Report to the Joint Committee of PCTs by Dr Patricia Hamilton CBE, Chair of the *Safe and Sustainable* Steering Group, on behalf of Steering Group members

This paper sets out the Steering Group's further advice to the JCPCT having taken into account the evidence submitted by respondents during public consultation

17 October 2011

1. Introduction

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1.1 As an outcome of public consultation Steering Group members have received and considered the following evidence:

i. Report on the outcome of consultation published by Ipsos Mori on 23 August 2011
ii. Report on the outcome of focus groups held by Ipsos Mori, published on 25 August 2011
iii. Responses to consultation made by organisations by letter or email (and a summary of such responses prepared by the secretariat)
iv. Report on the consultation events dated August 2011
v. Notes of the meeting between the Steering Group and members of the British Congenital Cardiac Association held on 12 July 2011
vi. Health Impact Assessment interim report dated August 2011

1.2 Additionally, a number of Steering Group members were present at public consultation events as members of the panel (attendance details are provided in the summary report on the consultation events).

1.3 This paper sets out the Steering Group's further advice to the JCPCT having taken this evidence into account. The Steering Group's advice to JCPCT Members was agreed at a meeting of the Steering Group on 13 September 2011 and covers the:

i. Proposed *Safe and Sustainable* standards for Specialised Surgical Centres
ii. Proposed model of care that envisages the development of congenital heart networks across England comprising Children's Cardiology Centres and District Children's Cardiology Centres
iii. Recommendations made by the Steering Group for improving the monitoring and reporting of outcome data
iv. Implementation of the JCPCT's eventual decision
v. Responses to consultation on which the Steering Group's advice has been sought on relevant clinical issues

2. Proposed *Safe and Sustainable* standards for Specialised Surgical Centres

2.1 Having considered the evidence submitted during public consultation Steering Group members advise the JCPCT to agree the standards as set out in the consultation document.

2.2 Steering Group members further advise the JCPCT to accept the additional standards as set out in Appendix A subject to further advice that is being sought from the British Association of Perinatal Medicine around proposed standards A29 to A31 (the Steering Group's final advice will be reported at the meeting of the JCPCT in November 2011).

3. Proposed model of care

3.1 Having considered the evidence submitted during public consultation Steering Group members advise the JCPCT that the proposed model of care is viable. Specific elements of the model of care considered by the Steering Group are as follows:

Viability of the proposed Children's Cardiology Centres (CCCs)

3.2 Steering Group members were conscious that this issue has generated significant debate during consultation and that the medium to long-term viability of the CCCs has been questioned by some respondents; these concerns are based around the potential loss of specialist expertise at these centres given the JCPCT's proposal that they do not provide interventional cardiology services in the future.

3.3 Steering Group members advise the JCPCT that the CCCs are a viable proposition, and they are mindful of existing precedents such as the successful transition of the Cardiff centre from a surgical centre to a non-interventional cardiology centre in the past decade.

3.4 However, there are potential risks that need to be managed. When surgery is lost to a cardiology unit, a potential risk is that there may be insufficient motivated staff to make the CCC model work. Based on the Cardiff experience, staff turnover may be high. After an unsteady three years following the decision to cease surgery the service was made stable, due in part to the appointment of a cardiologist dedicated to making the model work. The inducements for retaining key staff could include favourable job plans, clear PAs for joint working and sufficient allowance in job plans for travel.

3.5 Steering Group members recommend that designation standards are developed for the CCCs and that potential risks are addressed during the phase of implementation.

Role of the proposed Children's Cardiology Centres / Interventional Cardiology / Diagnostic Catheterisation

3.6 Based on existing professional guidance the JCPCT's consultation document proposed that CCCs do not provide interventional cardiology services nor diagnostic catheterisation services given the (small) risk of an emergency requiring surgical support.

3.7 On 13 September Steering Group members received a briefing from the President of the British Congenital Cardiac Association (BCCA) which suggests that the revised professional guidance (due in October 2011) is likely to continue to recommend that interventional cardiology services should only be performed in designated surgical centres; but that diagnostic catheterisation may be performed in the proposed CCCs. On the understanding that this description is reflected in the impending BCCA guidance the Steering Group members advise the JCPCT to reflect this guidance in the model of care and the standards for the Specialised Surgical Centres and the CCCs.

