Leeds CITY COUNCIL

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Report of the Head of Scrutiny and Member Development

Report to the Joint Health Overview and Scrutiny Committee (Yorkshire and the Humber)

Date: 22 September 2011

Subject: Proposed Reconfiguration of Children's Congenital Heart Services in England: Additional information from Leeds Teaching Hospitals NHS Trust (LTHT)

Are specific electoral Wards affected? If relevant, name(s) of Ward(s):	☐ Yes	☒ No
Are there implications for equality and diversity and cohesion and integration?	☐ Yes	☒ No
Is the decision eligible for Call-In?	☐ Yes	☒ No
Does the report contain confidential or exempt information? If relevant, Access to Information Procedure Rule number: Not applicable Appendix number: Not applicable	☐ Yes	☒ No

Summary of main issues

1. The Joint Health Overview and Scrutiny Committee HOSC (Yorkshire and the Humber) forms the statutory overview and scrutiny body to consider and respond to the proposed reconfiguration of Children's Congenital Heart Services in England – taking into account the potential impact on children and families across the region.

2. In considering the proposals set out in the *Safe and Sustainable Consultation Document: A new vision for Children's Congenital Heart Services in England (March 2011),* Members of the Joint HOSC have sought to consider a wide range of evidence and engage with a range of key stakeholders.

3. As part of the public consultation on the future of Children's Congenital Heart Services in England, HOSCs have been given until 5 October 2011 to respond to the proposals.

4. The Joint HOSC has previously considered information provided by Leeds Teaching Hospitals NHS Trust (LTHT). The purpose of this report is to provide additional information provided by the Trust, in response to the information provided by the JCPCT. This information is provided at Appendix 1.

5. Representative from LTHT will be in attendance at the meeting to discuss the additional information provided and address any further questions identified by the Joint HOSC..

Recommendations

6. Members are asked to consider the details associated with this report and identify/ agree any specific matters for inclusion in the Committee's report to be presented to JCPCT later in the year

Background documents

- A new vision for Children's Congenital Heart Services in England (March 2011)

APPENDIX 1

The Leeds Teaching Hospitals NHS
NHS Trust

As outlined in Sir Neil Mckay's letter. Leeds Teaching Hospitasl NHS Trust (LTHT) (like all other surgical centres) were asked if we would be prepared to deliver any of the 3 nationally commissioned services :

- ECMO
- Transplant
- Tracheal Surgery

The process involved completing a proforma and returning it to the Safe and Sustainable team. The Safe and Sustainable team advised that an expert group then reviewed the information and provided comment /scored the submission. The Trust received high level feedback on its submission to deliver/ provide the 3 nationally commissioned services.

The Trust's completed proforma is attached at Annex A, in response to the very late invitation to provide a declaration of interest/option appraisal for delivery of the Nationally Commissioned Services (NCS), Transplant, ECMO and Complex Tracheal Surgery.

It should be noted that the template was received on 13th April 2010 for return by 7th May 2010, which equates to **16 working days**. The outcome of the expert panel review of our submission has influenced the decision about where these services could be delivered in the future. As such, it is our view that the NCS has now proven to be a fundamental factor in the consultation options and as such more time should have been afforded to this key part of the process.

We would also make the following additional points:

1) The timescale to complete the information was short , as this information was requested after the rest of the self assessment information.

2) The Trust has never been provided with the detail of the expert panel's view or given the scores / rationale as to why the team were not confident we could provide these services. The only reference to the outcome of the option appraisal is on page 103 -104 of the Safe and Sustainable new vision for children's congenital heart services in England Consultation document.

As for any centre who currently does not provide them , there would be a need to expand some of the skills / resource to deliver any of the 3 NCS. Therefore, without having any specific feedback regarding the Trust's submission , it is difficult to know why the expert panel took this view.

For ECMO specifically , of the 3 NCS this is the easiest to implement - we have perfusionists, surgeons , nurses in theatres and on ITU who have these skills and it would not be difficult to expand this if required.

