University Hospitals of Leicester NHS
NHS Trust

Leicester Royal Infirmary
Leicester LE1 5WW

Tel: 0300 303 1573

Will Huxter
Director of Specialised Commissioning
London Region
Skipton House
80 London Road
London SE16LH

13th October 2016

Dear Will

Congenital Heart Disease Review

Thank you for your letter dated 27th September. I hope that the information below will provide the clarification requested.

1 As requested I include the slide deck used in the meeting and to which we referred in our discussions. (Appendix 1)

2 We support the desire of the NHS England Board to ensure the implementation of the standards for CHD services across the country, but refer to page 17 par 59 of the final standards report published July 2015 (https://www.england.nhs.uk/wp-content/uploads/2015/07/Item-4-CHD-Report.pdf) where it states (our emphasis):

> "*NHS England must reserve the right not to commission services from a provider that is* ***so significantly at variance from the standards as to cause safety/quality concerns****. Such a decision would only be taken following a* ***risk assessment of the costs and benefits*** *of both closure and non-closure"*

We therefore request clarification of the risk assessment exercise you propose to undertake to identify the costs and benefits of both closure and non-closure.

We emphasise that the services offered to patients in the East Midlands Congenital Heart Centre are of high quality and we see no reason why that would not continue. We request that NHS England clarify and quantify '***significantly at variance from the standards'*** and what warrants a ***'quality / safety concern'***. For example you have expressed concern that we undertook 198 catheter procedures rather than the 200 specified by the relevant standard, a variance of just 0.5%. I should emphasise that we are firmly on track to reach the standard for interventional catheters in the 2016-17 year. I attach clarification of this in Appendix 2.

3 Achieving 375 surgical cases

We are on track to meet the 375 surgical activity standard averaged over the next three years as the standard stipulates. We are continually striving to improve the efficiency of our working practice and improve the effectiveness of our network. We anticipate that we will undertake 375 cases this year although if we do not quite achieve this, the variance will be insignificant and will not impact quality or safety, which is a position in line with the relevant standard.

In your letter you state 'NHS England does not support the delivery of services under on-going derogation'. If this is NHS England's position we seek explanation as to why other CHD centres' plans for mitigation have been accepted and why other specialist commissioned services currently in the NHS are allowed derogations with acceptable action plans. We ask NHS England to demonstrate how and by whom the decision not to derogate in respect of CHD specialist commissioning was agreed?

4 You ask about our waiting lists and I am pleased to be able to say that our continuous efforts to improve efficiency have led to our waiting times being improved over the last three years and data in relation to our waiting lists is as follows:

Month end	Congenital Cardiac patients awaiting surgery
31/03/14	25
31/03/15	22
31/03/16	11

It should be noted that this is a snap shot in time which demonstrates our improvement in process and is a very positive situation for our patients. There is however, a natural variation across the months with demand and the ability to admit patients for surgery varying significantly.

5 Impact and potential risk

We note your concern that we are not presenting the potential risk to CHD services in the region fairly but we do not agree. We ask you to explain why the public should not be concerned about the potential loss of Level 1 services at EMCHC. Without the risk assessment stated above, the outcome from the acknowledged review of ECMO, PICU, General Surgery and Transport implications, and in the absence of a published plan as to how services will be relocated, there is no evidence to reassure our patients that the impact on services will not be as we predict.

6 Your statement that we will carry on delivering specialist cardiology medical services at EMCHC is debatable, and we ask you to refrain from further (and retract previous) incorrect statements about what is possible in a Level 2 Paediatric Cardiac centre. Stating that 'most of the care would still be maintained in EMCHC except the surgery', is simply not accurate. Based on our specialist consultants' knowledge of the specifications needed for such activities, virtually no invasive procedures would be possible. Our view is additionally informed following recent discussions with colleagues in Oxford, Manchester and Cardiff. The very concept of Level 2 centres is

unproven as was recognised by the IRP in their review of the 'Safe and Sustainable' proposals.

