University Hospitals of Leicester NHS
NHS Trust

East Midlands
Congenital Heart Centre

Paediatric Cardiac and Adult Congenital Heart Disease Compliance Assessment

University Hospitals of Leicester NHS Trust

7th November 2016

University Hospitals of Leicester NHS Trust welcomes the opportunity of providing an updated self-assessment in respect to the standards as outlined in the letter from NHS England dated the 13th October 2016.

For completeness we have responded to all of the standards listed in the letter irrespective of whether these were deemed compliant in the last assessment or not.

Requirement 1.1 – Standard A9 (L1)

Specialist Children's Surgical Centres will adhere to their Congenital Heart Network's clinical protocols and pathways to care that will:
a) Requires all paediatric cardiac surgery, planned therapeutic interventions and diagnostic catheter procedures to take place within a Specialist Children's Surgical Centre;

b) Allow neonates with patent ductus arteriosus (PDA) to receive surgical ligation in the referring neonatal intensive care unit (level 3)1 provided that the visiting surgical team is dispatched from a designated Specialist Children's Surgical Centre and is suitably equipped in terms of staff and equipment (this is the sole exception to the requirement that heart surgery must be performed in a designated Specialist Children's Surgical Centre). It will be for each Congenital Heart Network to determine whether this arrangement is optimal (rather than transferring the neonate to the Specialist Children's Surgical Centre) according to local circumstances, including a consideration of clinical governance and local transport issues;

c) Ensure that emergency balloon atrial septostomy and temporary pacing, if undertaken outside of a Specialist Children's Surgical Centre, can be safely conducted if clinically indicated. Networks will develop clear guidelines that govern this process;

d) Ensure that patients requiring electrophysiology must be treated in dedicated paediatric services, with paediatric cardiac surgical support not adult services; and
e) Enable access to hybrid procedures (those involving both surgeons and interventional cardiologists) in an appropriate facility either in the Specialist Children's Surgical Centre or in another Specialist Children's Surgical Centre, if the need arises.

Timeframe: Within 3 years

We can confirm that East Midlands Congenital Heart Centre (EMCHC) adheres to the Congenital Heart Network (CHN) clinical protocols and pathways of care.

Part (a).This standard is met completely**.**

Part b) The East Midlands has 3 (Level 3) neonatal units, one at the Leicester Royal Infirmary (LRI) as part of the University Hospitals of Leicester NHS Trust (UHL), and (one unit, over split sites at Nottingham University Hospitals (NUH). The University Hospitals Coventry and Warwickshire (UHCW) also has a Level 3 neonatal unit, which occasionally refers neonates to UHL for PDA ligation when Birmingham Children's Hospital cannot accommodate them.

Currently, when referred to UHL, surgical PDA ligation in premature neonatal patients is performed at the Glenfield Hospital (GH). There is a network-wide agreed protocol in place with specific documentation and transport arrangements. In general, patients are transferred on the day of surgery from their Network NICU to GH PICU by the regional neonatal transport service. This team remain on the unit whilst the baby is in theatre, and pick up the postoperative care in conjunction with the anaesthetic and surgical teams as well as the PICU staff. After surgery, the patient is observed for few hours and then transferred (the same day) by the NNU team to an appropriately staffed NICU which is usually their nearest level 3 centre until they are ready to return to their more local NICU. (*Please see Appendix 1)*

This protocol is constantly under review with our network partners and if their preferred model should change we have the capability to accommodate this.

c. The vast majority of Emergency Balloon Atrial Septostomies and Temporary Pacing are conducted at EMCHC and we do not envisage this changing. Some Septostomies are currently performed on the NICU at Leicester Royal infirmary by the same team that would undertake it at Glenfield i.e. 1 or more Consultant Paediatric Cardiologists and a scanning SpR, on the same basis as at Glenfield. There is no level 2 centre in the East Midlands Network therefore no standard network arrangement is in place. We do not routinely provide outreach Septostomy due to the large geographical network area; (one has been undertaken in the last 10 years only, in Derby.)Temporary External Cardiac Pacing has been undertaken on an occasional and individually supported basis at the LRI Level 3 neonatal unit (publication submitted). Emergency Transvenous pacing on older children in our network centres would only be provided in cases of extreme emergency by the local adult cardiologists (again only twice in 10 years has this been required.)