The reality is (as previously identified to the Joint HOSC by Mr Watterson) any centre that has surgeons who are trained, perfusionists , PICU nurses who are trained and cardiac anaesthetists could provide and of these services if commissioned to do so. Clearly, there would be a period of training required (as there would for any centre new to set up), however there is at least a year between the planned decision and implementation of the new configurations which is more than sufficient time.

Leeds Teaching Hospitals NHS Trust

APPENDIX 1

September 2011

Safe and Sustainable

Assessment of Nationally Commissioned Service (NCS) provision

Overview

1) Introduction

There are three services that are nationally commissioned by the National Specialised Commissioning Group (NSCT) and that are currently provided at some paediatric cardiac surgery centres in England. It is necessary for the *Safe and Sustainable* review to consider and address the future of these services as part of the process for delivering recommendations for reconfiguration of paediatric cardiac surgery services.

The nationally commissioned services are:

- Paediatric Cardiothoracic Transplantation and Mechanical Device as a Bridge to Heart Transplantation (currently provided at Freeman Hospital, Newcastle and Great Ormond Street Hospital)
- Extracorporeal Membrane Oxygenation (ECMO) for severe respiratory failure (currently provided at Great Ormond Street Hospital, Glenfield Hospital, Leicester and Freeman Hospital, Newcastle)
- Complex Tracheal Surgery (currently provided at Great Ormond Street Hospital)

These services all require cardiac surgery or surgical back up in order to operate safely.

The NSCT is not looking to increase the number of centres providing these services in the future. However it does need to be assured that whatever the future configuration of paediatric cardiac surgery provision, the nationally commissioned services can continue to be provided to a good standard of care with good geographical access across England.

It is important that you consider whether, if designated as a paediatric cardiac surgery provider in the future, you would also want to be in the position to provide one or more of the nationally commissioned services. Because final decisions on the designation of providers for Nationally Commissioned Services can only be made by the Secretary of State, he or she will need to be assured that all viable options for paediatric cardiac surgery services also enable high quality provision of these national services.

If you do not wish to provide one of the nationally commissioned services in the future, you should declare this now by emailing that as your response on the 7th May 2010.