7 Our clinical training specialists believe your proposal will have serious effects on training within the East Midlands, affecting all people involved in paediatric care. We believe that in the short term our current trainees (medical and surgical staff) would have reduced clinical teaching, exposure and options. Medium term there would be a further reduction in the reputation of our training programs and thus difficulties in recruiting. Finally, in the long term, as most of our staff come from our own training programs there would be a reduction in the quality of paediatric care.

8 NHS England has identified the University Hospitals of Leicester (UHL) as one of the five Tier 1 providers of acute Specialised Services in the Midlands and East Region. Our PICU is part of the network of centres serving a population of around 17 million. In common with all other specialised PICUs in England, patients with complex needs from quaternary services are essential to maintain the expertise of our staff and attract and retain the best clinicians. We therefore stand by our assessment that any significant change in the flows of children with complex heart problems away from UHL will seriously impact on our PICU and risk destabilising the wider network.

9 We would also ask you to confirm what plans have been developed that describe how a Level 2 centre in Leicester would function. In the absence of a Level 1 centre in Leicester, patients would have to migrate to Birmingham, London or Leeds, depending on geography. Could you please describe how you envisage this would work and how the relationship with our proposed Level 2 centre would function?

10 A detailed assessment of the knock-on effect of decommissioning Level 1 Congenital Cardiac at UHL on other services is a complex piece of work that requires, if it is to be accurate and recognisable to all parties, a broader approach. Catherine O'Connell, Regional Director of Specialised Services (NHS England), has agreed to support work to define the scope of the assessment, identify and access relevant data sources and then interpret what it is telling us. The overall deadline for completing this will be confirmed by Catherine's team. The outputs of this exercise will need to be considered in conjunction with the nationally planned reviews of ECMO, PICU, General Surgery and PIC Transport, once they are available.

11 Independent reviews of PICU, General Surgery, ECMO and Transport

We are pleased that there is agreement on the importance of a common understanding of fact relating to the implications for other services (ECMO, General Surgery, Transport and PICU) of the proposal to decommission UHL as a Level 1 CHD provider. For complete transparency we request timely publication in advance of the proposed reviews of:

- The timescales; to ensure they fully align with the proposed public consultation and include the ability for the findings to be reviewed as part of the CHD public consultation, and before any final decisions are taken by NHS England
- Details of the expert clinicians proposed to lead the reviews, with assurance of appropriate specialist qualification/understanding and conflict of interest statements to enable appropriate challenge of constituency if required.

- Details of governance arrangements, including decision-making processes and publication of minutes, reports etc
- Arrangements for the involvement of all affected organisations (including UHL)

12 Achieving 500 surgical cases and network development

We were disappointed that you felt that the graphical information presented to you did not clearly demonstrate the number of patients (obtained from NICOR data) from our proposed network who required CHD surgery. The data shows that the current population in the proposed network already generates the required 500 cases. The fact that almost a quarter of these cases, despite being geographically closest to EMCHC, are referred elsewhere is the root of the problem. We wish you to consider the following propositions:

12.1 Your suggestion that this is due to patient choice ignores the fact that the patients who are referred to Great Ormond Street are those who live in Peterborough or Northampton. It would of course be understandable that one or two patients in these towns might choose to travel to London because they have connections there, but the proposition that all the patients in Northampton exercise a choice to go to London whilst all those who live in Kettering choose to go to Leicester is starkly implausible. NHSE have heard evidence during the New Congenital Cardiac Review that certain referrers do not offer UHL as an option for treatment. Given our recent results this cannot be based on an informed opinion about the quality of the services being provided. We would be interested to hear your views on how this, in any way, supports patient choice.

12.2 Providers in the South East offering to do clinics for nothing or at a subsidised rate so as to attract patients is an emerging issue and is undermining your desire to see all the centres you commission do 500 cases per annum. These providers already have over 600 cases per annum and thus their activity distorts the even distribution of patients (which would maximise geographical access).