d. Fully compliant as a)

e. Fully Compliant as a)

Requirement 2.1 – Standard B10 (L1))

Congenital cardiac surgeons must work in teams of at least four surgeons, each of whom must be the primary operator in a minimum of 125 congenital heart operations per year (in adults and/or paediatrics), averaged over a three-year period. Only auditable cases may be counted, as defined

by submission to the National Institute for Cardiovascular Outcomes (NICOR). VAD surgery and cardiac transplant surgery may also be counted.

Timeframe: Teams of at least three immediate, teams of at least four within 5 years
125 operations: immediate

Consultant numbers

East Midlands Congenital Heart Service (EMCHC) currently has three full time Consultant Congenital Cardiac Surgeons, therefore meeting the standard for 2016.

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 and the third is accredited as a specialist in paediatric cardiac surgery in his native country.

A substantive consultant role is advertised and by the end of November 2016 we expect to have reviewed the applications and secured a substantive consultant appointment.

Our third consultant is employed as a Locum Consultant by virtue of UK immigration and employment law; having been employed as a substantive Consultant Congenital Cardiac surgeon abroad with significant experience. He previously worked in a similar role at Great Ormond Street from whence he came with a very favourable reference. He is now preparing his application to the GMC for inclusion on the specialist register; after which he can be considered for a substantive role. This is normal practice in NHS Trusts employing specialists from overseas and any perceived risk regarding the sustainability of this appointment has been mitigated by the Trust providing a long term Locum contract to cover the period until his registration process is complete.

Caseload

We confirm that EMCHC **is** on track to meet the 375 surgical activity standard averaged over the next three years as the standard stipulates

University Hospitals of Leicester Five Year Plan – 'Delivering Caring at its Best', outlines the Trust's overall vision and strategy to become more specialised and clinically and financially sustainable, delivering specialist services from two, rather than three, big hospitals in five years' time. The development and growth of the EMCHC is fully in line with this.

The Trust's strategic objectives describe the things we must do, concentrates on creating a single integrated local health and social care system and developing and formalising partnerships with a range of providers for tertiary and secondary services.

UHL Trust is working with other providers of tertiary services to look at how we work better together to lead on the planning and provision of specialised services across a wide geography.

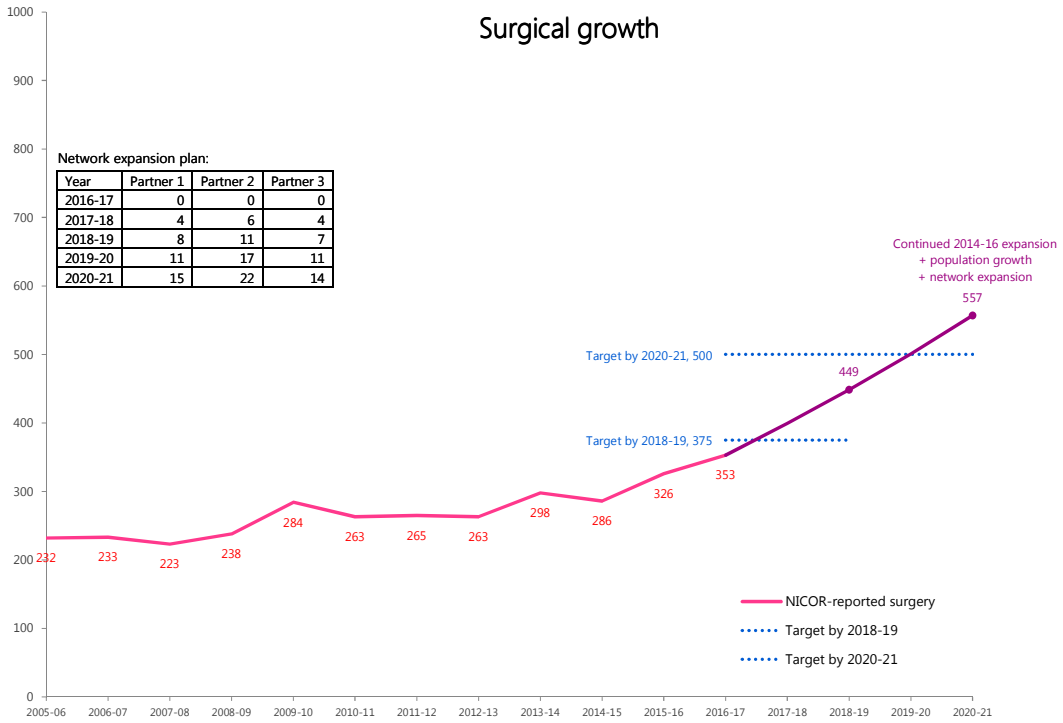
The UHL Children's Hospital Partnership Strategy forms part of the Trust wider strategy and includes the provision of Congenital Heart Disease services for the population of East Midlands. However,

