have to meet the cost of treating more patients;

[8] See Page 40-41 Consultation document

2 Before they treat those patients they will have to pay off the interest and the capital on the facilities into which they have had to invest, so there will in fact be less money per patient for many years to come;

3 Either NHS England will find some way of compensating this trust for losses or they will expect us to make cuts in the amount available to treat other sick patients.

Against that introductory assessment we will now examine some specific aspects of NHS England's proposals, we will explain more clearly the strength of what is being achieved here in Leicester and the harm that will be done by the de-commissioning of our service.

2 The case for Flexibility

2.1 Virtues of Scale

We recognise that large centres have some advantages, especially when called upon to perform rare procedures. However, the extent and nature of this advantage is obscure. The original American review by Welke et al looked at the results of thousands of cases treated in hundreds of centres over decades and concluded that in terms of mortality, unit volume was "little better than a coin-flip."[9] Other studies have found some advantages, but either only when comparing some much smaller hospitals that still exist in America, or some very unusual complex procedures that are frequently referred to the most experienced surgeons in this country.

The team from University of Sheffield were asked to conduct a review of the substantial world literature that has since accumulated on the subject, and we think it is material that when NHS England stated that their findings supported the 125 standard they were sharply corrected by the authors[10].

The more important point is that all mainstream English NHS centres are now either large or very large by international standards. The original Kennedy Report into Bristol said that there should be at least two surgeons, each doing at least 50 operations per year. The Monro report in 2003 concluded that centres should all aim for 300 cases per year and noted the EACTS proposal that each centre should manage 250 cases. They disapproved of occasional practice, but noted that there was no evidence of this in the English service.

Since then nationally the total number of procedures has doubled, and two centres have closed, so the average case volume has increased.

	Centres	Operations	Average
2001/02	13	3,382	260
2015/16	11	4,649	422[11]

The American studies seeking to find some advantage in scale have mostly defined a large centre as one doing 300 cases a year so that all our centres are either large or very large. In short, whilst large centres have advantages and complex or rare procedures should be referred to senior surgeons with experience of them wherever they work,

[9] Current Assessment of Mortality Rates in Congenital Cardiac Surgery ; K F Welke. M D Opens et al ; The Annals of Thoracic Surgery. Vol 82, 1 2006 164-171

[10] Turner J, Preston L, Booth A et al, What evidence is there for a relationship between organisational features and patient outcomes in congenital heart disease services? A rapid review, School for Health and Related Research (ScHARR), University of Sheffield, 2014

[11] NICOR. The totals have been adjusted, because NICOR include cases from Scotland Wales and Ireland, as well as cases that are dealt with locally, either because the emergency is too extreme or the procedures are too minor. They also include cases at Manchester which has since stopped and private cases done at the Harley Street Clinic.

this is not a valid reason for closing centres that can demonstrate outcomes that are good by international standards.

2.3 The Benefits of Flexibility

NHS England appears to approve of this approach because there is a clear intention to retain commissioning of Newcastle upon Tyne Hospitals NHS Foundation Trust, despite the centre not meeting two of the key standards relating to a) the ability to reach the required caseload by 2021 and b) co-location. We support this.

It is said that the derogation is time limited but there is no indication of the time period that has been provided for Newcastle to meet the standards despite the fact it is requiring all other centres to meet the published time periods. It is plain that the geographic location and population of Newcastle will make it impossible for them ever to meet the 500 caseload standard without a significant shift in referral to them from other areas much further away. Not only is their population modest, it is not growing very fast, (unlike that in the East Midlands which has one of the fastest growing populations in the country.) The comparison with Newcastle is instructive for a number of reasons:

1. *Transplants*
   The justification given for maintaining the centre is that they manage 15 paediatric transplants a year. The more cogent justification is not the operations, but the ability to manage the prolonged bridge to transplant medical service: it would be harder to recruit the skilled nursing staffs that are needed to supply this service – if it could be done it would take time when these nurses are in very short supply as we have emphasised above.

2. *ECMO*
   The comparison between the Newcastle transplant service and the Leicester ECMO service is in this respect telling: not only does their transplant, like our ECMO, create a USP, a single major justification for keeping the service open, it also means that both Newcastle and Leicester should be recognised as centres that should not be measured simply on the basis of the number of operations performed per year. Because of transplant there and ECMO here, our PICUs handle a larger volume of cardiac work than would be expected from centres that only support the same number of CHD operations per annum.
   We do not want to labour points about ECMO that we have previously made to NHS England colleagues, but we will remind them that Leicester handles:
   - About 50% of the ECMO in England – twice any other centre.
   - Our results are materially better than any other centre – so this *really is* an area where there is evidence that experience and scale makes a difference.
   - We are the only centre performing neonatal diaphragmatic hernia repairs on babies on ECMO , this improves the prognosis for these patients who otherwise have to have their surgery delayed until they can come off ECMO, this type of service takes years to develop the staff experience and expertise across the MDT to manage this particular patient group successfully
   - We provide the only mobile ECMO service in the country, so that we are regularly asked to transport patients from one of our colleague hospitals to another.
   - It is wrong to suppose that this is because NHS England has chosen to commission this mobile service from us. Our ECMO service and the mobile ECMO vehicle were both built

on charitable funds long before any commissioning tariff was provided. There is still no commissioning tariff or uplift for provision of Mobile ECMO

One of the problems that NHS England has not resolved is how it would handle the ECMO work if we closed our service and how it would avoid the potential poorer outcomes if the service were transferred to centres that have less experience and lower volumes. If the main proposal can be criticised for the lack of support in the form of outcome evidence, this aspect is commissioning directly against the evidence that is available and has previously been provided to NHS England.

ECMO is also important to NHS England's decision because we now understand[12] that only 19% of mortality associated with cardiac surgery is caused by events in the operating theatre, and less than half of that is avoidable. This is the POCMA work which was done at the University of Michigan looking first at adult surgery, (but the same issues are involved in paediatrics). Events in the ITU are responsible for many more deaths; pre-operative delays and other administrative issues are responsible for more than the avoidable deaths arising from events in theatre. This shows two things:

1 There should be far more emphasis on the scale of cardiac work in PICU in judging the size of a unit. A big unit is not only one doing a lot of operations, it is also one where there is a large stable team handling many cases in PICU; and
2 The exclusive focus on the number of operations as a yardstick of size also indicts the process as being rooted in the past, in the era before we had specialist intensivists when these issues were managed by surgeons. That is another change that has transformed the specialty since Bristol. We now know that whilst surgeons may be the most important member of the team on the day of surgery, the patient's success depends on a long term process of care involving a large team of professionals, easy to dismantle but very hard to select and train.