12.3 There are significant disadvantages from your point of view in allowing our patients to be referred this way because the London tariff is 25% higher than our tariff. For illustrative purposes 125 operations costing £12k each at Leicester will cost an additional £375k alone in London excluding the cost of catheters, outpatients, imaging etc. (ref Market Forces Factor data 2015-16)

12.4 Whereas the proposition that patients are choosing London on a level playing field is unsupportable, there is no doubt that our patients are choosing our centre. Closing Leicester will frustrate the choice that 375 surgical patients are making every year and the thousands of other patients who are dependent on our service. Your proposal would in effect require the accommodation of around 1000 admissions per annum (current EMCHC activity) to as yet unspecified providers in more distant and inconvenient centres: this cannot be consistent with support for patient choice.

13 We would also draw your attention to the Verita report commissioned by NHS England in 2014 which stated:

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

Could you please tell us whether this recommendation was accepted and if so what has been done about it?

14 The standards ratified by the NHS England Board and published in July 2015 (p11 paragraph 26) also make reference to referral and the need for (our emphasis) '**Networks supporting clinicians to meet the activity standards for procedures.** Under these arrangements clinicians will need to undertake minimum levels of surgical/interventional activity to maintain their skills. **Networks will need to establish systems to ensure that referrals to and between centres are managed in such a way as to ensure that each clinician is able to achieve their numbers,** that each patient receives care from a clinician with the appropriate skills and that the flow of patients appropriately matches the capacity of each institution.'

15 We strongly believe our proposal to establish referral pathways in line with NHS England recommendations/standards is in the best interest of our patients, will reduce the risk associated with the potential closure of a Level 1 centre and accommodation of its patients, and will deliver a sustainable service for the future at reduced cost to the NHS. We would therefore ask for NHS England to publically support us in this request and ensure the implementation of the standard as stated above in our hospital.

16 The majority of the patients referred out of area are treated at Great Ormond Street Hospital (GOSH). Based on the fact that GOSH undertake almost 700 operations per year, and are likely to gain additional cases should the CHD Level 1 service cease at the Royal Brompton Hospital, any change in referral pattern would not adversely affect the ability of GOSH to achieve 500 cases a year. Even if Level 1 services were retained at the Royal Brompton, the proposal we are making would not compromise Level 1 services in London from achieving the activity standards.

17 We do however note that the ability of Bristol, Southampton, Newcastle and possibly Evelina (after Belfast patients move to Dublin for treatment) to undertake 500 cases per year, appears to be dependent on decommissioning Level 1 services at UHL and RBH. It would therefore be helpful if you could explain how you justify commissioning proposals that see centres achieving the surgical activity standard only by closing other centres and how you decided which centres fell into which commissioning category. Equally, we would be interested to learn how the centres mentioned above stated to you how they would achieve the 2021 activity standard based on their existing network activity whilst not knowing that centres were to be closed. We can only assume that any putative networks to emerge from this commissioning model would require a number of patients to travel to centres that are not their nearest, a concept roundly criticised in the IRP's assessment of the flawed Safe and Sustainable review, and wholly inconsistent with respect for patient choice.

18 Our proposal is intended to enhance choice for the vast majority of patients in the East Midlands, offering them the opportunity of receiving high quality care close to home. In our proposal, we would not envisage any required change to doctor-patient/provider relationship for existing patients. We gave detailed clarification of how this would work in our Network submission in October 2015 (Appendix 3). Our proposal is aimed at new and transitioned patients and we are willing to support this proposal through the provision of network clinics in the relevant hospitals by our own specialist consultants.

19 With reference to your query about patients from outside our region who attend EMCHC for their treatment, any such any patients will be those who clinically require our specialist ECMO services, those who come here through patient choice, or those who have been accommodated here due to lack of capacity elsewhere. One of the points that we believe your proposals completely overlook is that the service nationally has a shortage of capacity, mainly because none of the centres find it easy to recruit and retain staff. We would emphasise that we have no network clinics outside the region and our activity projections are not dependent on treating patients from outside of our proposed network.

