

Standards for Congenital Heart Disease Services

1. Introduction

The new congenital heart disease review aims to ensure that:

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

The development of national standards to be applied through a national service specification is at the heart of the review's approach. This reflects the views of stakeholders from across the spectrum and is recognised in the review's objectives which commit to developing standards to give improved outcomes, minimal variation and improved patient experience for people with congenital heart disease.

This paper:

- describes the process to date in developing a single set of standards to cover fetal, paediatric and adult congenital heart disease care;
- presents the standards for review, discussion and approval by the clinical advisory panel as a suitable basis for full public consultation (following assurance by NHS England);
- highlights areas of potential controversy within the standards, describes relevant evidence and the views of stakeholders as expressed in pre-consultation engagement so far and makes recommendations on proposed standards to be tested in consultation; and
- sets out the expected process and indicative timetable for assurance, consultation and decision on the standards.

2. Background

At the beginning of the review three sets of standards were in existence.

- a) the paediatric standards developed by the *Safe and Sustainable* programme
- b) adult standards developed by a group established by the National Specialised Commissioning Team.

- c) further paediatric standards in development in response to the Safe and Sustainable Joint Committee of Primary Care Trust's (JCPCT's) mandate to develop further standards for tiers two and three of the service model – specialist and local children's cardiology centres.

Sir Bruce Keogh wrote to Professor John Deanfield (who had chaired the group that developed the adult standards¹) and Dr Tony Salmon (who was chairing the group developing the additional paediatric standards²) and asked them to ensure that a comprehensive and consistent set of standards was developed that would cover the whole pathway. Sir Bruce asked Professor Deirdre Kelly to oversee the process of bringing together the standards in to a single consistent set.

Sir Bruce was clear that as the aim was to ensure that services achieve the highest possible quality within the available resources, now and for future generations. It was quite likely that there would be some standards that were very challenging for existing providers. Further he stated that it was important that the standards represented the ideal – and that any issues that arise, if one or more provider was unable to meet some of the standards, would be managed by commissioners and did not need to be taken into account in setting the standards.

Sir Bruce also asked the two chairs to be clear about the nature and limitations of the available evidence and where it had been necessary to rely on expert opinion.

Dr Salmon's group has completely refreshed the paediatric standards with a particular focus on:

- cardiology;
- tiers 2 and 3 of the service; and
- harmonising the paediatric standards with the more recently developed adult standards.

Professor Deanfield and Dr Salmon have worked together to further harmonise the adult standards with the paediatric standards ensuring in the process that consistent language is used. They have taken advice from Mr David Barron, Chair of the congenital group of Society of Cardiothoracic Surgery (SCTS) and Mr David Anderson, Vice-President British Congenital Cardiac Association (BCCA) to ensure that the surgical perspective has been properly represented.

3. The Standards

a) Range

Proposed standards have been written for the following areas of service organisation and practice:

- The network approach

¹ See appendix 1 for membership of the group

² See appendix 2 for membership of the group

- Staffing and skills
- Facilities
- Interdependencies
- Training and education
- Organisation, governance and audit
- Research
- Communication with patients
- Transition
- Pregnancy and contraception
- Fetal diagnosis
- Palliative Care and Bereavement
- Dental

For each of these areas proposed standards have been developed for all three tiers of the hospital service:

- Specialist CHD Surgical Centres
- Specialist (Children's Cardiology/ACHD) Centres
- Local (Children's Cardiology/ACHD) Centres

While this is a wide ranging set of standards there are some areas of practice that have now been included in scope for the review for which standards have not been set, principally extra corporeal membrane oxygenation (ECMO) for children.

b) What's new in the paediatric standards?

The standards developed in the Safe and Sustainable process were approved by the JCPCT and were not subsequently challenged or overturned by the judicial review or Independent Reconfiguration Panel (IRP) review of that process. The standards were incorporated into NHS England's current specification for paediatric congenital heart disease services which has been operational since 1 April 2013.