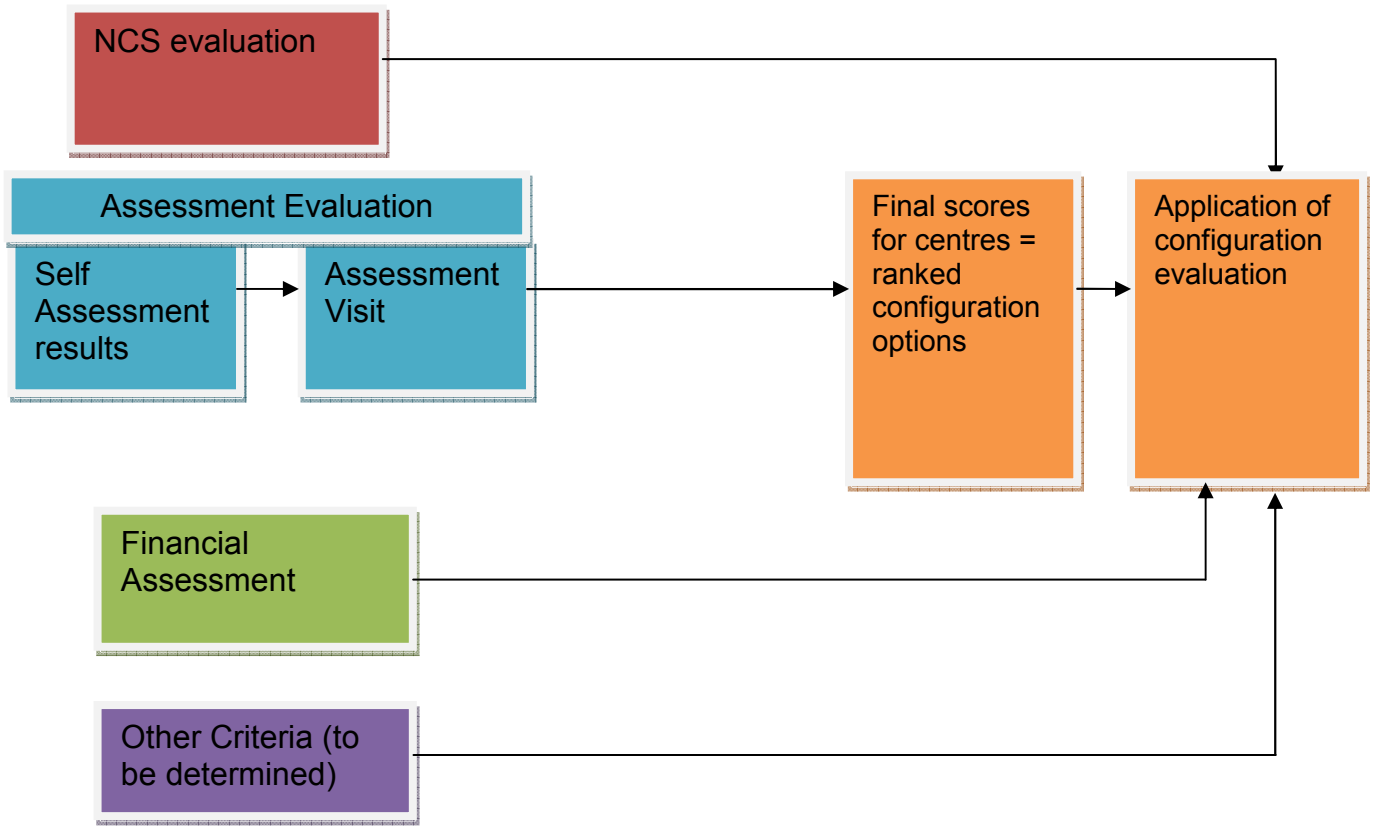
2) Process

The completion of this NCS template is separate from the self-assessment template that was sent you on the 22nd March 2010.

The self assessment template is attached again for your information (Appendix A). The scores derived from the completion of the self-assessment template will, with the assessment visits, enable us to arrive at a number of configuration options. Those configuration options will need to be tested against a number of criteria, in order to evidence the best configuration scenario for patients.

The information gained from this return will contribute to addressing one of those criteria – risk to other dependent services. Details of the other criteria to be used will be made available to you once known.

Although the NCS template is scored, these scores will not form part of the individual organisation assessment scoring – the scores will only be used when testing configuration options. This is illustrated below:



3) Service Guidelines

For each of the 3 Nationally Commissioned Services, we have attached some guidelines which indicate the level, type and complexity of the service.

This template asks you to consider these guidelines, and to judge the implications to your organisation in providing these services.

Paediatric Cardiothoracic Transplantation and Bridge to Transplant (Appendix B):

The guidelines have been taken from:

1. The existing NSCAG designation standards
2. The NHS Blood and Transplant National Standards for Organ Retrieval from Deceased Donors.

Respiratory ECMO (Appendix C): the criteria have been derived from the Extracorporeal Life Support Organization (ELSO) guidelines for Paediatric Extracorporeal Membrane Oxygenation, most recently updated in 2002.

Complex Tracheal Surgery (Appendix D): the criteria have been derived using the case definition applied by Great Ormond Street Hospital and agreed with existing clinical and commissioning experts.

4) Scoring

The information you supply in this exercise will be assessed as one of the criteria used in determining the configuration evaluation.

In order that we can apply the criteria fairly, we need to be able to quantitatively evaluate the potential of each centre that wishes to provide each of the Nationally Commissioned Services.

For each service that you do not currently provide, we require you to consider the guidelines for each service, and to assess your ability to provide the service in the future, if required.

The areas in which you will be scored against are your assessment of:

- Workforce requirements and risks
- Ability to meet the required capacity
- Team working and infrastructure
- Network arrangements
- Continuous professional development, training and education
- Governance structure and risk management.