20 We attach a breakdown of the increase in activity from 2010/11 to 2015/16 to include the impact of the implementation of a change in referral pathway from Kettering General Hospital. This equates to 19 surgical procedures. (Appendix 4).

21 Are we sending complex cases to Birmingham?

We are disappointed that you make reference to the surgical support received from Birmingham with a negative connotation. It is a professional obligation, enshrined in GMC Good Medical Practice, that second opinions are sought when in the best interest of patients or by patient choice. The standards themselves (p17 Para 5) make reference to rare and complex case management and state, "O*ur proposals for bigger surgical teams are intended to ensure that, in every team, the skills are available to perform most operations. Rare and complex cases would be managed either by referral to an appropriate specialist or by inviting a specialist to provide support at the patient's usual centre. Bigger surgical teams working across larger networks will ensure that the great majority of cases can be managed by the network team."*

This modus operandi was also recommended in the Report of Paediatric Congenital Cardiac Services Review Group, one of the precursors of the New Review, in 2003. Evidence of our commitment to this principle is found in our joint submission of a pan-Midlands network with Birmingham Children's Hospital and Queen Elizabeth Hospital Birmingham (Appendix 3).

We would also draw your attention to standard A4 (L1) d which states that Specialist ACHD surgical centres will "facilitate access to second opinions and referrals to other centres/services (reflecting that collectively they provide a national service)".

The details of the five cases where we have had in-reach support from Mr David Barron at Glenfield since 2013 are given below. This represents less than 0.4 % of our total caseload over this period.

Date	Surgeons	Procedure
Pre-Oct 2015	DB (BCH) -lead AL (UHL) - support	1. pulmonary atresia, ventricular septal defect, major aortopulmonary collateral arteries 2. Ross operation
Post-Oct 2015 (within the last 12 months)	DB -lead SS (UHL) -support	1. neonatal aortic valvotomy 2. Ross operation
	SS –lead DB - support	1. neonatal aortic valvotomy (clear evidence of progression following previous mentoring and support)

I can also confirm that in the last 3 years we have only referred 4 cases to Birmingham Childrens Hospital;

- 2 complex pulmonary atresia, VSD, MAPCAs and
- 2 patients requiring a double switch;

All of which were following an appropriate MDT discussion.

You will notice that our PRAiS data shows that we do the vast majority of our own complex surgery, including our own Norwood's and arterial switch procedures, and we have only lost one patient in total in the last 18 months. What we have done is to seek the assistance of our colleagues in Birmingham in order to develop the skills of our team and where we have properly identified a tiny number of patients who would be more appropriately treated at another centre where they have more experience of their very rare conditions. We are grateful for the support of our Birmingham colleagues and feel that your pejorative reference to this relationship is unfortunate.

22 ECMO

It is also appropriate at this stage to remind you that our ECMO team has been, and continues to be, pivotal in the training of adult and paediatric ECMO internationally and across the UK. In fact our current ECMO Training course has attendees from seven different nations and three different UK centres.

The ECMO team are frequently asked for management advice/support or to accept the more complex cases from around the UK. This is especially true of patients with congenital diaphragmatic hernia (currently one of the commonest neonatal indications for ECMO globally) for whom we are the only centre in the UK to routinely repair the diaphragmatic defect on ECMO. We also support other centres treating adolescent patients in whom our extensive experience of adult ECMO helps facilitate management.

Requests for help transporting patients on ECMO are common and are the result of our experience gained from more than 300 mobile ECMO transfers completed by the Glenfield ECMO team since 2009. We are the only UK centre that has this expertise or

who offer this service. Can you please assure us that the same high level of service, quality and outcomes will be possible if your proposed decommissioning of CHD services at EMCHC goes ahead?

23 EMCHC Surgical Workforce

With respect to our surgical workforce, again we are struggling to understand the rationale behind your question, especially with our improved outcomes and quality status. Whilst NICOR publish three year averages for surgical mortality, that very clearly does not exclude observable improved performance within that rolling time period.