despite the fact that the East Midlands network area already generates over 500 cases of CHD surgery per annum, EMCHC surgical activity currently falls below this figure. Our strategy is intended to remedy this; by enhancing choice for the vast majority of patients in the East Midlands, offering them the opportunity of receiving high quality care closer to home. In our proposal, we do 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 2). Our proposal is principally aimed at new and transitioning (to ACHD services) patients and we are willing to support this proposal through the provision of network clinics in the relevant hospitals by our own specialist consultants.

Based on this strategy, and since our last self-assessment, we have successfully established a complete lifetime referral pathway with Kettering General Hospital. We have also had positive discussions with two other network hospitals to establish lifetime referral pathways. These new partnerships are being established despite the uncertainty surrounding the new review into Congenital Cardiac Heart Surgery and in some cases the implementation of new pathways may be contingent on referring centres knowing that they will have access to EMCHC going forward (something with which NHS England could assist – see below). These changes will contribute to our growth plan towards the 500 cases from 2021 averaged over 3 years. We are currently continuing to encourage similar changes for other geographically appropriate units, on the principal basis that this will secure the best services for ALL East Midlands patients in the longer term (the greater good for the greatest number), without compromising the ability of other regional centres to achieve the standards.

However, as this is early in our new referral relationships and understanding of the exact impact is not fully understood, should we not quite achieve this; we believe the variance will be insignificant, and will not impact quality or safety, which is a position in line with the relevant standard.

(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) *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)*



The above graph shows our actual surgical activity to 2015/16 and our projected activity for the period up to 2021. As recognised in the report of the New Cardiac Review 2015 , and accepted by the Board of NHS England, the drivers for the projected increase are: population growth , technical advances, and in our case changes in our network to allow patients choice to attend EMCHC and facilitate nearest centre attendance (as per the modelling produced by NHS England for the Impact Assessment exercise) There is clearly uncertainty around these projections as recognised by NHS England, but it is clear from the graph that any uncertainty does not lead to significant variance from the standards, nor would warrant any safety or quality concerns.

Recruitment of a fourth surgeon will be planned to coincide with our caseload growth which will be delivered by our network development plan. It is essential that the recruitment is phased to ensure that each surgeon still is able to meet the minimum 125 caseload requirement. This is in line with the intentions of the New Cardiac Review report. Further details of timescales can be found with our growth model above.

EMCHC has excellent Clinical, Quality, and Personal outcomes as illustrated by our latest Quality Report (Appendix 3) and the level of public outrage already demonstrated across the country by the threat of decommissioning our Level 1 Services.