Each area will be equally weighted, and will be scored as follows:

1	**Inadequate (the centre is unable to meet this requirement)**
2	**Poor (it is unlikely that the centre will be able to meet the requirement)**
3	**Unsatisfactory (there are significant risks or issues involved in the centre meeting this requirement)**
4	**Good (evidence supplied is good, and we are assured that the centre is in a good position be able to meet the requirement)**
5	**Excellent (evidence is exemplary and we are absolutely certain that the centre can meet the requirement)**

Each assessment will be scored by a panel of experts, once the submissions are returned on the 7th May. Further details of the membership of the panel will be sent to you in due course. There is a possibility that the evaluation panel will request clarifications/interaction with your centre in respect of this submission. This is likely to take place in late May 2010.

As discussed, the scores will be considered alongside other criteria, as part of the Configuration Evaluation stage. Full details of the configuration evaluation criteria will be sent to you once known.

Assessment

Please attach any additional information you feel necessary, such as strategies or project plans that demonstrate the answers to the questions.

1. Paediatric Cardiothoracic Transplantation and Bridge to Transplantation

Please refer to the guidelines in Appendix B

Area of Assessment
Are you confident that you will be able to recruit and sustain the required workforce for the service? What risks do you envisage, and how would you mitigate against these risks? Recruitment of an additional surgeon required to complete the additional paediatric cardiac procedures provides an opportunity for appointing a paediatric cardiac surgeon with a specific interest in transplantation although our current surgeons have had training in transplant surgery and would ensure the on call rota would cover transplant and bridge to transplant patients after appropriate re-training. The addition of paediatric cardiac transplantations adds additional requirements to the service and we would need to actively develop our staffing (both through training and recruitment) and infrastructure to meet this challenge. We believe that our service is capable of accommodating transplantations. A risk when considering development of such a service would be an inability to recruit appropriate clinical leads (e.g. a surgeon with a special interest), but given that this assessment document makes it clear that the NSCG is not considering increasing the number of providers in England the development of paediatric

cardiac transplants in Leeds would presumably mean the cessation of activity in another centre and the redistribution of existing skills should help mitigate against this risk.

We would invest in dedicated clinical nurse specialists and coordinators for transplantation who, if not already fully experienced, would be supported to gain the required knowledge and skills needed to care for this group of patients, through structured education and experience in transplant centres.

The activity for these services across England in 08/09 was:
Paediatric Cardiac Transplantation: 32 transplants
Paediatric Lung Transplantation 6 transplants
Bridge to Transplantation: 22 procedures

The length of stay in paediatric intensive care for transplantation varies considerably, but in 08/09 the range of was between:
For Assessment 0 to 0.6 OBDs
For Transplant – ITU 17 to 22 OBDs, ward 12 to 22 OBDs
For Follow up – ITU 0 to 0.4 OBDs, ward 1.5 to 2.5 OBDs
Outpatient attendances 704

For Bridge to Transplantation the average length of stay in paediatric intensive care was between 31-63 OBDs.

What is your assessment of the capacity required to run this service? What evidence do you have that your centre would be able to dedicate the required capacity?

Our current clinical footprint would require expansion to manage this increase in demand and would require a detailed project to allow for increased physical space and extra staffing. We would need to amend our existing designation capacity modelling plan to include the additional activity generated by providing transplant services. This includes required bed capacity for ICU, HDU and ward beds, as well as theatre sessions, and outpatient appointments. Using this information we would also be able to calculate the required staffing cohort that would need to be recruited.

The local reconfiguration required to accommodate this activity can be flexed quite substantially as there are several adult services that could be moved from the Leeds General Infirmary (LGI) site to the St James' University Hospital (SJUH) site in order to allow for further space at the LGI. This would allow Children's Services to remain centralised on one site and provide an opportunity to improve clinical adjacencies across the Trust, and have similar benefits for the Adult services. The Trust's Senior Management team are aware this plan would require significant capital investment for refurbishment of the LGI and providing new accommodation for adult services at SJUH and are committed to taking these plans forward as part of the emerging Clinical and Estates Strategy. Leeds Teaching Hospitals Trust has a proven track record of successfully completing highly complex service reconfigurations, the most recent of which has been to centralise Children's Services in the Leeds' Children's Hospital.

Referring to the guidelines at Appendix B, what is your assessment of the infrastructure and multidisciplinary team working required to effectively run this service? How can you evidence that this is, or will be, in place?