Compared with the original Safe and Sustainable standards, the sections on 'Pregnancy & contraception', 'Palliative care, end of life and bereavement' and on 'Dental Care' are completely new.

c) What's changed in the paediatric standards?

Substantial changes have been proposed throughout the standards. Most of the proposed standards have either been amended or are new. Given this, it is impossible to summarise the changes, however significant changes are:

- the development of standards for Specialist and Local Children's Cardiology Centres has been so extensive as to be, in effect, a new development;

- standards relating to cardiology (rather than cardiac surgery) are now more developed across all three tiers of the service;
- standards relating to interdependencies have been completely re-worked. These are now no longer expressed in terms of geographic location (except for that small number of services and facilities which it is widely agreed must be on the specialist surgical centre site). The proposed standards recognise that while this would be the ideal arrangement for a much wider range of services, those services must function as part of the extended multidisciplinary team (MDT), and the responsiveness required for each supporting service (rather than location) is then defined in terms of the time from call to bedside or call to advice as appropriate; and
- revised proposals for surgeon numbers and surgical activity have also been developed. These seek to recognise the need for a developmental trajectory to reach new, demanding standards, whilst also providing assurance of service quality and resilience.

d) What's new in the adult standards

The standards developed for ACHD services were not formally adopted and as a result there is no current NHS England specification for this service. Nonetheless, the standards underwent two periods of extensive engagement and are thus quite widely known and understood. Compared with these standards, the sections on 'Palliative care, end of life and bereavement' and on 'Dental Care' are completely new.

e) What's changed in the adult standards

- Many minor changes to wording have been proposed throughout the standards to ensure harmonisation with the paediatric standards.
- A substantial number of standards have been added to ensure that whenever appropriate, there is always an ACHD standard to match each paediatric standard.
- Standards relating to interdependencies are now no longer expressed in terms of geographic location (except for that small number of services and facilities which it is widely agreed must be on the specialist surgical centre site). In most cases the standards now recognise that while this would be the ideal arrangement for a much wider range of services, those services must function as part of the extended multidisciplinary team, and the responsiveness required for each supporting service (rather than location) is then defined in terms of the time from call to bedside or call to advice as appropriate.
- Revised proposals for surgeon numbers and surgical activity have also been developed. These seek to recognise the need for a developmental trajectory to reach new, demanding standards, whilst also providing assurance of service quality and resilience.

3. Model of Care

The standards are built on a model of care common to both previous sets of standards. This proposes that:

- CHD surgery and intervention should only be undertaken by CHD specialists working in recognised specialist CHD centres; and
- CHD specialist surgical centres should all be set up in such a way as to be able to manage the vast majority of CHD. Designation of sub-specialist units is not proposed; rather a system is envisaged that ensures that every patient receives care from an appropriate surgeon/interventionist by facilitating the provision of support by experienced operators and centre to centre referrals.

Care should be delivered as locally as is clinically appropriate. To support this, standards have been developed for a three tier service – specialist surgical (and interventional) centres, specialist (medical) cardiology centres and local cardiology centres.

Hub and spoke provider CHD networks around each specialist surgical centre will have responsibility for ensuring that standards are met throughout the network, that joint pathways and protocols are adopted to smooth the patient journey and that effective working relationships are established with non-CHD services that CHD patients depend upon.

Paediatric and adult CHD services are fully integrated within each network, and even when specialist surgical and interventionist services for adults and children are provided on different sites, they must operate as a single, fully integrated service.

Each network will have one specialist surgical centre and a number of local cardiology centres. Whether a network has one or more specialist cardiology centres will be determined by local circumstances including levels of demand and geography.

4. Knotty Issues

A high degree of agreement has been achieved amongst the members of the two standards groups responsible for developing the standards. This has also been seen more widely among stakeholders during early pre-consultation conversations.

A number of issues were contentious during the earlier processes of standards development and these were therefore discussed in more detail with the review's clinician group and with the Clinical Reference Group (CRG). These issues and what we have heard so far are reported below. Following these discussions, only one standard remains contentious – that relating to the number of surgeons that should form the surgical team in each specialist CHD surgical centre.

a) Interdependencies

Three groups of interdependencies have been identified as important:

- Between paediatric congenital heart surgery and other tertiary paediatric and supporting services.
- Between adult congenital heart surgery and other adult tertiary and supporting services.
- Between paediatric congenital heart surgery and adult congenital heart surgery.

