

**BOARD PAPER - NHS ENGLAND**

**Title:** New review of congenital heart services

**Clearance:** Bill McCarthy, National Director: Policy

**Purpose of paper:**

- To describe the challenge facing NHS England in improving congenital heart disease services
- To outline early thinking on the way forward

**Key issues and recommendations:**

On 12 June 2013 the Secretary of State announced in Parliament that the safe and sustainable proposals for children's congenital heart services could not go ahead in their current form. He went on to say that "it is right we continue with this process, albeit in a different way".

NHS England is the body responsible for commissioning specialised congenital heart services and for taking forward the process.

A new review is being established to consider the whole lifetime pathway of care for people with congenital heart disease (CHD), to ensure that services for people with CHD are provided in a way that achieves the highest possible quality within the available resources.

**Actions required by Board Members:**

- To note the proposals for conducting a review of congenital heart disease services

## **New review of congenital heart services**

### **Summary**

Following the outcome of judicial review, the report by the Independent Reconfiguration Panel (IRP) and the Secretary of State's announcements relating to the safe and sustainable review of children's congenital heart services, NHS England is now the responsible body for taking forward the process. A new review is now being established to consider the whole lifetime pathway of care for people with congenital heart disease (CHD).

The ambition of this review is to ensure that services for people with CHD are provided in a way that achieves the highest possible quality within the available resources:

- the best outcomes for all patients, not just lowest mortality but reduced disability and an improved opportunity for survivors to lead better lives.
- tackling variation so that services across the country consistently meet demanding performance standards and are able to offer resilient 24/7 care
- great patient experience, which includes how information is provided to patients and their families, considerations of access and support for families when they have to be away from home

We recognise that continued uncertainty is a risk to the service and unsettling for patients. We must therefore set ourselves the target of delivering the new review at pace. But we know that speed cannot be an excuse for imposing a top down solution or for running a process where people feel excluded from the real discussions, so we will be setting ourselves the additional challenge of achieving new levels of transparency and the highest levels of genuine participation. We know that this will need a new approach. We want to make sure that as well as mobilising NHS England's resources from right across the organisation, that we also work closely with partners and stakeholders to design the way forward.

By the end of September we will have established the new programme, co-designed a process for the work going forward and undertaken initial work on how to secure high quality resilient services.

By June 2014 working closely with stakeholders, we will have developed, tested and revised a proposition, undertaken work to identify a preferred approach to implementation, and completed the necessary preparatory work.

### **Background**

1. Around eight out of every 1,000 babies have some form of congenital heart disease (CHD) – around 5,800 babies in 2011. The number of children born with CHD is expected to rise, as the birth rate rises. As technology and expertise continue to develop, it is possible to do more than ever before to improve their lives, so that more children with CHD are surviving to adulthood.
2. NHS cardiac surgery for children is currently provided by 10 hospitals in England. Specialist paediatric cardiology is also provided by a further three centres. Around 3,700 paediatric surgical procedures and 2,000 paediatric interventional cardiology procedures are carried out each year.

3. A recommendation for the concentration of medical and nursing expertise in a smaller number of centres of excellence was made as far back as 2001, in the report of the public inquiry into children's heart surgery at the Bristol Royal Infirmary. Since that time, there have been major improvements in outcomes, so that analysis of risk adjusted mortality for 2009-12, published this year by the National Institute for Cardiovascular Outcomes Research (NICOR), shows that no surgical unit has a mortality rate significantly above the "expected" rate, and on this evidence (for example, mortality rates alone) services are currently "safe".
4. For adults, around 850 surgical procedures and 1,600 interventional cardiology procedures are carried out each year and reported to NICOR by 25 hospitals in England, however a further 10 hospitals have undertaken procedures in recent years but not provided data to NICOR.

