

## Appendix 7: Evidence base for the new standards & specifications

The development of standards has been at the heart of the review; they describe how services should be organised, both adult and paediatric, at each of three levels of the service. Few of these standards are informed by direct clinical evidence, but represent the best advice from expert clinicians and patient representatives.

“In my experience, the amount of quantitative scientific evidence available to guide us in deciding how best to organise health services is often much less than we would like. In these circumstances we rely heavily on the views of experts, both specialist clinicians and those who are expert because of their experience of using the services in question. The views of experts, while qualitative rather than quantitative, are also valid and an important source of evidence in our deliberations.”

**Professor Sir Michael Rawlins, Chair, new CHD review Clinical Advisory Panel**

We commissioned a review of the international literature<sup>1</sup> conducted by SchARR at Sheffield University. Their report focused on two questions:

- What is the current evidence for the relationship between institutional and surgeon volume and patient outcomes and how is that relationship influenced by complexity of procedure and by patient case mix?
- How are patient outcomes influenced by proximity to/co-location with other specialist clinical services (e.g. co-location of services such as specialist cardiac paediatric intensive care)?

Good data on CHD activity and outcomes is also available from the National Congenital Heart Disease Audit run on behalf of NHS England by the National Institute for Cardiovascular Outcomes Research (NICOR). NICOR was asked to examine its data and to advise what this showed about service factors that could influence outcomes. We have also had extensive support from NHS England analysts, working with a range of data supplied independently, and from CHD clinicians and patient groups.

We have good data on post-operative mortality internationally and on 30 day mortality in this country, but the best data relates only to children’s services, and we have little information about longer term outcomes, morbidity or patient experience. Some believe that it is the lack of broader measures that hinders us in being able to show the benefits of larger scale services, arguing that 30 day mortality is a relatively insensitive indicator of good care. Without the data we cannot know the truth of this argument, but one of the review’s six objectives has been to develop proposals for a

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<sup>1</sup> Turner J, Preston L, Booth A et al, What evidence is there for a relationship between organisational features and patient outcomes in congenital heart disease services? A rapid review, School for Health and Related Research (SchARR), University of Sheffield, 2014

wider range of relevant timely metrics other than just 30 day mortality, to inform commissioners and support patient choice. These proposals will form part of the report we are bringing to the Board in July.

The evidence from published literature can guide our thinking on the scale of services. But the arguments for size of surgical teams, individual surgeon caseload and our approach to subspecialisation are inferred, and relate to the resilience and reliability of systems rather than to outcomes.

Overall then, there is a body of evidence to support most of the challenging standards, some of it from academic studies, some inferential, some based on expert advice. The nature of the evidence is such however that it does not give precise answers to questions about the organisation of the service, or show what size is too small or what size is big enough, and neither can this data be extrapolated to show what improvements in outcomes might be expected. As a result it cannot tell us whether the benefits gained would outweigh the risks of change – the upheaval, the cost, the upset, specialist care delivered further from some patients' homes<sup>2</sup>, the risk of destabilising some units or other services linked to or dependent upon CHD services. This has informed our thinking in seeking to develop solutions that give many of the benefits of working as part of a larger team, without the disruption of reconfiguration.

To avoid one of the pitfalls of *Safe and Sustainable* we have been very open about the limitations of the evidence base, and where we have therefore had to rely on judgement, and what the basis for that judgement is. We have published the minutes of every substantive discussion, bringing the debate into our various engagement groups. As a result, the vast majority of the proposed standards are uncontroversial and widely endorsed. But we readily concede that those standards where there has been most contention have been developed by listening to expert advice and argument, not by proving that there is sufficient weight of evidence from research. Our stakeholders know this and would expect us to be able to show the audit trail for any new proposals we now bring forward.