3. NHS England is right to discount the fact that Newcastle can never meet the colocation standards. The Newcastle service was deliberately set up as it is, in a modern centre with paediatric CHD surgery being supplied at The Freeman Hospital alongside other cardiac sciences and away from other children's services at the RVI. As far as we can see NHS England has decided to accept the Newcastle pattern of colocation indefinitely. Obviously it does not concern us directly since NHS England has accepted our colocation arrangements, but it does emphasise the importance of an equitable approach to flexibility in all centres.

4. The third reason to continue commissioning services from Newcastle, a centre that will probably never meet the numerical or colocation standards, is the simplest and most compelling: they are good at what they do and deliver a fine service as measured by the statistics and in the eyes of the profession and their patients. In short, we say that everything that applies to Newcastle applies to Leicester as well.

3 **Leicester can meet all the standards**

[12] Phases of Care Mortality Analysis

3.1 NHS England's current position, (i.e. without us being sighted to the view of our growth plan) is that UHL does not meet standard 2.1 and is unlikely to do so in the timescales expected. On 14th November 2016 NHS England wrote to the Trust and stated that;

> **Standard 2.1 requires a team of at least 3 cardiac surgeons, each of whom must have been the primary operator in a minimum of 125 congenital heart operations per annum as at April 2016, averaged over the previous 3 years (and therefore averaged over that period a minimum of 375 cases per year for the team of surgeons as a whole is required).**

3.2 The actual wording in the standards document states 'averaged over 3 years' not, 'averaged over *the previous* 3 years'. So, not only has the standard been applied for a purpose for which it was never designed, (the closure of centres) it has also been re-written or misinterpreted. As such we would suggest that this standard has never been endorsed by the committee NHS England assembled to formulate it.

3.3 It is the interpretation of the clinicians and stakeholders from UHL who contributed to the standards and others in the CHD profession, that the timescales for the implementation would be measured from the date of approval of the standards by NHS England. At no time was it suggested that any of the standards would be interpreted or applied retrospectively. The introduction of an 'immediate' timeframe by NHS England (not the standards committee) therefore was interpreted as being measured from April 2016 onwards; meaning there would be three years to meet some standards and five years for others.

3.4 In both the Leicester consultation meetings NHS England clearly stated that the only standard that UHL currently does not meet is 2.1 with a requirement to deliver a surgical caseload of 500 cases from 4 surgeons by 2020/21. At both meetings it was stated by NHS England that if they had sight of a robust growth plan from UHL they would be able to assure the NHS England Board that UHL met all the required standards for continued commissioning.

3.5 We have taken what was said at face value and have submitted a revised growth plan to NHS England on the 3rd May 2017. This 41 page document uses NHS England's catchment area for us and the population growth predictions as described in the consultation documentation to demonstrate that UHL will meet the requirement for three surgeons delivering 375 surgical cases averaged over the last three years by 2018/19, and will be able to meet the 2020/21 requirement of four surgeons delivering 500 surgical cases. The plan has received written support from all the network hospitals that would need to increase referrals to UHL for the plan to be viable.

3.6 The level of detail in this growth plan clearly demonstrates its validity; it does not require another centre to close in order to reach the numbers and without sight of the growth plans from Bristol, Southampton, or Newcastle to make a comparison in respect of detail, UHL cannot imagine that it would be deemed unacceptable. We are not asking NHS England to force patients to go where they do not want to – but would ask for recognition that the current proposals will force over 350 surgical patients to go out of the East Midlands for their care.

Summary:

For the reasons set out over the previous few pages and in the context of the contradictory evidence on such issues as case volume and the inconsistency around equity of approach, we do not support the proposals of the new CHD

Review. However, we recognise that we are required to respond to the specific consultation questions and these responses can be found below.

4. **Three hospital trusts have been assessed as not able to fully meet the standards within set timeframes. NHS England therefore proposes that surgical (level 1) services are no longer commissioned from: Central Manchester University Hospitals NHS Foundation Trust (adult service) Royal Brompton & Harefield NHS Foundation Trust (services for adults and children); and University Hospitals of Leicester NHS Trust (services for adults and children).**

   Can you think of any viable actions that could be taken to support one or more of the trusts to meet the standards within the set timeframes?

   As we have already said, we do not accept the premise of this statement: we say that if the standards are interpreted as intended by the authors we would be found to be compliant. We will not comment on the proposals relating to Manchester. Otherwise our comments are as follows:

   4.1 EMCHC's growth plan is robust and supported by other hospitals in the region. We recognise this will require relationships to be developed further building on the excellent support already received. This will take time but it will resolve the issue of numbers because the population is here and it is expanding.

   4.2 We would ask for NHS England's support during the development of these relationships, thus reducing the need for thousands of patients in the East Midlands to be denied care close to home and the choice of being treated at UHL, thus saving NHS England 25% of the higher tariff it is paying to centres in London

   4.3 We would ask that NHS England acknowledge the fact that EMCHC is the fastest growing centre in the country and accept the growth plan.

   4.4 We would ask NHS England to fully understand our growth plan and help implement standard B5 L1 which encourages Network referral to sustain the viability of Level 1 centres in a Network.

   4.5 We would ask NHS England to apply the same degree of intelligent flexibility to UHL as has been applied to Newcastle.

   4.6 We would ask NHS England to remove the cloud of uncertainty from UHL, enabling us to continue to build the expertise of our team.

Central Manchester University Hospitals NHS Foundation Trust and University Hospitals of Leicester NHS Trust

If Central Manchester and Leicester no longer provide surgical (level 1) services, NHS England will seek to commission specialist medical services (level 2) from them, as long as the hospitals meet the standards for a level 2 service. To what extent do you support or oppose this proposal?

Neither support nor oppose

We do not comment on the proposal regarding Manchester.

The East Midlands region is one of the largest geographical regions in the UK. Establishing EMCHC as a Level 2 centre with no Level 1 centre within the region will require every patient to go out of the region for level 1 care. This is likely to be delivered from one of four other Level 1 centres, providing significant complexity and uncertainty of referral and challenges in respect of continuity of care. There is no evidence that a referral model involving four different Level 1 centres does not pose significant problems for those in primary and secondary care who have to work with each of them in respect of small numbers of patients.

In the consultation document NHS England describes how Oxford has successfully moved from a Level 1 centre to become a Level 2 centre. The inference is that Oxford and Leicester are comparable. They are not. Oxford was only performing around 100 surgical cases per year at the time it closed, with real safety and outcome concerns, of which there are none at EMCHC. This was therefore a significantly smaller team to relocate compared to that from a centre delivering 350 surgical cases a year, >400 catheter cases and by far the largest volume of ECMO in the country. In addition there are the associated other inpatient procedures for patients from a much wider geography.