### **The safe and sustainable review**

5. The safe and sustainable review was established in 2008, with a view to reconfiguring surgical services for children with CHD. Taking into consideration concerns that surgeons and resources may be spread too thinly across the centres, the review considered whether expertise would be better concentrated in fewer sites.
6. At the end of the four year programme, in July 2012, a joint committee of Primary Care Trusts (JCPCT) made a series of decisions on the future of children's congenital heart services in England, covering:
  - the development of congenital heart networks,
  - service standards,
  - improving the collection, reporting and analysis of outcome data, and
  - the configuration of surgical services, which would have reduced the number of centres providing children's heart surgery from ten to seven, with surgery ceasing at Leeds, Leicester and the Royal Brompton.
7. The decision regarding configuration resulted in two separate challenges: a judicial review (JR), and referrals to the Secretary of State, who in turn asked the Independent Reconfiguration Panel (IRP) to consider the JCPCT findings.
8. The JR was decided on 7 March 2013, when the High Court declared that both the consultation process and the decision making process of the JCPCT were unlawful and quashed the decision to reconfigure surgical services. The judgement was based on a narrow point of process and the Court recognised "the compelling and urgent clinical case for the reform of existing paediatric congenital cardiac services" stating that the judgment should not be "construed as advocating a need to return to the start of the consultation process". Following legal advice, NHS England initially sought leave to appeal this decision but - in the light of the IRP's report and the Secretary of State's response (see below) - has since withdrawn this request.
9. The IRP were of the view that children and adults with CHD in England and Wales would benefit from services commissioned to national standards for the whole pathway of their care. They agreed that congenital cardiac surgery and interventional cardiology should only be provided by specialist teams large

enough to sustain a comprehensive range of interventions, round the clock care, training and research. However, the IRP concluded that the JCPCT's decisions were based on "flawed analysis of incomplete proposals and their health impact, leaving too many questions about sustainability unanswered and to be dealt with as implementation risks".

### **Addressing the IRP findings**

10. On 12 June 2013 the Secretary of State announced in Parliament that he accepted the IRP's advice, and that "the [Safe and Sustainable] proposals cannot go ahead in their current form". He went on to say that "it is right we continue with this process, albeit in a different way" and that "NHS England now must move forward on the basis of these clear recommendations".
11. The IRP's report highlighted the need to align the review of children's CHD services with ongoing work to consider the provision of adults' CHD services. Since the same surgeons operate on the same patients at different times in their lives, there are considerable dependencies between adults' and children's services, especially in the availability of surgical teams to provide 24/7 cover.
12. The IRP were also concerned that while the Safe and Sustainable process received 75,000 responses to its public consultation, some stakeholders were nonetheless left feeling that their views were not fully heard or understood, or that they were not given all the information they needed to contribute fully. This in turn created, for some, the perception of a pre-determined outcome.
13. The IRP's report called for NHS England to develop a strategic framework for commissioning that reflects the complex interdependencies between specialised services provision and population need as a context within which any decisions about congenital heart services should be taken.
14. Importantly, neither the Courts, nor SofS nor IRP have questioned the need for change to ensure the resilience, sustainability and excellence of these services.

### **The challenge for NHS England**

15. The challenge for NHS England is how to ensure that services for people with congenital heart disease are provided in a way that achieves the highest possible quality, within the available resources, now and for future generations:
  - Securing the best outcomes for all patients, not just lowest mortality but reduced disability and an improved opportunity for survivors to lead better lives.
  - Tackling variation so that services across the country consistently meet demanding performance standards and are able to offer resilient 24/7 care
  - Delivering great patient experience, which includes how information is provided to patients and their families, considerations of access and support for families when they have to be away from home
16. To do this, we need to develop a process which is as transparent and inclusive as it can be, particularly in the use of evidence and data. Almost as important as the thoroughness of our work will be the need to be seen to be engaging as widely as possible, bringing patients, clinicians and their representatives together

in the joint pursuit of an effective and equitable solution, in the interests of all service users now and in the future. What we do for CHD services will in some ways be seen as a template for whether and how NHS England undertakes other major service change in future.