### *Evidence for the relationship between unit size and outcomes*

The SchARR literature review<sup>3</sup> identified a substantial number of studies reporting a positive relationship between volume and outcome and concluded that while the evidence demonstrates a relationship between volume and outcome in the majority of studies, this relationship is not consistent. The relationship is stronger for single complex conditions or procedures. It remains unclear whether the impact of volume

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<sup>2</sup> SchARR reported that two studies examined the relationship between distance from a specialist cardiac centre and mortality and both found no relationship between distance and mortality. NICOR found no association was shown with distance from home

<sup>3</sup> Ibid

on outcome is largely a consequence of higher volume units organising and providing a complex service with all the “right” components, or whether it remains an independent factor directly related to the advantages of dealing with a larger number of cases<sup>4</sup>. The lack of any UK studies to contribute to the review indicates a serious gap in evidence relevant to service provision in the NHS.

Two additional publications<sup>56</sup> on volume and outcomes were brought to the attention of the review. They were not included in the ScHARR review because they had not been published at the time it was written. Reviewing these studies CAP concluded that they confirm that generally, greater volumes are associated with better outcomes. They do not, though, conflict with the findings of the ScHAAR review; nor should they lead to changes in the volumes contained within the current set of standards. The study by Kansey et al was however notable in that it was based on European rather than American data.

The ScHARR review confirmed the findings of an earlier literature review<sup>7</sup> carried out for *Safe and Sustainable* which found that the literature confirmed the association of volume with in-hospital mortality, but that precise recommendations on volume thresholds were difficult. This review also found that the relationship was stronger with increasing complexity.

While the data linking larger units with better outcomes is widely accepted, it is not clear over what range this relationship holds. Most of the published evidence comes from the US where units operate across a much wider size range. As a result of the banding of centres into small, medium and large, units bigger than 350 operations per year are classified as large. This means that while studies show better outcomes at larger centres, it is not possible to determine whether even bigger centres would be better still. Much of the published evidence considers only paediatric volumes, and it is also unclear how these numbers should be applied to services that deliver both paediatric and adult services. Our smallest units are currently undertaking around 300 operations annually (240 paediatric operations)<sup>8</sup>.

As a result of stronger regulation and a centralised national health service, the UK is already in a far better position than both the US and many European countries in

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<sup>4</sup> The evidence is equivocal – some studies found lower complication rates in high volume centres; others found no association between volume and complication rates. Two studies found low volume centres were associated with longer length of stay. Two studies also assessed costs and both found a relationship of higher costs associated with low volume centres.

<sup>5</sup> Kansey A, Ebels T, Schreiber C et al Association of Center Volume With Outcomes: Analysis of Verified Data of European Association for Cardio-Thoracic Surgery Congenital Database. *Ann Thorac Surg* 2014;98:2159–64

<sup>6</sup> Karamlou T et al. Surgeon and Center Volume Influence on Outcomes After Arterial Switch Operation: Analysis of the STS Congenital Heart Surgery Database. *Ann Thorac Surg* 2014;98:904–11.

<sup>7</sup> Ewart E, The relationship between volume and outcome in paediatric cardiac surgery, PHRU Oxford, 2009

<sup>8</sup> Sources: National Congenital Heart Disease Audit, NICOR data for 2013-14; NHS England analysis.

having a consolidated paediatric CHD surgical service – a striking change since the original Kennedy Report, when the surgical centre in Bristol had been undertaking around 47 paediatric operations per year. At the time of the Munro report in 2003, six centres in England and Wales were doing fewer than 200 cases a year and two were doing fewer than 100. Since that time the paediatric surgical service at Oxford has closed, and in the past year surgical practice has ceased in Belfast.

In the context of the NHS in England, while published evidence gives support to the view that units should undertake at least 350 operations per year, interpretation of this is complicated by analysis of UK outcomes which showed no significant association between annual centre volume and 30-day survival outcome<sup>9</sup>. This complexity was recognised in our consultation document<sup>10</sup> where we stated that “the evidence did not tell us the best size for a specialist surgical centre. As a result our Clinical Advisory Panel told us that ... the evidence was broadly supportive of the relationship between volumes and outcomes, but did not provide a compelling argument for change.”