We already manage a significant amount of pre and post transplant care for our patients that receive transplant surgery elsewhere. The standards outlined in Appendix B reflect good clinical care, appropriate clinical assessment, data collection and communications with patients and families which are an important part of our existing philosophy of care. We would ensure appropriate clinical facilities and trained staff to deliver the services. We would adapt our electronic databases and systems (including additional data audit clerks) to ensure appropriate information recording.

We would develop appropriate structures to ensure communication and access for patients and families at all times and initiate appropriate communications and interactions between other transplant centres in the UK and further afield where appropriate. The current paediatric and congenital facility includes a full electrophysiology service, which is particularly important for children with end-stage cardiac failure, as

some may require implantable cardioverter-defibrillators and because cardiac resynchronisation therapy is emerging as an important alternative therapy for some transplant candidates. Transplant specific records would be created and would be available 24/7.

The co-location with other specialist children's and adult services clearly add to our ability to holistically manage these patients and we have existing experience in managing other transplant groups including renal, hepatic and bone marrow.

Please describe the network arrangements that you think need to be in place in order to ensure the effective operation of the service?

There has been a significant amount of time and energy invested into the development of a focussed paediatric cardiac services network, fit for purpose and aimed at achieving and maintaining high clinical standards. We feel that this provides the assurance that our wider service meets the current standard. Expansion of the service to cover a greater geographical area and transplantation and bridge to transplant would require us to work with a larger number of local commissioners and hospital Trusts. The current network model has proven successful and effective thus far and if managed appropriately and sensitively, including a two way dialogue with new network partners, we have no concerns that this expansion would have a detrimental effect. The network membership and remit is continually reassessed and has the mechanisms in place to be able to adapt to accommodate new stakeholders.

How will you ensure that training, education and continuous development is made available to all members of the team? How would you ensure that your service continued to improve so as to ensure sustainability?

LTHT is committed to support all staff through a process of ongoing appraisal and personal development plans to access role specific training and education.
We have strong links with Leeds University and would be able to utilise this relationship for future education and transplant research, particularly focussing on the immunology of rejection.

What service specific governance arrangements would you have in place?

We have a well defined clinical governance structure and clinical governance is an integral part of the Trust's performance management process. On a bimonthly basis the divisional medical manager produces a composite clinical governance report which is presented to the executive directors.

Within paediatric cardiac and cardiology services there is a monthly clinical governance meeting which comprises a morbidity and mortality meeting, audit meeting and a focus on general governance themes.

Within the Network there is a quarterly paediatric cardiology clinical network meeting which is attended by LTHT consultants, link consultants from peripheral hospitals and other professional staff. This meeting has a varied agenda which includes audit and governance issues.
There is recognition of the need to strengthen both clinical governance arrangements and research activity across the Network. In terms of governance, there are plans to create a Governance and Quality manager to ensure best practice is embedded in practice and lessons are learned across the Network. We recognise there are opportunities to learn from the experience of services such as Obstetrics and Oncology where these posts have been created and brought added focus and leadership to governance activities.

We acknowledge that there will need to be a focus on transplantation and bridge to transplant drawing on the experience of other centres but we feel our current governance arrangements are strong and are provide and excellent model for future service developments.