Leicester stands by its predictions that, if the proposals are enacted, for paediatric patients, no inpatient work requiring paediatric cardiac anaesthesia will be possible; this precludes all catheter procedures (diagnostic, intervention and electrophysiology procedures, all non-cardiac surgery on cardiac patients and much imaging). Most of the inpatient work that could be undertaken would be little different from that undertaken in level 3 centres. It is possible that limited diagnostic and minor interventional procedures on adults could be undertaken, but nonetheless most specialist work would need to be re-provided elsewhere. All paediatric ECMO would move elsewhere. This activity totals almost 1,000 admissions each year. We believe the only service realistically able to be offered in a Level 2 centre is outpatient clinics. Since <1/4 of the East Midlands patients actually live in Leicester, Leicestershire and Rutland, (LLR) , it is not clear why patients from the wider region would be better coming to Leicester for these than being seen in their own level 3 centres. In the long term we will not be able to retain a workforce of outstanding cardiologists if they are not able to do complex interventions. Why should patients go to a centre that lacks such doctors, knowing that they will have to be referred when they need an intervention? It may make sense for a small number of patients from the East Coast, but not for those for example from Nottingham.

The Independent Reconfiguration Panel's recommendations following the failed Safe and Sustainable review stated that ;' *For the current service and any proposed options for change, the function, form, activities and location of specialist surgical centres, children's cardiology centres, district children's cardiology services, outreach clinics and retrieval services must be modelled and affordability retested*.' The consultation documentation does not provide any detail of how the Level 2 model will be implemented; and there is no indication of affordability or viability from a workforce perspective should this proposal be implemented.

Royal Brompton and Harefield NHS Foundation Trust

5. **The Royal Brompton could meet the standards for providing surgical (level 1) services for adults by working in partnership with another hospital that provides surgical (level 1) services for children. As an alternative to decommissioning the adult services, NHS England would like to support this way of working.**

To what extent do you support or oppose the proposal that the Royal Brompton provide an adult only (level 1) service?

Neither support nor oppose

Newcastle upon Tyne Hospitals NHS Foundation Trust

6. **NHS England is proposing to continue to commission surgical (Level 1) services from Newcastle upon Tyne Hospitals NHS Foundation Trust, whilst working with them to deliver the standards within a different timeframe. To what extent do you support or oppose this proposal?**

Strongly Support

Meeting the standards - the geographic location and historical growth information for Newcastle makes it impossible for them to meet the 500 caseload standard without significant shift in referral to them from other centres. NHS England has made it very clear that it will not influence referral pathways and as such should not support this assumption. Thus the continuation of commissioning from Newcastle is inconsistent with the decision to close Leicester.

As we have said, Newcastle is also extremely unlikely to be able to meet the co-location standard. The risk associated with closing a centre that delivers 12-15 Transplant cases a year is being cited as why Newcastle are being treated differently. In the consultation documentation there has been no clear indication of the real risk of implementing the proposals which will see over 350 surgical cases, >400 interventional cases, all associated inpatient spells, 65 ECMO cases, 12 PICU beds and hundreds of outpatient appointments from the East Midlands being re-provided across **four** other level 1 centres.

Inconsistency of approach;- Irrespective of the rationale for this deviation of approach based on the transplant services offered by Newcastle, it means that NHS England is prepared to commission against the standards, and doing so (by NHS England's own interpretation of the standards,) will constitute a sub optimal service against the standards expectations. It is therefore inconsistent, not to apply the same degree of flexibility to UHL and show the same respect for the internationally renowned ECMO services and mobile ECMO provided by UHL.

UHL's growth plan clearly demonstrates that even in the worst case scenario, without the anticipated network development UHL will meet the 500 caseload standard with four surgeons **within one year** of the timescale required. The 'risk', (if indeed risk exists), associated with a timescale derogation of one year (which may not be needed due to the fact **every** network hospital has supported the growth plan) is far less than the risk associated with implementation of NHS England's proposals. Letters of support from the network hospitals are attached.[13]

[13] Appendix 1

Financial year	Growth based on 2014-16 activity	Continued 2014-16 growth + population increase + network expansion
2016-17	345	345
2017-18	375	381
2018-19	403	419
2019-20	435	459
2020-21	471	515
2021-22	509	546

UHL provides the vast majority of mobile ECMO, and ECMO training in the UK. There appears to have been no regard shown for the respiratory ECMO caseload. Caseload has featured as the key standard in the CHD review.

NHS England's assumptions are that the current caseload for ECMO delivered by UHL can easily and safely be delivered by the remaining 10 level 1 centres, reducing the number each centre will deliver each year in comparison to the numbers performed by UHL, despite the fact none of these centres currently provide any mobile ECMO at all. This is in direct contrast to NHS England's own quote from Mr Martin Kostolony highlighted on page 12 of the consultation document and again shows an inconsistency of approach.

"From my perspective there are three main clinical advantages for having high volume congenital cardiac surgical centres. Firstly, as an individual surgeon the more I do the better I become. There's lots of evidence for this in other surgical specialties, in particular showing that high volume centres reduce the number of post-operative complications and improving long-term quality of life. This also works for the whole team providing the care: the more the team does, the better they become, and this gives a huge opportunity for people to learn from each other in a large multidisciplinary setting. And finally, higher surgical volumes enable specialisation in areas such as neonatal, congenital and device treatments. Importantly, these are all important for the next generation of surgeons coming up through the system - they will be less experienced when they become consultants than in the past - and they will need to fit into a large team to nurture them into becoming the surgeons of the future."

Mr Martin Kostolony - Head of Clinical Service - Cardiothoracic Surgery, Great Ormond Street Hospital for Children NHS Foundation Trust

Travel

It is accepted that some patients will have to travel further for the most specialised care including surgery if the proposals to cease to commission surgical (level 1) services from Central Manchester University Hospitals NHS Foundation Trust (adult service); Royal Brompton & Harefield NHS Foundation Trust (services for adults and children); and University Hospitals of Leicester NHS Trust (services for adults and children) are implemented.

7. Do you think our assessment of the impact of our proposals on patient travel is accurate?

No

8. What more might be done to avoid, reduce or compensate for longer journeys where these occur?

UHL seriously questions the validity and credibility of any analysis that suggests that children who currently come to UHL for treatment will have a journey time increase of 14 minutes, whilst adults from the same region currently travelling to UHL will have an increase of 32 minutes.