17. It is widely acknowledged that the uncertainty which has been caused by recent developments is one of the greatest risks to the current delivery of the service. Patients and families are now unsure about precisely where and how they will receive treatment. Surgical centres are hamstrung in their planning, and recruitment and retention is made more difficult by the lack of a clear service model. This in turn creates a risk that the safety and quality of services may not be able to be maintained, that service levels could reduce or there could be unplanned closure(s). Charities, clinicians and other stakeholders gave a huge commitment to support change; many say they are demoralised, frustrated, exhausted and angry. Some doubt that there is the will to make the necessary changes happen.
18. These concerns need to be addressed as part of the new process. To support this measures designed to give commissioners early warning of any emerging concerns at units providing children's congenital heart services will be rolled out across the country, (and to adapt it to include adult services) accepting that it is still a developmental approach, and used as the basis of regular conversations between area teams and providers. A system will be established to ensure that aggregated information is regularly provided to the board committee.
19. In the light of all this, NHS England must bring forward an implementable solution within a year, ie by the end of June 2014. Given the complexity of the issues, the enlarged scope (children AND adults), the legitimate but differing views of stakeholders, and the need to build as much consensus wherever possible (in circumstances where some of the relationships have been badly bruised) this is a demanding but important ambition. We simply cannot re-run the previous process and hope to achieve a different outcome in a quarter of the time.
20. Instead, we must find ways to do this differently. As the sole national commissioner of specialised services NHS England has an opportunity not open to our predecessors. This creates a significant opportunity to drive service improvement including reduced variation in access and quality. We can focus on national standards for a national service, commissioned through a single model which enables us to drive change in the interests of patients.

### **Principles / Approach**

21. We propose the following principles and approach:
  - **Patients come first:** the new review must have patients and their families at its heart, with a relentless focus on the best outcomes now and for the future. That aim over-rides organisational boundaries.
  - **Retaining what was good from earlier work:** although the JCPCT's decision on configuration of children's congenital heart services has been overturned, much else was developed as part of that process and the subsequent implementation programme including a model of care, service standards, and well-developed thinking about network working. Similarly standards for adult services have also been developed and are ready for

formal consultation. This work has had extensive clinical and patient input and has the potential to be applicable to whatever service configuration is decided. Therefore NHS England must work with stakeholders to determine how much of this work can be retained.

- **Transparency and participation:** NHS England is committed to openness, transparency and participation. We should work with user, clinical and organisational stakeholders to ensure that we develop an approach to take the work forward that is true to those values. Our work should be grounded in standards, rigour, honesty and transparency.
- **Evidence:** the IRP reflected criticism of the way in which Safe and Sustainable used evidence to support its conclusions. The new review will need to be clear about the nature and limitations of the available evidence, and about any intention to rely on expert opinion in the absence of evidence. Notwithstanding the comment above about “retaining what was good”, we must have no preconceived notions about the outcome. Wherever there is an assumption it must be made explicit, and justified.

22. We have not attempted to develop a full plan describing how the work will be taken forward, because we want to take time to understand from stakeholders what was good and should be retained from the previous process and what did not work well. We believe however that it is likely that a standards driven process – developing, testing, adopting and applying best practice standards for every part of the pathway – has much to commend it, and we will be testing this with stakeholders.

### **Governance**

23. The Board has established a committee which will provide formal governance of this work. The committee is chaired by Sir Malcolm Grant, Board Chairman, and includes Margaret Casely-Hayford and Ed Smith (non-executive directors), Sir Bruce Keogh (Medical Director), and Bill McCarthy (National Director for Policy). To support the committee, arrangements will be put in place for clinical, organisational and service user representation.
24. Bill McCarthy is the senior responsible officer for this work. John Holden (Director of System Policy) will co-ordinate the work within NHS England and ensure the full involvement of the many different stakeholders.

### **Stakeholder engagement and communications**

25. We are drawing up a stakeholder engagement plan, based on how these stakeholders tell us they wish to be involved, and identifying the different groups, their preferred channels of communication and the key messages throughout the process. For example we know that some of the existing surgical centres have well established patient groups and using these channels may be one way to reach the majority of those most directly affected. For patients, families and their representatives we have sought expert external help from three charities - National Voices, Involve and Centre for Public Scrutiny (CFPS) – to help us design and implement effective and appropriate engagement. They can also

help us manage our risks (eg CFPS are experienced in working with oversight and scrutiny committees and can help us better understand the local government dimension). Due to their limited size these bodies are unable to be directly involved in the work but all have agreed to act in a mentoring capacity. For clinicians, Sir Bruce is convening a clinical advisory panel which will guide him throughout the process and will help design broader clinical engagement and address specific issues which may arise. He has identified the need for some international perspective on this work and will take some soundings from his international peers to determine how best international advice is provided.