On 27th October 2016 NICOR validated EMCHC 2015-16 data submissions and gave us an overall data quality indicator (DQI) of 97%. This is an improvement of 3.5% on our previous DQI, an impressive achievement which is made all the more remarkable because NICOR expected all participating hospitals to experience a slight drop in the first 1-2 years due to an expanded dataset (increased by 30% more data items). This achievement was made possible by the commitment of the

EMCHC team to complete transparency, to providing the highest quality of information and to establishing data quality processes to review and confirm data sent to the national audit.

We will continue to work with our other network colleagues to sustain the high quality, family friendly service offered at EMCHC. We are sure that the confidence in and levels of support for EMCHC demonstrated recently will continue to grow, and enable referral pathways currently driving patients outside the region, to be changed. These conversations however will take time to develop fully, but based on current success we feel these are possible, and will ensure we meet the 500 cases per annum by 2021

We were encouraged that you agreed with us that all centres achieving the standards should be commissioned and welcome your support in ensuring that we do this. It would seem extraordinary that despite our continued success in this strategy, (especially in the short timescale since the last self-assessment) if this increase in patient choice by a small change in referral pathways were to be viewed as more difficult to achieve than the prospect of allocating >1000 episodes of inpatient care per annum from EMCHC (against patient choice), to other units out of region as now proposed.

Public support from NHSE for this initiative will provide the remaining referring units with additional confidence that their patients will have the longevity of care from EMCHC that is assumed from the other Level 1 centres in the UK. As such we request you acknowledge the progress we have made in this initiative and formally support it. This is in line with the standards ratified by the NHS England Board and published in July 2015 (p11 paragraph 26) which 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.'

Requirement 3.1 – Standard B9 (L1)

Consultant congenital surgery cover must be provided by consultant congenital surgeons providing 24/7 emergency cover. Rotas must be no more frequent than 1 in 4. Each Specialist Children's Surgical Centre must develop out-of-hours arrangements that take into account the requirement for surgeons only to undertake procedures for which they have the appropriate competence. The rota will deliver care for both children and adults. If this means that the surgeon is on-call for two hospitals, they must be able to reach the patient bedside at either hospital within 30 minutes of receiving the call.

Timeframe: Rota: 1 in 3 immediate, 1 in 4 within 5 years. Other requirements: immediate

We are compliant to the standards and copies of our 1:3 Consultant Congenital Surgical rotas can be found in Appendix 4

As described above , our growth and development plan will deliver the required 500 cases necessary to sustain a 4th Congenital Cardiac Surgeon by 2021, and the recruitment timetable will be in line with the requirement for all surgeons to achieve the minimum 125 case load .

Once appointed a 1:4 rota will be established and a draft is attached in Appendix 4

Requirement 3.2 – Standard B15 (L1)

Consultant interventional cardiology cover must be provided by consultant interventional paediatric cardiologists providing 24/7 emergency cover. Rotas must be no more frequent than 1 in 4. This could include interventional cardiologists based at a Specialist Children's Surgical Centre or a Specialist Children's Cardiology Centre. Each Specialist Children's Surgical Centre must develop out-of-hours arrangements that take into account the requirement for interventionists only to undertake procedures for which they have the appropriate competence. The rota will deliver care for both children and adults. If this means that the interventionist is on-call for two hospitals, they must be able to reach the patient bedside at either hospital within 30 minutes of receiving the call.

Timeframe: Within 1 year

We are compliant with this standard.

We have previously submitted the 1 in 3 rota for this; a change in personnel means that this will remain as presented but will have a different number 3 operator from December 2016.

We can confirm the salary for recruitment of a fourth interventional cardiologist is already in place in our 3 year business plan, identified for recruitment in 2017.

Requirement 3.4 – Standard B1 (L1)

Each Specialist Children's Surgical Centre must provide appropriately trained and experienced medical and nursing staff sufficient to provide a full 24/7 emergency service within compliant rotas, including 24/7 paediatric surgery and interventional cardiology cover. A consultant ward round will occur daily. Each Specialist Children's Surgical Centre must provide a 24/7 emergency telephone advice service for patients and their family with urgent concerns about deteriorating health.