At the launch of the consultation we requested the raw data to enable us to analyse how the figures have been derived and have not as yet been provided with this. This was also requested at the public consultation meeting on March 9th 2017. It has not been provided.

In the public consultation meeting on the 9th March 2017, NHS England stated that the travel time analysis was for ambulance times, although the consultation documents stated car travel. Travelling by ambulance with the ability to apply sirens and lights is not the same as normal travel times by car. Families do not travel by ambulance. Significant numbers of our patients rely on public transport and have no cars of their own. Rural accessibility to public transport is seriously limited, especially for patients who live on the far east of our region along the Lincolnshire coast. Patients from the east coast of Lincolnshire who rely on public transport and have an appointment in the morning in Birmingham would need to leave the night before. We seriously challenge that the proposals will only add this amount of time onto their journeys. Since the majority of our patients live on the opposite side of Leicester from Birmingham, these figures have to be incorrect

We accept that parents will drive to the moon and back if it would benefit their child, but we do not think they should be compelled to. We would therefore ask:

- What benefits to the patients of East Midlands are being delivered by these proposals?
- Have those benefits been analysed against the risks associated with longer emergency travel times, less family support, mental health issues, increased family costs, and possible increased NHS costs?
- Have the additional transport requirements been calculated in respect to the EMAS ambulance service transporting patients back to the Level 2 centre post operatively?

Equalities and health inequalities

We want to make sure we understand how different people will be affected by our proposals so that CHD services are appropriate and accessible to all and meet different people's needs.

9. In our report, we have assessed the equality and health inequality impacts of these proposals. Do you think our assessment is accurate?

No

10. Please describe any other equality or health inequality impacts which you think we should consider, and what more might be done to avoid, reduce or compensate for the impacts we have identified and any others?

Congenital Heart Disease is a life-long condition, and our patients have to visit hospital regularly throughout their lives, this is not a one off inconvenience. Whole families will be affected by the proposals. Support from family is crucial, especially when the patient has siblings who are fit and well and in main stream education. Increasing the separation through journey time and distance will impact the ability of whole family support.

It also matters to the parents of children who need surgery. It is a time of enormous physical and psychological stress to the families as well as these patients but it is essential that we support them and protect the family dynamic. The parents may well have other calls on their time, having jobs to maintain and other children to support and care for at the same time as they are trying to be with the patient in their days of maximal need. Those who are cared for at EMCHC not only have the advantages of proximity, meaning shorter journeys home, they also benefit from our family accommodation that has been paid for by our charity and recently been refurbished. The availability of readily available on-site car parking gives them enormous advantages. Practical access means much more than just proximity. The East Midlands and Leicester have a unique population which UHL is uniquely able to serve having grown around them. This is not transferable or reproducible and has not been considered.

Congenital Heart Disease patients have a higher propensity for learning difficulties, Downs and other syndromes and complex needs. Consistency and familiarity of care are crucial for these patients to have a positive outcome and experience. The proposals will introduce significant change and additional steps in the treatment pathway of these patients, and will increase the risk of confusion, stress and less favourable outcomes.

The role of the Cardiac Liaison Nurse is crucial in support of CHD patients and their families. Often this support is provided at the patient's home or school, with advice being offered to extended family, carers and teaching staff as to the care, management and capabilities of the patient. With the limited resource levels in the NHS it is extremely unlikely that the reach of the Cardiac Liaison Nurse based in Level 1 centres out of the East Midlands region, will extend to provide such a vital support to our CHD patients and families.

Other impacts

11. We want to make sure that the proposed changes, if they are implemented, happen as smoothly as possible for patients and their families/carers so it is important that we understand other impacts of our proposals.

Do you think our description of the other known impacts is accurate?

No

12. Please describe any other impacts which you think we should consider, and what more might be done to avoid, reduce or compensate for the impacts we have identified and any others?

13.1 Risk;

The consultation documents do not provide any detailed risk assessments for implementation of the proposals. Despite impact assessments clearly raising significant concerns regarding

- lack of the necessary capital funding for receiving centres to accept the additional capacity,
- transition to adult care
- availability of specialist trained workforce,
- concern regarding the re-provision of PICU and ECMO capacity,
- the impact on training and development of crucial CHD staff,
- Issues concerning staff retention

NHS England states that detailed risk assessments will be done after the consultation process has finished. This precludes any proper consultation because consultees are unable to comment on the appreciation of the risks and dangers associated with the proposed changes. These should have been made available for consideration and debate.

Affordability:

NHS England say that its proposals are not about saving money – but fail to acknowledge that one way or another it is going to end up costing a lot more money. The replacement centres will have to divert resources on a significant scale to finance the replication of UHL capacity; it may well be that they will finance this out of their own borrowing, but this means that for years to come, every pound spent by commissioners on this service will be top-sliced to meet the interest and capital repayments required to finance their proposed expansion. This is particularly problematic given the unprecedented shortage of capital in the system. At best this will provide uncertainty and delay to other capital development plans.

In addition, with NHS England proposing to cease Level 1 commissioning at UHL, patients from the south of our region will continue to be offered existing out of area referral to London. In view of the present constraints on NHS resources, it is not reasonable to do this when the London tariff means that each of these cases is costing 25% more. This is not a good use of NHS money when high quality provision is available within the region at no additional tariff.

Clinical training;

Not only the UHL / East Midlands clinical training specialists, but national bodies such as the Paediatric Cardiology Specialist Advisory Committee believe the NHS England proposals will have serious effects on training within the East Midlands, affecting all people involved in paediatric services as well as congenital cardiac care. We believe that in the short term our current trainees (medical, surgical, nursing and associated professions staff) would have reduced clinical teaching, exposure and options. Medium term there would be a further reduction in the reputation of our training programmes and thus difficulties in recruiting. Finally, in the long term, as many of our staff come from our own training programmes there would be a reduction in the quality of paediatric care. Cardiac Surgery nationally already has significant staffing challenges: only 1 surgical trainee applied last year for the 3 training posts, even though the general CTS training course was over-subscribed 500%: this year there has been no applicant at all for CHD surgery. UHL currently provides around 15% of the UK's congenital cardiology medical training which would also be lost if the proposals go ahead; re-providing this training elsewhere will be extremely challenging.

Transition;

We have identified that one acknowledged weakness in CHD medicine, in Britain as elsewhere in the world, is transition from paediatric to adult CHD care. The consultation document makes reference to the need for a clear transition process but it fails to acknowledge that this is the one area that is regarded as a weakness in British CHD care. It is doubly unfortunate that the two centres with the best transition process, with services co located on the same site so that transition can be a seamless process using the same set of clinical notes and continuing to attend the same clinic so long as it suits the patient, are both at risk of decommissioning in the current proposals.