26. Our communications will be as open and as often as possible – we have already initiated a fortnightly blog on the NHS England website where we will trail forthcoming meetings and provide a summary of recent progress and discussions. With the support of the NHS England Director of Communications and his team, we are also considering the potential for dedicated web pages, or other IT applications which allow documents and other information to be freely exchanged. We want to give anyone who is interested a simple and easy to use way to find out what is going on and to become involved. We will use social media as appropriate – and if our stakeholders find it helpful – to discuss and share information. We are also considering how we can address the needs of those who do not have access to the internet or do not use English as a first language.

### **Resources**

27. We need to take this opportunity to review the resourcing of this work. It will be important to ensure that it is a priority for the whole organisation and that the resources of the whole organisation are appropriately mobilised to support the work. The cost of dedicated programme management and administrative support will be met from recycling funds previously reserved for the Safe and Sustainable process. The estimated annual cost of this support is £500k.

### **Conclusion**

28. As the body responsible for commissioning specialised congenital heart services, NHS England is setting out ambitious plans to ensure that services for people with CHD are provided in a way that achieves the highest possible quality within the available resources. To achieve this, a new Congenital Heart review is being established to consider the whole lifetime pathway of care for people with CHD. The Board is asked to consider and comment on the proposed approach.

**Bill McCarthy**

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**July 2013**

## **Annex 1: Programme Plan**

Our indicative timetable is follows:

### Phase 1 – up to October 2013

Co-design a process for the work going forward

- Take advice from external experts to help shape listening exercise *[done]*
- Review previous stakeholder input in order not to lose what has already been achieved; and check its continuing relevance with stakeholders *[under way]*
- Begin communications as per stakeholders preferences, eg blog, shared resources on webpage/sharepoint *[under way]*
- Agree approaches to participation, identify preferred communications channels

Establish the programme

- Establish governance, advisory and stakeholder arrangements *[under way]*
- Develop programme plan, update Board, secure agreement, update Secretary of State *[under way]*
- Identify resources *[underway]*

Initial work on how to achieve programme aims of higher quality services

- Agree with stakeholders what should be taken forward from previous processes
- Complete work on proposed paediatric cardiology standards *[underway]*
- Bring together adult and children's standards and agree process for approval and adoption *[underway]*
- Develop proposals for testing/implementing formal network arrangements *[underway]*
- Work with stakeholders to identify any fixed points and how these would influence service design. This is likely to include (but not be limited to) discussion of the provision of transplant services, the need for children's heart surgery and other tertiary paediatrics to be provided on the same site, and the need for children's and adults' surgery (and interventional cardiology) to be provided in close proximity
- Develop a "proposition" – not a list of sites, but a straw man of what a high quality and sustainable service looks like for adults and children, unconstrained by current configuration – the optimal model
- Consider and weigh, with legal advice, possible approaches for a managed process to translate these fixed points into firm proposals for structuring services, test with stakeholders, outline agreed process
- Establish the required capacity of the service in future years
- Set an ambitious timeline to have completed the work and be ready to implement.

### Phase 2 – up to February 2014

Develop, test and revise the proposition

- Using multiple channels, including local and national clinically led events, engage on the clinical appropriateness and user acceptability of the proposition



- Benchmark existing provision against the proposition – considering access as well as service quality
- Test any emerging alternative proposals
- Review dependencies – eg for children, neonatal and paediatric intensive care (PICU) and retrieval services, extracorporeal membrane oxygenation (ECMO). While the IRP recommended that decisions about the future of transplant services and respiratory ECMO should be contingent on final proposals for congenital heart services, in practice the level of interdependency may mean that they need to be considered together
- Weigh alternative implementation approaches: early thinking suggests that some fixed points could constitute 'hurdle criteria' for potential providers within a commissioner led standards driven approach, however alternative approaches need to be considered including option appraisal and designation and provider led regional solutions.
- Agree revised proposition with clinical and patient groups

### Phase 3 – up to June 2014

#### Preparation for implementation

Work in this phase will of course be dependent on the nature of the proposition developed and the measure of agreement with that approach.

- If the solution is for a national plan in which current centres continue/cease to provide surgery, then – subject to legal advice - there may need to be further full formal consultation. This could take the timeline for implementation beyond one year.
- If the solution is a commissioning approach to enforce a set of national standards which invites providers to cooperate to provide the service, any consultation could be undertaken sub-nationally as part of the development of tenders. Assuming local resolution and provider cooperation, the focus of this period would be on developing the tender exercise.