All our Congenital Cardiac Surgeons have completed specialist training programmes in Congenital Cardiac Surgery. Two are on the General Medical Council specialist register with accreditation in Cardiac Surgery. A substantive consultant role is advertised and within the next 28 days we expect to have reviewed the applications and secured a substantive consultant appointment (with a possible further appointment). Our third consultant is employed as a Locum Consultant having been employed as a substantive consultant cardiac surgeon abroad. He previously worked in a similar role at Great Ormond Street from where he came with a very favourable reference. He is now preparing his application to the GMC for inclusion on the specialist register.

24 Consultant Turnover

There has been high consultant turnover in CHD units across the UK, especially over the last 5 years, largely as a result of the uncertainty generated by the previous failed review. This has necessitated the use of locum consultant staff, part time contracts with surgeons based overseas, surgeons moving from one UK centre to another and employing surgeons from abroad to work in the NHS. At least four senior UK based surgeons have left the UK to work overseas in this period.

The Verita report produced for NHS England in 2014 concurred with this analysis:

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

25 Congenital Surgical Workforce, UHL, 2012 -2016

year	Surgeon 1	Surgeon 2	Surgeon 3
April 2012-Sept 2012	GP	AL	
Oct 2012 - Dec 2014	GP	AL	SS
Jan 2015-Feb 2015	AL	SS	
Mar 2015 – Oct 2015	AL	SS	AC
Nov 2015-to date	SS	AC	BM

This level of turnover in no way justifies your assertion of "Longstanding issues with our surgical team" and the outcomes and quality we have demonstrated over the last 12 months are a testament to the quality and cohesiveness of our current staff.

26 Co –location of paediatric services

We can confirm that the capital costs associated with the co-location of CHD services to the Children's Hospital at LRI are within our discretionary capital and have been allocated accordingly. I can also confirm that the plans for the co-location are programmed to be complete before April 2019.

Adult CHD services will be retained at Glenfield Hospital in order to meet the necessary co-location standards associated with Adult Cardiac and Vascular services.

I can also confirm that the project to enhance and develop our Children's Hospital is not directly dependent upon the retention of Level 1 CHD services. Whilst we try to understand what services we might be able to provide without cardiac surgery we cannot fully scope the design of a new children's hospital. However, without the inclusion of EMCHC, we fear that we will not be building the type of children's hospital that the public is expecting and which would befit a region with the population of the East Midlands.

27 Specific sub- speciality co-location requirements

With respect to the provision of associated specialist services, we were able to clarify at the time of your visit that the standards are ambiguous and have led to confusion. The intention relates to the ability of a unit to provide GI endoscopy for the management of gastrointestinal emergencies, hence the need for the 30 minute on-call standard. We were able to explain clearly that this service at UHL, (and indeed at the majority of paediatric units in the UK), is usually provided by the paediatric surgeons. In most centres, paediatric gastroenterology is a non-acute speciality. For the avoidance of doubt, we attach the UHL guideline for this, the on-call paediatric surgical rota (again) and a recent award winning abstract on the subject (Appendix 5).

28 Conclusion

I trust that this response provides you with the clarification you were seeking. In particular, we have clarified that the standards related to the following are met:

- co-location of vascular services with ACHD
- provision of emergency response to paediatric gastroenterological emergencies
- expectation of co-location of all paediatric services by 2019

As such, we ask that amendments are made to your analysis of UHL's self-assessment against these standards, and that this correction is acknowledged in the public domain.

Finally, following our meeting with you on 16th September and our factual corrections, we respectfully suggest that you change your commissioning intention with respect to our service. We believe that this would be appropriate and will reassure our staff and patients. It is hard to over-emphasise the damage that is done to a service when it is undermined in this fashion and the distress that is caused to patients who believe that the service on which they depend may be closed down for reasons that they find as difficult to understand as we do.

Yours Sincerely

John Adler

Chief Executive
University Hospitals of Leicester NHS Trust