#### *Evidence for four surgeons in a team*

UK surgeons agree that teams of four surgeons are ideal, and some leading individual surgeons have argued passionately in our meetings for this to be the requirement. But the consensus view of the profession<sup>11</sup> is that three rather than four should be the minimum. This appears to be a change from the position during the *Safe and Sustainable* process when there was a consensus for teams of at least four and which is therefore reflected in the current service specification, in use today. This position was supported by the IRP in their recommendations<sup>12</sup>:

*‘Patients should receive congenital heart surgery and interventional cardiology from teams with at least four full-time consultant congenital heart surgeons and appropriate numbers of other specialist staff to sustain a comprehensive range of interventions, round the clock care, training and research.’*

The arguments in favour of larger teams are inferential rather than directly taken from research evidence. They relate to the pressure on individual surgeons working in smaller teams and the vulnerability of such services to the absence of one member of the team. Larger teams are also more able to subspecialise to handle rare, complex and innovative procedures.

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<sup>9</sup> Using data from 13 paediatric surgery centres, NICOR’s analysis of 12,186 episodes of care in paediatric heart surgery from April 2009 to March 2012 inclusive showed no significant univariate association between annual centre volume and 30-day survival outcome.

<sup>10</sup> Proposed congenital heart disease standards and service specifications: a consultation, NHS England, 2014

<sup>11</sup> Personal communication from David Barron, Society of Cardio Thoracic Surgeons

<sup>12</sup> Independent Reconfiguration Panel, Advice On Safe And Sustainable Proposals For Children’s Congenital Heart Services, 2013

The combination of professional, annual and study leave will mean that members of 3 surgeon teams will spend almost half the year working a 1:2 on call. The Royal College of Surgeons, the Royal College of Anaesthetists, the Royal College of Paediatrics & Child Health and the Royal College of Nursing all told our Clinical Advisory Panel that this was not acceptable. Norman Williams (then president of RCS) advised that the pressures this placed on individual surgeons could potentially jeopardise patient safety.

Despite this, surgeons who argue the case for larger surgical teams are not usually motivated by concerns about out-of-hours arrangements or work life balance. Rather, the number of surgeons is used as a proxy for the scale of the unit – perceived advantages being greater sub-specialisation within surgical teams, better supporting facilities and staffing, more attractive units for recruitment, and greater opportunities for training and research. These are not seen as ends in themselves, but as vital contributors to higher quality services that will improve outcomes.

Most of the evidence on the volume/outcome relationship comes from studies that examine centre volumes. Some studies have also examined individual surgeon volumes and most found decreased mortality with increasing surgeon volumes for complex procedures<sup>13,14</sup>. Some English centres, because of their size, see only low numbers of complex cases so that individual surgeons may do only one or two of each per year. Our proposals aim to improve this situation by ensuring that surgeons work in teams of at least four (with at least 500 cases between them, so that each team has higher numbers of complex cases) and by an explicit approach to sub-specialisation aimed at concentrating this work in the hands of fewer surgeons. So our proposed standard maintains the current requirement rather than lowering the bar to a “minimum of three”. However, by proposing four surgeons per team, rather than per unit, we create the potential for some flexibility in implementation, which is missing from the current standard.

#### *Evidence for 125 cases per surgeon*

Maintaining regular operative experience is fundamental to any surgeon, especially in technically demanding specialties like CHD. Two studies suggest a relationship between individual surgeon volumes and outcomes for adults with CHD - one study found outcome was associated with surgeon volume. Another found a similar association with adult procedure volume indicating the influence of expertise on outcome. The requirement in the proposed standards for a minimum of 125

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<sup>13</sup> Turner J, Preston L, Booth A et al, What evidence is there for a relationship between organisational features and patient outcomes in congenital heart disease services? A rapid review, School for Health and Related Research (SchARR), University of Sheffield, 2014

<sup>14</sup> Karamlou T, Jacobs M, Pasquali S et al, Surgeon and Center Volume Influence on Outcomes After Arterial Switch Operation: Analysis of the STS Congenital Heart Surgery Database, *Ann Thorac Surg* 2014;98:904–11

operations per surgeon has been strongly supported by the Society for Cardiothoracic Surgery, by the community of congenital cardiac surgeons themselves, and by the Royal College of Surgeons.