There has been detailed discussion about the requirements for the full range of service interdependencies resulting in detailed proposals. In each case the standard makes clear that the ideal would be for both services to be provided on the same site by groups of clinicians working as an extended multidisciplinary team. It would be hard to argue that care is improved by having the services on separate sites. This ideal cannot be achieved at present but it was considered important to state the ideal to inform the appropriate direction of travel in the longer term.

The detailed requirements are now principally expressed in terms of speed of response required from other services to give advice, intervene or take over care. Some of the detailed requirements will be likely to be very challenging for existing providers within the present arrangement of services.

Evidence and Opinion: the review is not aware of research evidence that informs the questions of service interdependency. The standards set represent the consensus of expert opinion of those clinicians who worked as part of the two standards groups. The review has asked the School of Health and Related Research (SchARR) and National Institute for Cardiovascular Outcomes Research (NICOR) to advise whether there is published evidence or data from English hospitals that should be taken into account when considering interdependency.

What we are hearing

- Co-location of paediatric congenital heart surgery with other paediatric services; and adult congenital heart surgery with other adult tertiary services is ideal; paediatric congenital heart surgery with adult congenital heart surgery is also ideal
- Other arrangements may be acceptable with appropriate responsiveness and integration
- Joint rotas and the need to minimise losses to follow up at transition mean that paediatric congenital heart surgery and adult congenital heart surgery need to be in close proximity if not co-located
- Excellent and timely communication and information sharing between specialties is essential

b) Surgeon numbers

There is consensus that surgeons need to work in teams. Both Safe and Sustainable and the ACHD advisory group set a standard that surgeons should work in teams of at least four to ensure resilient 24/7/365 service delivery with a reasonable work-life balance for surgeons. This is reflected in the existing paediatric CHD service specification, though not all units currently have four surgeons.

Teams of four surgeons would ensure:

- availability of a team of surgeons with a range of skills to be able to deal with the great majority of congenital heart surgery and concentration of expertise;
- coverage of all activities during the working day;
- enhances training, mentorship and succession planning: four surgeons in a group allows for dual consultant operating and a process of professional development; and
- most surgeons would prefer a 1:4 rota which will give a better work-life balance. Patients are entitled to receive their care from a surgeon who is fresh enough to give of his/her best. Taking account of annual leave, research commitments, conference attendance and so on, each surgeon is available to participate in the on-call rota for approximately 42 weeks per year. On a 1 in 3 rota there would therefore be 30 weeks of the year when one of the surgeons was unavailable and the others were therefore working a 1 in 2 rota. This is not considered acceptable.

There has been renewed professional debate about this standard with some arguing that three surgeons are sufficient. Others have argued equally strongly that four is the minimum. This was reflected in the opinions of the paediatric standards sub-group which could not reach agreement on this standard.

Following discussion with surgical representatives, the chairs of the two standards group therefore formulated a proposed standard, which has been presented to and discussed by the review's clinician group and the CRG. This states:

A Consultant Congenital Cardiac Surgeon must not partake in an on-call rota more frequent than 1:4 (requiring a minimum of four surgeons). In centres with three surgeons, there will be the potential for commissioners to agree a 1 in 3 rota for a defined period while working towards a 1 in 4 rota.

This change recognises that not all centres presently have four surgeons while setting a clear direction of travel.

The number of interventional cardiologists has also been specified but this has not been controversial.

Evidence and opinion: the review is not aware of research evidence that informs the question of surgeon numbers.

What we are hearing

- Agreement with the principle that teams of four surgeons are ideal but concern about the practicalities of implementation and the impact on units.
- While important, surgeons consider this a less important determinant of quality than the number of cases per surgeon - if there was a choice for a 400 procedure unit between 3 surgeons achieving 125 cases and 4 surgeons not achieving 125 cases, the former is preferable.
- All surgeons agree that a 1 in 2 rota is not acceptable.
- Some surgeons believe that a 1 in 3 rota is acceptable.