2. Extracorporeal Membrane Oxygenation (ECMO) for severe respiratory conditions

Please refer to the guidelines in Appendix C

Area of Assessment
Are you confident that you will be able to recruit and sustain the required workforce for the service? What risks do you envisage, and how would you mitigate against these risks? Many of the issues are analogous with those described in the transplant sections above. Recruitment of an additional surgeon required to complete the required additional procedures provides an opportunity for appointing a paediatric cardiac surgeon with a specific interest in ECMO although our current surgeons also have the skills to provide ECMO and ensure the on call rota would provide cover to the ECMO patients. Our current paediatric thoracic surgeon who is currently responsible for most of the non-cardiac thoracic and airway surgery in children is keen to join the ECMO team. Currently ECMO is already used in Leeds as a short term bridge after cardiac surgery by our existing team and we have a sufficient complement of trained perfusionists to provide this service 24/7. It can be assumed that if existing centres are no longer commissioned to deliver ECMO services there will be a number of staff with the appropriate skills who will relocate to the Leeds service. There are varying degrees of ECMO support, from short term post cardiac surgical support to long term ECMO support in non-cardiac patients with respiratory disease. Although we feel we have the potential infrastructure and critical interdependencies to support the development of any level of service, the implications and development issues vary enormously. Mitigating against risks would require a clear understanding of what level of service is required and development of the necessary infrastructure. We would invest in dedicated ECMO specialists, who, if not already fully experienced, would be supported to gain the required knowledge and skills needed to care for this group of patients, through structured education and experience in ECMO centres.
The activity for these services across England in 08/09 was 59 patients. **The length of stay in paediatric intensive care varies considerably, but in 08/09 the range was between:** **For Assessment 0 to 6 OBDs** **For ECMO procedure 7 to 17 OBDs** **What is your assessment of the capacity required to run this service? What evidence do you have that your centre would be able to dedicate the required capacity?** Our current clinical footprint would require expansion to manage this increase in demand and would require a detailed project to allow for increased physical space and extra staffing. We would need to amend our existing designation capacity modelling plan to include the additional PICU activity generated by providing ECMO services. This includes required bed capacity for ICU, HDU and ward beds and neonatal cots. Using this information we will also be able to calculate the required staffing cohort that would need to be recruited. The local reconfiguration required to accommodate this activity can be flexed quite substantially as there are several adult services that could be moved from the Leeds General Infirmary (LGI) site to the St James' University Hospital (SJUH) site in order to allow for further space at the LGI. This would allow Children's Services to remain centralised on one site and provide an opportunity to improve clinical adjacencies across the Trust, but also have mutual benefits for the Adult services to gain improved clinical adjacencies. The Trust's Senior Management team are aware this plan would require significant capital investment for refurbishment of the Clarendon Wing at the LGI and providing new accommodation for adult services at SJUH and are committed to taking these plans forward as part of the emerging Clinical and Estates Strategy. Leeds Teaching Hospitals Trust has a proven track record of successfully completing highly complex service reconfigurations, the most recent of which has been to centralise Children's Services in the Leeds' Children's Hospital.

Referring to the guidelines at Appendix C, what is your assessment of the infrastructure and multidisciplinary team working required to effectively run this service? How can you evidence that this is, or will be, in place?

Our current infrastructure is already supportive of many of the guidelines for providing ECMO. By 4th May 2010, all Children's services (including the specialised services mentioned in appendix B) will be provided on the same LGI site, co-located with paediatric and congenital cardiac services. Many of the paediatric services provided are well developed tertiary services such as respiratory medicine and neonates. We have dedicated paediatric and adult cardiac ICUs as well as general PICU/ICUs that provide tertiary level services.

Please describe the network arrangements that you think need to be in place in order to ensure the effective operation of the service?

We have provided significant detailed evidence with regard to the strength of our current network arrangements, which we believe are robust enough to accommodate ECMO pathways successfully. Detailed and focussed work on ECMO would be required, but we have strong systems and processes in place across the network to facilitate this service development.

How will you ensure that training, education and continuous development is made available to all members of the team? How would you ensure that your service continued to improve so as to ensure sustainability?

LTHT is committed to support all staff through a process of ongoing appraisal and personal development plans to access role specific training and education.
We have strong links with Leeds University and would be able to utilise this relationship for future education, development and research.

What service specific governance arrangements would you have in place?
We have a well defined clinical governance structure and clinical governance is an integral part of the Trust's performance management process. On a bimonthly basis the divisional medical manager produces a composite clinical governance report which is presented to the executive directors.

Within paediatric cardiac and cardiology services there is a monthly clinical governance meeting which comprises a morbidity and mortality meeting, audit meeting and a focus on general governance themes.