Workforce availability

It is wrong to assume that the specialist staff currently working at EMCHC will relocate to Birmingham. It is much more likely for nursing and associated professions that staff will either retire or assume other roles within

UHL. Medical and surgical staff may be more likely to move, but given that many of these skilled professionals are from overseas they may be lost to the UK speciality as a whole. The extent to which this loss to the CHD service as a whole is significant will obviously vary with the extent to which their skills are transferable to other areas of patient care; however the loss to the Paediatric Critical Care service can also be measured by the problems the other centres will face in recruiting new staff to fill these gaps and the posts generated by the increased demand. Currently across the UK most centres have beds that cannot be filled due to a shortage of specialist staff. Birmingham Children's Hospital state in their own impact assessment that the recruitment of the specialist staff needed to accommodate the additional surgical caseload from EMCHC would be 'challenging', and is likely to be at the detriment of either the CHD profession elsewhere, or to other speciality recruitment internally.

Paediatric Intensive Care Transport

The East Midlands Paediatric Transport Service (EMPTS) is responsible for the transport and repatriation of East Midlands children to and from level 3 critical care units, and the transport of patients requiring level 2 paediatric critical care. There are a number of patient pathways that will be affected by the implementation of the proposals to decommission cardiac surgery from the East Midlands Congenital Heart Centre:

- *East Midlands children presenting with a cardiac emergency or with an acute emergency of no obvious cause where a congenital cardiac disease needs to be excluded*

Currently these children present at their local hospital, are stabilised and transferred by EMPTS to the East Midlands Congenital Heart Centre where they receive definitive care. Following the decommissioning of services in the East Midlands, these patients would need to be transferred urgently to the nearest cardiac surgical centre with a bed. For families from the East Midlands, this would be Birmingham, Great Ormond Street Hospital, or Leeds. It is noted that even without the increased pressure of having to absorb UHL's cardiac work and ECMO, Birmingham Children's Hospital PICU is regularly full and unable to admit patients. So the likelihood is that children from the East Midlands will need to be transferred further. This will increase journey times for the child and their family, decrease transport team availability and increase patient morbidity and mortality (see below)

- *Children on PICU or HDU who require cardiac investigation in the level 1 centre (MRI, Catheter etc.)*

The proposals for children's cardiology centres mean that specialist diagnostic work (such as diagnostic catheters) will only be undertaken in the surgical centre, and therefore children will need to be transferred to the surgical centre for these investigations. Paediatric Critical Care Transport teams will need to pick up this additional work. As many of these will require the child to be transferred, have their investigation and return to the referring unit, this will place a considerable burden on transport services.

- *Repatriation of children from the level 1 centre following cardiac surgery*

The proposed model of care suggests that children from cardiac surgical centres are transferred nearer to home as soon as possible after surgery. Indeed, if surgical centres are to cope with the increased activity, this would be essential. These transports will either be from Level 3 Critical Care Unit to another Level 3 PCCU (i.e. Birmingham Children's Hospital to Leicester Children's Hospital), or to a Level 2 Critical Care Unit (i.e. Derby Children's Hospital) depending on acuity. This activity is not currently undertaken, and needs to be considered

- *Repatriation of children from the level 1 centre following a cardiac investigation or procedure.*

Most children admitted to the surgical centre for a cardiac procedure (such as a catheter procedure or pacemaker change) will recover and not need prolonged recovery in a paediatric critical care facility. But a small proportion will, and the proposed model of care suggests that they should be transferred to another PCCU nearer home. These transports will need to be undertaken by a PCC Transport team, and are currently neither necessary nor accounted for.

- *Children with cardiac disease requiring non-cardiac interventions.*

Children with cardiac disease will present with non-cardiac medical and surgical problems just like other children. In the same way as paediatric general surgical activity has declined in non-specialist centres following centralisation, so non-cardiac centres (in the absence of specialist paediatric cardiac anaesthesia) will become increasingly reluctant to intervene in children with cardiac disease, particularly complex congenital patients (for instance, the seven year old who has a Fontan circulation, and who now presents to his local hospital with acute appendicitis). These children, who may be acutely ill, will require transport to Cardiac surgical centres by a PCC Transport team, and are currently not accounted for.

Any other comments

13. Do you have any other comments about the proposals?

What problem are we trying to solve?

NHSE colleagues have said that without action the speciality will be left to be only 'adequate'. Since the events around Bristol in 1991 and the subsequent reviews, UK CHD service provision has been transformed and in fact should be seen as a major success story for NHS England; it is far from 'just adequate':

- National Mortality rates have gone from 14% to 2%
- The number of CHD centres has gone from 17 to 10
- Occasional practice has gone from 190 cases to 5 cases p.a.

'Data published today by the National Congenital Heart Disease Audit (NCHDA) shows survival for children undergoing cardiac procedures for congenital heart disease has continued to improve in recent years. In the 3 year period 2012 -2015, there were 75 fewer deaths than predicted, demonstrating the continuing rise in the quality of congenital cardiac surgery in the UK. Survival 30 days after heart surgery for children was also good or better than predicted in each of the paediatric centres providing care.'[14]

"Overall survival after congenital heart procedures continues to improve and remains as high as anywhere in the world."[15]

The NCHDA, now in its 16th year, is managed by NICOR and is the largest and most comprehensive national audit of its kind in the world. The audit collects data from all centres undertaking congenital cardiac surgery and interventional procedures in the UK (since 2000) and RoI (since 2012).

[14] Reference: HQIP (Healthcare Quality Improvement Partnership) Published: 04 Apr 2016 Congenital cardiac surgery continues to improve in the UK
[15] Reference: Dr Rodney Franklin, Clinical Lead for the NCHDA

NCHDA is commissioned by the Healthcare Quality Improvement Partnership as part of the National Clinical Audit Programme and clinically led by the British Congenital Cardiac Association and The Society for Cardiothoracic Surgery in Great Britain and Ireland.

'The value of the NCHDA, as a single trusted source of information upon activity and outcomes, is considerable.' [16]

International Comparison of results

British Congenital Cardiac Association and The Society for Cardiothoracic Surgery in Great Britain and Ireland as published in NICCOR (2015-2016) showed UK mortality rates for CHD as 2.1%. In the last 36 months UHL has had a mortality rate of 1% for paediatric CHD surgery

Japan as published in The Japan Congenital Cardiovascular Surgery Database April 2015: have a rate of 2.3%.