- Some surgeons believe that a 1 in 4 rota should be the minimum that all centres aim for, not least because a 1 in 3 rota is 1 in 2 for 30 weeks of the year
- On-call is not usually onerous except in transplant centres, where a 1 in 5 rota (or better) may be appropriate.

c) Surgical volumes

Safe and Sustainable set a standard that each centre should deliver at least 400 paediatric operations annually, sensibly divided between the four surgeons.

The ACHD standards set a standard that each surgeon should undertake at least 125 operations per year (paediatric or adult). All surgeons now support this standard.

Congenital cardiac surgeons 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).

The minimum volume of activity to be undertaken by interventional cardiologists has also been specified. This has not been controversial.

Evidence and Opinion: there is evidence of a general relationship between surgical volumes and good outcomes.

There is evidence showing a general relationship between individual surgeon activity and outcomes. However the review is not aware of research evidence that gives directly relevant evidence. The review has asked ScHARR and NICOR to advise whether there is published evidence or data from English hospitals that should be taken into account when considering surgical volumes.

Most of the CHD literature has focussed on unit volumes. At present no standard is proposed for unit volumes. This position will be reviewed once the results of the literature evaluation commissioned from ScHARR and the further analysis of English data commissioned from NICOR are available.

What we are hearing

- Surgeons consider this standard vital to ensure quality and regard 125 cases as the absolute minimum
- Standards need to be set to reflect our view of best practice

d) Sub-specialisation

Neither of the previous sets of standards explicitly described an approach to sub-specialisation. The potential for sub-specialisation was been raised with the new review both by the patient and public engagement and advisory group and the provider engagement and advisory group.

Professional opinion has largely agreed with the position adopted by Safe and Sustainable that teams of four surgeons each undertaking 125 procedures per year would be sufficient to ensure the availability of the skills to undertake the great majority of operations and that rare and complex cases can be managed within appropriate clinical governance frameworks.

However, some have suggested that at least some centres should be bigger and that they should be specifically designated to undertake more specialist work.

The proposed standards state:

Consultant interventional paediatric cardiologists and congenital cardiac surgeons must only undertake procedures for which they have the appropriate competence. In other cases, either:

- a. the support of a competent second operator/interventionist must be obtained from within the network or another Specialist Children's Surgical Centre; or*
- b. the patient must be referred to an alternative Specialist Children's Surgical Centre where a surgeon/interventionist has the appropriate skills.*

A related standard states:

Arrangements must be in place in each Specialist Surgical Centre both for consultant interventional cardiologists and for congenital cardiac surgeons to operate together on complex or rare cases.

This seeks to recognise the concerns expressed by patient representatives by making explicit the expectations of the service including collaboration between surgeons and between centres. This is further reinforced in another proposed standard:

SSCs and networks must work together to develop and support national, regional and network collaborative arrangements that facilitate joint operating, mentorship and centre to centre referrals.

Evidence and Opinion: the review is not aware of research evidence that directly informs the questions of sub-specialisation in congenital heart surgery. The standards represent the consensus of expert opinion of those clinicians who worked as part of the two standards groups. The review has asked SchARR and NICOR to advise whether there is published evidence or data from English hospitals that should be taken into account when considering subspecialisation.

What we are hearing

- surgical centres should be set up in such a way as to be able to do the vast majority of CHD surgery with no further formal sub-specialisation
- a two tier service could emerge if some centres were designated for sub-specialist work. There is evidence that second tier centres would contract and decline

- it is important for individuals and units to recognise their limitations - the standards should consider the need for competent teams not just individual surgeons/interventionists
- networks should manage competence through peer review and audit
- the service should support:
 - the free movement of surgeons to mentor and work alongside other surgeons for difficult cases; and
 - the managed introduction of new techniques.

e) Congenital surgery only by specialist congenital surgeons

Both Safe and Sustainable and the ACHD advisory group agreed that congenital heart surgery should only be undertaken by specialist congenital surgeons. The new review has followed this line. This has not been controversial amongst CHD professionals. The benefits are considered to relate to improved decision making following discussion of patients at a specialist MDT, enhanced data collection and improved governance arrangements as well as the more obvious assurance that comes from the involvement of a specialist surgeon/interventionist.