Within the Network there is a quarterly paediatric cardiology clinical network meeting which is attended by LTHT consultants, link consultants from peripheral hospitals and other professional staff. This meeting has a varied agenda which includes audit and governance issues.
There is recognition of the need to strengthen both clinical governance arrangements and research activity across the Network. In terms of governance, there are plans to create a Governance and Quality manager to ensure best practice is embedded in practice and lessons are learned across the Network. We recognise there are opportunities to learn from the experience of services such as Obstetrics and Oncology where these posts have been created and brought added focus and leadership to governance activities

We acknowledge that there will need to be a focus on ECMO drawing on the experience of other centres but we feel our current governance arrangements are strong and are provide and excellent model for future service developments.

3. Complex Tracheal Surgery

Please refer to the guidelines in Appendix D

Area of Assessment
Are you confident that you will be able to recruit and sustain the required workforce for the service? What risks do you envisage, and how would you mitigate against these risks? The LTHT currently undertakes complex tracheal surgery as defined in Appendix D. Children are admitted under the care of the complex regional respiratory service which is lead by a respiratory paediatrician and a paediatric thoracic surgeon. Treatment is provided by the paediatric thoracic surgeon, paediatric cardiac surgeons, paediatric ENT surgeons and paediatric radiologists, depending on the nature of the case. We maintain a regular practice with tracheal resection, aortopexy, endobronchial stenting. We are confident we can expand this service to cope with increased demand. This would involve investment in staff, who, if not already fully experienced, would be supported to gain the required knowledge and skills through structured education and experience in other centres.
The activity for these services across England in 08/09 was 28 patients. **The length of stay in paediatric intensive care varies considerably, but in 08/09 was:** **ICU stays: between 2 to 17 days** **Ward stays: between 1 to 4 days** **What is your assessment of the capacity required to run this service? What evidence do you have that your centre would be able to dedicate the required capacity?** Our current clinical footprint would require expansion to manage this increase in demand and would require a detailed project to allow for increased physical space and extra staffing. We would need to amend our existing designation capacity modelling plan to include the additional PICU activity generated by providing Complex Tracheal Surgical services. This includes required bed capacity for ICU, HDU and ward beds and neonatal cots and theatre sessions. Using this information we will also be able to calculate the required staffing cohort that would need to be recruited. The local reconfiguration required to accommodate this activity can be flexed quite substantially as there are several adult services that could be moved from the Leeds General Infirmary (LGI) site to the St James' University Hospital (SJUH) site in order to allow for further space at the LGI. This would allow Children's Services to remain centralised on one site and provide an opportunity to improve clinical adjacencies across the Trust, but also have mutual benefits for the Adult services to gain improved clinical adjacencies. The Trust's Senior Management team are aware this plan would require significant capital investment for refurbishment of the Clarendon Wing at the LGI and providing new accommodation for adult services at SJUH and are committed to taking these plans forward as part of the emerging Clinical and Estates Strategy. Leeds Teaching Hospitals Trust has a proven track record of successfully completing highly complex service reconfigurations, the most recent of which has been to centralise Children's Services in the Leeds' Children's Hospital.
Referring to the guidelines at Appendix D, what is your assessment of the infrastructure and multidisciplinary team working required to effectively run this service? How can you evidence that this is, or will be, in place? Our current infrastructure is already supportive of the guidelines for providing Complex Tracheal Surgery. By 4th May 2010, all Children's services will be provided on the same LGI site, co-located with paediatric thoracic surgery, paediatric cardiac surgery, paediatric ENT surgery and paediatric radiology. Many of the paediatric services provided are well developed tertiary services such as respiratory medicine and neonates. We have dedicated paediatric and adult cardiac ICUs as well as general PICU/ICUs that provide tertiary level services.

What service specific governance arrangements would you have in place?

We have a well defined clinical governance structure and clinical governance is an integral part of the Trust's performance management process. On a bimonthly basis the divisional medical manager produces a composite clinical governance report which is presented to the executive directors.

There are monthly clinical governance meeting which comprises morbidity and mortality meeting, audit meeting and a focus on general governance themes.

We acknowledge that there will need to be a focus on Complex Tracheal Surgery drawing on the experience of other centres but we feel our current governance arrangements are strong and are provide and excellent model for future service developments.