North America: The Society of Thoracic Surgeons Congenital Heart Disease database published September 2015 showed a rate of: 3.9%.

PICU capacity

UHL currently has two PIC Units, one at the Leicester Royal Infirmary and one at Glenfield Hospital. The consultation document suggests that the PICU at Glenfield is due to be closed anyway, when the service co-locates with the wider children's hospital in 2019. This is totally incorrect as the PICU facilities currently at Glenfield will be re-provided as part of the co-location project. The inclusion of this inaccuracy in the public consultation document underplays (we assume inadvertently) the associated risk.

UHL has a current PICU capacity of 21 beds (9 at the LRI, 12 at GH), of which 13 are commissioned (6 at the LRI, and 7 at GH); our current usage is averaging 10.9 beds (4.8 at the LRI and 6.1 at GH). Our mean length of stay since 2014 has reduced despite a national increase of PICU bed-days year on year. This efficiency comes despite the fact that UHL PICU has the second highest acuity in the country, with more than 70% of our ICU/ specialist care (20% of which is ECMO) constituted by ITU basic care or higher (and <30% of it HDU).

The risk to cardiac PICU capacity across the UK from these proposals is significant. Any decision to decommission cardiac surgery at UHL will also inevitably lead to the loss of the associated PICU capacity, at least in the short term, due to the loss of specialist staff needed. The current situation with PICU capacity means that even a short term reduction is untenable.

The residual PICU provision remaining (at the LRI) will be too small to retain high quality clinical staff in the longer term, and the recruitment of any quality replacements will be near impossible. UHL does not host any other major specialities requiring PICU and therefore the PICU would essentially become seasonal and hence its viability would be seriously challenged.

Regionally, UHL provides 70% of the PICU bed days in the East Midlands. This accounts for a total of 2,542 bed days a year of which 474 are for ECMO. Assuming 80% occupancy an additional 10.3 PICU beds would need to be re- provided elsewhere to cover the work currently done by the Glenfield PICU. This makes no allowance for the likely growth in demand which will occur irrespective of whether services persist in UHL or not.

Should the PICU at the LRI become unsustainable then 17.16 PICU beds would be required to be re-provided.

[16] (Bristol cardiac review Gray, Kennedy 2016)

Crucial information needed to inform the consultation

The review into ECMO and PICU services is a crucial aspect of this consultation and it is inappropriate that the detailed results of that review are not part of this consultation process. This was a recommendation from the previous Independent Reconfiguration Panel following the Safe and Sustainable review. It was also highlighted again to NHS England in a letter from UHL on the 5th December 2016 where we requested that;

The programme timescale:

- ensures the review [of PICU etc.]fully aligns with the proposed public consultation
- includes the ability for the findings to be reviewed as part of the CHD public consultation,
- Allows for its completion and full consultation before any final decisions are taken by NHS England.

None of these requests have been accepted and the output from these crucial elements of the CHD service will not be available for public review or scrutiny.

An interim report on the PICU and ECMO review has been published this June and we note the following in respect to this consultation response;

- The Review has set up a work-stream to consider ECMO but there is no separate work-stream for CHD patients – who dominate PICU bed days in Level 1 CHD centres
- The review is recommending a model that will allow children to be treated closer to home – this is in direct contrast to the CHD proposals which will force the entire CHD population of the East Midlands to travel out of the region.
- Within the review there is no reference to any changing need for provision of cardiac intensive care or ECMO should the CHD proposals be implemented. The rationale is that it is not possible to do this before a decision has been made but we strongly challenge that this precludes any appropriate scrutiny of the options during the consultation period and in fact what should be happening is that a number of different future scenarios should be being modelled and consulted upon.
- Main users of planned PICU beds are cardiovascular patients but significantly there were also over 6,000 unplanned cardiovascular admissions. This somewhat negates the assumption that cardiac emergencies are rare. These numbers also bear no resemblance to the numbers used by NHSE to ask 'receiving units' to model their growth needs
- The next steps clearly state they are awaiting the outcome of the CHD review to impact their findings – not the other way round. This is totally at odds with the IRP recommendations.

Specialist ECMO knowledge - The assumption is that there will be appropriately trained clinical and nursing staff available to deliver the same level of specialist care across all of the UK's units as is currently provided by UHL. This is severely challenged by the fact that the majority of ECMO provided by UHL is provided for children with catastrophic respiratory and cardiac failure not related to cardiac surgery, and in which other Level 1 centres have less expertise. Replicating this expertise will be at least as difficult as for transplant surgery – the key rationale for the derogation being applied to Newcastle.

Patient Choice

The reality of the NHS England proposals is that it will deprive the thousands of patients in the East Midlands who currently are treated at UHL, and are delighted with the quality of their care, of the right to choose to be

treated in the hospital of their choice, nearest their home. They feel passionately about this, and this is indicated by the scale and proportion of responses to the consultation proposals from the East Midlands.

Transparency

UHL has requested on numerous occasions that the raw data used by NHS England to model its proposals and impact should be shared so that we are able to conduct our own modelling and analysis. This has not been released despite it also being requested at the public consultation meeting. Publication of all the growth plans for those Level 1 centres not yet achieving 500 surgical cases per year has also been requested and not received.

Inappropriate Data

The data used to model the impact for both those Level 1 centres potentially at risk, and those potentially gaining from the proposals, is 4 years out of date and therefore currently inaccurate or misleading. For example: units were asked only to comment on their ability to accommodate a small proportion of our activity; Birmingham Children's Hospital was asked about accommodating 180 paediatric surgical procedures as 80% of UHL's surgical activity. Even allowing for this only to be 80% of our paediatric surgical activity this is incorrect.... 80% of the 276 paediatric surgeries carried out in the last year would be 221. Numbers of cardiac interventions estimated to require re-provision is not quoted but it is clear it does not include **any** diagnostic catheters and indeed we understand NHS England has worked on the assumption that these will continue to be provided at EMCHC.

EMCHC total catheter numbers for 2016-7 were 364 (198 Paediatric, 166 ACHD). ACHD re-provision at QEH is similarly underestimated. No numbers have been presented for example to account for non-surgical / interventional ICU or indeed ward stays, nor ECMO activity. This accounts for >1000 inpatient episodes a year; this cannot be left unaccounted for. This is also highlighted by the number of PICU bed days across the UK (>6000) for unplanned cardiac activity

This will have significant impact on the validity of the level 1 centres designated to adequately re-provide the necessary surgical and associated services to meet the demand.