Inevitably the setting of standards involves ‘picking a number’, and in the absence of data with a clear inflection point, this number will be arbitrary. That is sometimes the source of criticism but this of course ignores the fact that any number would be arbitrary. Similar numbers have been recommended by earlier reviews: the European Association for Cardio-Thoracic Surgery report<sup>15</sup> recommended that each surgeon should perform 126 cardiac surgical procedures on adults or children; the *Safe and Sustainable* review<sup>16</sup> recommended a minimum of 100 paediatric and ideally 125 paediatric operations per surgeon. Job plans for consultant surgeons include between 1.5 – 2.5 operating days a week and we would expect every surgeon to deliver a minimum of 42 weeks clinical work per year. Thus, even at the most conservative end of the spectrum (and including a minimum of emergency work) a consultant surgeon should expect to do 150 cases minimum<sup>17</sup>.

Surgeons have been unanimous in saying that they feel that individual case numbers are the single most important statistic to apply in terms of ‘numbers’, and there is very little argument against 125 being a helpful and achievable minimum standard.

*Evidence for four interventional cardiologists in a team /no. of cases per cardiologist*  
The studies identified in both literature reviews related exclusively to surgical practice. Most studies of catheter procedures have been small in scale and as such the available evidence base on which to make recommendations for treatment is limited. The new proposed standards are based on current professional guidelines<sup>18</sup> and the advice we received from clinicians.

*Evidence for paediatric CHD co-location with other paediatric services*  
The SchARR review<sup>19</sup> found no evidence on the effects of proximity of other services other than PICU, so the proposed standards are based on expert opinion.

Our clinical advisers strongly supported co-location with other paediatric services, even though they recognised that not everyone agrees. The Clinical Advisory Panel<sup>20</sup> considered that this brought the standards for CHD services into line with expectations in other specialist children’s services. They noted that while

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<sup>15</sup> Optimal Structure of a Congenital Heart Surgery Unit in Europe, Congenital Heart Surgery Committee on behalf of the European Association for Cardio-Thoracic Surgery, 2003

<sup>16</sup> Safe and Sustainable: A new vision for children’s congenital heart services in England, NHS Specialised Services, 2011

<sup>17</sup> Barron D, Personal communication, 2014

<sup>18</sup> Recommendations for therapeutic cardiac catheterisation in paediatric heart disease, British Congenital Cardiac Association, 2012

<sup>19</sup> Ibid

<sup>20</sup> Minutes of CAP, 18 June 2014 <http://www.england.nhs.uk/ourwork/qual-clin-lead/chd/meetings/cap/>

responsiveness was important, it was not the only thing that mattered – the interaction between teams on a daily basis was also important. They considered that it was not safe to care for children with complex conditions and co-morbidities (a high proportion of whom will need input from other specialties) in settings where other paediatric services were not on site.

In consultation<sup>21</sup>, the majority of respondents supported our proposals (albeit with comments and suggestions). Patients told us that they need good access to these services, and that there need to be good working relationships between clinical teams, making sure that services work together in the patient's best interest. Some consider that the best way to achieve this is to have all the services on the same site.

#### *Evidence for paediatric CHD and adult CHD interdependency*

The new proposed standards require that within a surgical service, adult and paediatric CHD services have a close relationship, and that surgeons and interventionists are able to respond with a call to bedside time of no more than 30 minutes (whether the adult and paediatric services are on the same site or not). This recognises the interdependency and shared staffing of the two parts of the service but does not require co-location. This standard is based on the clinical advice we received.

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<sup>21</sup> Consultation on draft standards and service specifications for congenital heart disease services, *Dialogue by Design*, 2015.