Timeframe: Within 6 months

We are compliant with this standard.

The paediatric cardiology service operates a "Consultant of the Week" (COW) system, where a named consultant is responsible for covering all in-house cardiology issues and providing network-wide advice. The COW does not carry out any elective activity during their hot week and works to the COW job plan during this period which includes daily ward rounds. At the weekend, the on-call

consultant job plan includes undertaking daily ward rounds in person There are multi-disciplinary business rounds seven days a week, which include consultants and senior team members in cardiology, cardiac surgery and intensive care.

The COW job plan and the paediatric cardiology on call rota reflecting day, night and weekend cover are included in Appendix 4

Requirement 4.1 – Standards D6(L1); D7(L1); D8(L1)

The following specialties or facilities must be located on the same hospital site as Specialist Children's Surgical Centres. They must function as part of the multidisciplinary team. Consultants from the following services must be able to provide emergency bedside care (call to bedside within 30 minutes).

Timeframe: 30 minute call to bedside: Immediate Co-location: within 3 years

D6 (L1) Paediatric Surgery

D7 (L1) Paediatric Nephrology/Renal Replacement Therapy.

D8 (L1) Paediatric Gastroenterology.

We are compliant with this standard

Thank you for the clarification in respect of the gastroenterology standard.

Currently immediate gastroenterology advice is available 24/7 from the gastroenterology team Emergency bedside care is provided within 30 minutes by general paediatric and neonatal consultant teams, supported by paediatric intensive care consultant. For surgical gastroenterological emergencies, bedside care is provided in 30 minutes by our paediatric surgical consultants.

We attach the relevant rotas, protocols in Appendix 5. As such we confirm that we meet standard D8 (L1).

For reference, we quote 2013/14 NHS England Service Specifications for Paediatric Gastroenterology: gastroenterology, hepatology and nutrition (E03/S/c) (page 6 Para 1)

'The components of a Paediatric Gastroenterology, Hepatology and Nutrition Service are; sufficient consultant numbers to provide consultant continuity with cross- cover and access to expert opinion by telephone 24 hours/day'

https://www.england.nhs.uk/wp-content/uploads/2013/06/e03-paedi-med-gastro-hepa-nut.pdf

By 2019 all paediatric specialist services will be co-located including paediatric cardiac services. This will ensure the co-location of the paediatric EMCHC service with other paediatric services at the Leicester Royal Infirmary site. The project, which will also see the expansion of space for the required increase in cardiac activity, will ensure compliance with the NHS England requirement 4.1

and co-location standards D6(L1), D7(L1), and D8(L1) within the given deadline (April 2019). The project will not require external capital funding, as it will be funded using a combination of the Trust's Capital Resource Limit and charitable donations. It will be designed as part of (but is not dependent upon) the wider Children's Hospital Project, to ensure the integration of paediatric services to create a defined Children's Hospital in Leicester. For the avoidance of doubt, we confirm the Trust's commitment and ability to achieve co-location by April 2019. Further details of the project can be supplied on request.

As acknowledged in your letter of the 31st October 2016 we are compliant to standard D7 (L1).

Finally, in addition to the standards listed in your letter 13th October 2016, we would like to formally register again, our response to the Adult standard D7 (L1) to enable a formal acceptance of our compliance and approved mitigation plan

D7 (L1) (Adult) – co location of Vascular services including surgery and interventional radiology

ACHD services are not currently co located on same site as Adult Vascular services, but this is mitigated by same the arrangements as for the established acquired adult cardiac surgical and interventional catheterisation programme. We can confirm that, as described and physically demonstrated and inspected during your pre-consultation site visit, the entire UHL vascular surgery and interventional radiology programme will be relocating to the GH site in May 2017 and we will then be fully compliant with this standard.