Risk of instability during transition

Should the decision be made to confirm the CHD consultation proposals there will need to be a period of transition to allow those centres destined to receive the additional volumes to make the necessary capital and organisational changes to accommodate the increased activity. There is an assumption that during this transition period, those centres affected by the decision to cease commissioning will continue to work and deliver activity as they currently do. There is a significant risk that as soon as a decision to cease commissioning is made there will be unsustainable pressure on the service with key staff choosing to leave. This situation is clearly illustrated by the experience in Manchester, where just the risk of decommissioning has resulted in the service becoming unsustainable. The impact of a similar scenario happening at UHL would be extremely serious with much higher numbers of patients being affected and needing immediate alternative provision, with receiving centres manifestly not ready to accommodate the additional demand.

Independent Reconfiguration Panel (IRP) recommendations

The IRP report was published on 30th April 2013 and the Secretary of State for Health accepted the recommendation to disregard the conclusions of Safe and Sustainable.

The IRP made 15 recommendations to the Secretary of State "to enable sustainable improvements for these services and learning for future national commissioning of health services".

The New Congenital Cardiac Review has not demonstrated compliance with the following IRP recommendations;

- *"Before further considering options for change, the detailed work on the clinical model and associated service standards for the **whole pathway of care** must be completed to demonstrate the benefits for patients and how services will be delivered across each network"*
  Non-compliant: Benefits for patients have not been demonstrated. Delivery of care across new networks resulting from closure of Glenfield has not been described (or conceived).

- *"For the current service and any proposed options for change, the function, form, activities and location of specialist surgical centres, children's cardiology centres, district children's cardiology services, outreach clinics and retrieval services **must be modelled and affordability retested".***
  Non-compliant: Options for change have not been modelled and there has been no reckoning of affordability. NHSE has stated that no money will be made available for the infrastructure change necessitated by their decision

- *"Further capacity analysis, including for paediatric intensive care units, should consider recent and predicted increases in activity, and patient flows".*
  Non-compliant: The PICU review running alongside the Cardiac review – is not factoring in the impact of the CHD review

- *"NHS England should reflect on the criticisms of the JCPCT's assessment of quality and learn the lessons to avoid similar situations in its future commissioning of specialist services*".
  Non-compliant: There appears to be no documentary evidence that NHS England has reflected on the failures of S&S. No measures of clinical quality, as generally accepted by the profession, have been used in the decision making process.

- *"More detailed and accurate models of how patients will use services under options for change are required to inform a robust assessment of accessibility and the health impact of options so that potential mitigation can be properly considered".*
  Non-compliant: No modelling or calculations regarding changes to accessibility and health impact as a result of the proposals have been undertaken to our knowledge. This is of particular importance with respect to the decision to decommission EMCHC as there is no alternative provider in the region. The other proposed commissioning changes would not have the equivalent adverse impact.

- *"Decisions about the future of cardiothoracic transplant and respiratory ECMO should be contingent on the final proposals for congenital heart services".*
  Partially compliant: The national review of ECMO services has been accelerated. No details from this have been available for full and public consultation. The proposals do include the decision to continue to commission cardiothoracic transplant services in Newcastle.
- *"NHS England should develop a strategic framework for commissioning that reflects both the complex interdependencies between specialised services provision and population needs".*
  Non-compliant: No such model has been presented. There appears to have been a failure to consider the expected above average population growth in the East Midlands or the impact of these changes on wider specialised paediatric services in the East Midlands.

- *"NHS England should use the lessons from this review and create with its partners a more resource and time effective process for achieving genuine involvement and engagement in its commissioning of specialist services".*

Non-compliant: At the initiation of the New Review, NHS England stated that they wanted to come to a conclusion by June 2014. We still face public consultation followed by a further period of decision making and possible challenge. To date, the process has occupied the congenital heart disease profession for over four years.

University Hospitals of Leicester NHS Trust

Caring at its best

Appendix 1

Chesterfield Royal Hospital NHS
NHS Foundation Trust

Calow
Chesterfield
S44 5BL

Tel: 01246 277271
Minicom: 01246 512611
www.chesterfieldroyal.nhs.uk

Chief Executive's Office
Telephone: 01246 513161
e-mail: simonmorritt@nhs.net

25 April 2017

John Adler
Chief Executive
University Hospitals of Leicester NHS Trust
Infirmary Square
Leicester
LR1 5WW

Dear John

Re: Congenital Heart Services

It was good to catch up with you the other day and discuss the services provided by The East Midlands Congenital Heart Centre (EMCHC) to patients from the East Midlands, and in particular those under the care of the Chesterfield Royal Hospital NHS Foundation Trust .

Whilst we do currently work together and send some of our patients with Congenital Heart Disease (CHD) to EMCHC , the majority of our patients tend to be referred to Leeds General Infirmary (LGI) and we are very happy with the service we receive from this arrangement. However, we are also very happy with the service and outcomes of those patients we have sent to EMCHC, and agree with you that patients from our hospital should be offered the choice of receiving their care at LGI or at EMCHC.

I also feel it is very important that the East Midlands retains a centre of excellence for congenital cardiac services, and that the EMCHC ECMO service is retained . I would be happy to work with you to ensure that our elective CHD patients are provided with information to help them make an informed choice with their consultants regarding where they receive their treatment.

There will of course be occasions when it is preferable from a clinical or personal perspective for the referral to remain with LGI , and in particular for those children presenting as an emergency who require urgent transfer by the EMBRACE critical care transport service commissioned for North Derbyshire, and for whom we would wish to continue with a single emergency pathway but I agree with you that the outcomes, reputation and proximity of EMCHC will be very attractive, and should result in an increase in patients choosing to come to your centre.

My clinicians would be very happy to meet with your clinical team to discuss how we might work together in the future and hope this increased support will aid your proposals to meet the NHS England standards for CHD services in England and enable your excellent services to remain available to the people of the East Midlands and beyond.

Yours sincerely

Simon Morritt
Chief Executive

C.C. Gail Collins, Medical Director
Dr A Unnikrishnam, Divisional Director

Northampton General Hospital
NHS Trust

From the office of: **Dr Sonia Swart - Chief Executive**
Telephone: 01604 545868
Email address: sonia.swart@ngh.nhs.uk
Our Ref: SS/gjj

Cliftonville
Northampton
NN1 5BD
Switchboard: 01604 634700

18 April 2017

John Adler
Chief Executive
University Hospitals of Leicester NHS Trust
Leicester Royal Infirmary
Leicester
LE1 5WW

Via email only: john.adler@uhl-tr.nhs.uk

Dear John

I would like to thank you and your team for the helpful meetings we have had in recent weeks with regard to the services provided by The East Midlands Congenital Heart Centre (EMCHC). We understand the critical importance of this issue not only to your organisation but also to NHS partners across the East Midlands and the patients that we jointly serve.