However it is likely that this standard is not currently being met as a number of non-specialist adult cardiothoracic surgery units are understood to be undertaking congenital heart surgery. It is therefore likely that these standards may be controversial amongst general adult cardiothoracic surgeons.

The agreed position that will be recommended for consideration by the Clinical Advisory Panel are standards that state:

All paediatric cardiac surgical cases must be carried out by a specialist paediatric congenital cardiac surgical team with expertise and experience in paediatric cardiac disease. All adult congenital cardiac surgical cases must be carried out by a specialist congenital cardiac surgical team with expertise and experience in adult congenital heart disease.

All paediatric congenital cardiology must be carried out by specialist paediatric cardiologists. All adult congenital cardiology must be carried out by specialist ACHD cardiologists.

Specialist Surgical Centres in partnership with the Congenital Heart Network and NHS commissioners will establish a model of care that delivers all aspects of the care and treatment of [patients] with congenital heart disease. The model of care will ensure that all congenital cardiac care is carried out only by congenital cardiac specialists (including investigation, cardiology and surgery).

Evidence and Opinion: the review is not aware of research evidence that directly informs this issue. The standards set represent the consensus of expert opinion of those clinicians who worked as part of the two standards groups. In general non-specialist units do not submit data to NICOR and it will therefore not be possible to use this data source to inform this question.

What we are hearing

- Inside the CHD world this is non-controversial so people are puzzled that it is identified as a knotty issue.
- Representatives of ACHD patients tell us that this is their number one concern.

5. Next Steps

a) Assurance

The timetable and critical path for approval to consult on the standards is shown below:

March 2014 – June 2014

- impact assessments (equalities/finance/workforce)
- develop service specifications with CRG
- seek CRG approval for service specifications and standards
- Programme of Care Board and Clinical Priorities Advisory Group (CPAG) reviews
- Gateway and Directly Commissioned Services Committee (DCSC) reviews

June 2014

- CAP agree standards for consultation taking account of:
 - views from pre-consultation; and
 - evidence from NICOR and SchARR

Summer 2014 – 12 week (minimum) consultation.

Autumn/Winter 2014 – analyse and consider consultation responses.

2015 – commission against the new specifications.

Further work needs to be done to agree in detail the relationship between the review's governance and NHS England's business as usual arrangement, with particular attention needed on decision making in relation to the contents of the standards and adoption of the service specification.

b) Engagement and Consultation

Additional work needs to be undertaken on pre-consultation engagement as well as detailed planning for consultation itself. The outline timetable is expected to be:

February – June 2014 – pre-consultation engagement with engagement/advisory groups including:

- targeted engagement (groups most affected);
- visits to specialist providers; and

- joint engagement/advisory group event to sense check the standard and build the consultation content.

Summer 2014 – 12 week (minimum) consultation.

Autumn/Winter 2014 – analyse and consider consultation responses.

6. Conclusion

The Clinical Advisory Panel (CAP) is asked to approve the standards presented in order that following NHS England's assurance process they can be subject to full public consultation. In doing so, CAP is asked to note that while the standards represent a consensus view of best practice, they are not being universally achieved by existing services and are not necessarily deliverable by the present service configuration. The costs of meeting the standards and the workforce and training requirements will be examined as part of the assurance process. Approaches to commissioning and change to ensure that the standards are fully implemented will be developed later in the work of the review (objectives 3 and 4).

CAP will review the standards again before consultation to ensure that feedback from pre-consultation, the views of the CRG, and additional evidence from SchARR and NICOR can be taken into account. Final decisions on the standards to be incorporated into NHS England's service specification will only be taken after consultation and after giving full consideration to the views expressed during consultation.