You will be aware at the present time we have a close working relationship with Great Ormond Street Hospital (GOSH) who not only offer excellent clinical outcomes for patients requiring surgery for Congenital Heart Disease (CHD) but who have also developed a model that provides much of the care to patients locally.

As a hospital we set out to respect and value the views of our clinicians and would always ask them to focus on the needs of the patient. I am convinced that as the service currently stands, our patients are well served and there is no reason for us to alter this pathway until such time as an alternative centre meets all the current standards.

However, we also greatly value the strategic relationship that we have with University Hospitals of Leicester NHS Trust (UHL) and must consider the long term plans that would stabilise services for the population. We also feel it is very important that the East Midlands retains a centre of excellence for congenital cardiac services, and critical that the EMCHC ECMO service is retained.

Whilst we support the view of our clinical team it is our duty to explore options for the future. We will work with them to ask that patients are offered the choice of referral to GOSH or UHL in future to ensure that patient consultation is considered an equally important part of decision making as the view of the referring clinician. Whilst this may not alter referral pathways, I consider it an important step to support our local partners.

We also explored what it would take to move our pathways to UHL in the longer term. It was clear from the discussion that this could only be considered when all relevant standards were met. At the same time, we agreed to work alongside your teams to understand the journey to this point and to assist in any way we can. Whilst we are focussed on the needs of our patients in Northamptonshire we accept that EMCHC supports patients far beyond our county and recognise the importance of this issue regionally.

Lastly we may wish to consider whether closer clinical links for this service may bring benefits to us both, in terms of sustainability for Northamptonshire and support for UHL in terms of patient numbers. This would be a long term piece of work but it would be in the interests of our patients to develop a cohesive model of care that supports clincal excellence whilst respecting the relationship that we already have with GOSH.

I accept entirely that this is a very contentious issue. We wish to offer you our support for EMCHC whilst repecting the views of our clinicians. We greatly value the relationship we have with UHL and will work with your teams to assist wherever we can.

Yours sincerely

Dr Sonia Swart
Chief Executive
Northampton General Hospital NHS Trust

c.c.
Chris Pallot – Director of Strategy & Partnerships, NGH
Jon Currington – Head of Tertiary Partnerships, UHL
Mr Andrew Furlong – Medical Director, UHL
Dr Mike Cusack – Medical Director, NGH
Dr Nick Barnes – Consultant, NGH
Dr Aidan Bolger, Consultant Cardiologist & Head of Service, UHL

NHS
North West Anglia
NHS Foundation Trust

Peterborough City Hospital
Bretton Gate
Peterborough
PE3 9GZ

19 April 2017

Mr J Adler
Chief Executive
University Hospitals of Leicester NHS Trust
Infirmary Square
Leicester
LR1 5WW

Dear John

Congentital Heart Services

It was good to catch up with you recently to discuss the services provided by The East Midlands Congenital Heart Centre (EMCHC) to patients from the East Midlands, and inparticular those under the care of the Peterbrough and Stamford Hospitals NHS Foundation Trust .

Whilst we do currently work together and send some of our patients with Congenital Heart Disease (CHD) to EMCHC , the majority of our patients are seen by Great Ormond Street Hospital (GOSH) due to existing antenatal referral pathways for mothers needing fetal echocardiograms and we are very happy with the service we receive from this arrangement.

However, we are also very happy with the service and outcomes of those patients we have sent to EMCHC, and agree with you that all patients from our hospital should be offered the choice of receiving their care at GOSH or at EMCHC.

I also feel it is very important that the East Midlands retains a Centre of Excellence for Congenital Cardiac Services, and critical that the EMCHC ECMO service is retained (which was so vital for two of our small patients recently.) I would be happy to work with you to ensure that all our CHD patients are provided with the appropriate information to help them make an informed choice with their consultants regarding where they receive their treatment . There will of course be occasions when it is preferable from a clinical or personal perspective for the referral to remain with GOSH , but I agree with you that the outcomes , reputation and proximity of EMCHC will be very attractive, and should result in a significant increase in patients choosing to come to your centre.

In order to help ensure my clinicians are able to present the most appropriate advice may I suggest the following;

- Our clinical teams meet to agree guidelines, referral pathways and MDT arrangements as soon as possible

- You confirm what resource you are able to provide to attend fetal, paediatric and adult outpatients clinics
- My key clinicians / nurses visit EMCHC to see your facilities and strengthen the network relationships; especially around your support for families at every stage of the process from diagnosis to lifelong follow up

We would be delighted to be able to work more closely with you, and hope this increased support would aid your proposals to meet the NHS England standards for CHD services in England and enable your excellent services to remain available to the people of the East Midlands and beyond.

Yours sincerely

Stephen Graves
Chief Executive Officer

cc Dr David Woolf, Clinical Director – Family & Public Health
Dr Tim Jones, Assistant Clinical Director – Family & Public Health

Poole Alison - Senior Manager Special Projects

From: Nichani Sanjiv - Consultant Paediatrician
Sent: 14 April 2017 12:39
To: Poole Alison - Senior Manager Special Projects
Subject: FW: Cardiac clinics

From: DURAIRAJ, Saran (UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST) [mailto:saran.durairaj@nhs.net]
Sent: 18 February 2017 10:45
To: Bolger Aidan - Consultant Adult Congenital Heart Disease; King Charlotte - General Manager; Nichani Sanjiv - Consultant Paediatrician
Subject: Fwd: Cardiac clinics

Sent from my iPhone

Begin forwarded message:

> **From:** "PUTTHA, radhika (GEORGE ELIOT HOSPITAL NHS TRUST)" <radhika.puttha@nhs.net>
> **Date:** 17 February 2017 at 20:49:27 GMT
> **To:** "DURAIRAJ, Saran (UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST)" <saran.durairaj@nhs.net>
> **Subject: Cardiac clinics**
>
> Dear Saran
>
> could you please mail me some dates from April to July to set up Cardiology clinics please
> You might be aware that Afzal is moving to HEFT.
> I hope we would be able to recruit someone with cardiology interest soon as the adverts are going out for substantive posts soon.
> I would like to purchase our own ECHO machine and I wonder if you could help me with some details for the business case (Machine, specifications etc)
> Have you received any letter from our CD?
>
> We, at GEH appreciate your commitment to provide the services closer to home and patients have given very positive feedback about your clinics. Thank you very much for all the help.
> We have a new manager who just started this wed and I hope we can sort the cardiology clinics as high priority now
>
> Many thanks once again
>
> best wishes
>
> **Radhika**