3.8 Steering Group members further considered the delivery of Electrophysiology (EP) for children with congenital heart disease. As with interventional cardiology and diagnostic catheterisation there is a small risk of an emergency requiring surgical support. Steering Group members advise that that the provision of EP can be delivered outside of a designated surgical centre provided that the local congenital heart network has developed clear protocols, including a consideration of local governance arrangements, and that local network governance arrangements determine the size and weight parameters for undertaking interventional EP on children without paediatric surgical backup. Steering Group members emphasise that children requiring EP should be seen in dedicated children's services, not adult services as is current practice in some parts of the country. It is recommended that this advice is reflected in future standards for CCCs.

Role of the proposed District Children's Cardiology Services

3.9 Steering Group members advise that the proposed District Children's Cardiology Services – which envisage a local service delivered by Consultant Paediatricians with

Expertise in Cardiology - is a viable proposition. Further work will be required during the implementation phase to establish appropriate governance arrangements across the network and to develop standards against which the DCCS will be measured.

4. Recommendations made by the Steering Group for improving the monitoring and reporting of outcome data

4.1 Steering Group members advise the JCPCT to agree the proposals for improving the monitoring and reporting of outcome data as set out in the JCPCT's consultation document.

5. Implementation issues

5.1 Potential impact to Paediatric Intensive Care Units (PICU)

5.1.1 In de-designated centres, a decrease in caseload resulting from the loss of cardiac work will have effects on staff retention in the first place then, potentially, recruitment.

5.1.2 In de-designated centres, there will be an expectation that the PICU can still meet demands of its catchment, particularly seasonal winter surges. Discussions held within the Steering Group have highlighted that PICUs that lose cardiac surgery may then lose the ability to flex their bed numbers by decreasing cardiac surgical throughput on a seasonal basis. This extent to which this flexibility can be extended to the PICUs that retain cardiac surgery is uncertain as these units will then be under pressure to perform more cases overall and with lower rates of cancellations than tolerated previously (as per the proposed standards).

5.1.3 Consequently, there may need to be a continuing investment in non-cardiac PICUs to avoid winter crises.

5.1.4 Cardiology is an essential service to PICU patients to detect hitherto undetected underlying cardiac disease, be that congenital or acquired. It was accorded 'Amber 3' status in the *Critical Interdependencies Framework* (meaning that it does not 'necessarily' require co-location with PICU) but care must be taken to preserve cardiology services in de-designated centres.

5.1.5 Already there are difficulties associated with admitting children from areas that border the catchments of other tertiary centres, particularly when they suffer from multiple conditions. These families can then be subject to

disparate referral patterns where they may be seen in two or even three different tertiary centres. In creating new referral flows to support the new cardiac surgical options, the congenital heart networks will need to develop mitigation strategies to ensure that such fragmentation of care is not exacerbated.

5.2 Potential impact to retrieval services

5.2.1 Steering Group members advise the JCPCT that the precise ramifications for retrieval services cannot be known until the JCPCT has made a decision on the future configuration of congenital heart networks. However, some potential difficulties are self-evident.

5.2.2 In all of the options submitted for consultation larger numbers of critically ill children will move over greater distances. However, the Steering Group advises that this does not present increased risk to the child provided the options comply with the maximum journey time thresholds as set out in the Paediatric Intensive Care Society standards for the care of critically ill children. The evidence is that these distances have not been shown to be associated with increased risk.

5.2.3 As an outcome of reconfiguration there may be more District General Hospitals that are relatively remote to the surgical centre. Some experience of this already exists in England such as the South West Peninsula and its relationship with the Bristol centre, and Great Yarmouth and its relationship with London. The evidence is that these distances have not been shown to be associated with increased risk. However, there is consensus within the Paediatric Intensive Care Society that, in the context of sparse and hitherto unreliable air transport infrastructure in the UK, the current limits of transfer times as set out by PICS standards are realistically safe limits. In the Northeast and Yorkshire Regions, for example, if one of the two cardiac surgical units ceases cardiac surgery the remaining unit will need to reach all the populations at the other 'extremity' through a working partnership with the other retrieval team (and perhaps other surrounding teams) with clearly defined operating procedures and, almost certainly, significant investment. The same principles would potentially apply to the South Central England,

Southwest England, East Midlands and Wales depending on the JCPCT's eventual decision.

5.2.4 Consequently, consideration needs to be given to consolidating the remaining retrieval services that have not amalgamated. In the last eighteen months, three new amalgamated services have been commissioned with sustainability and economies of scale in mind: 'NEWTS' (Liverpool & Manchester), serving NW England & NW Wales; 'WMPRS' (Stoke & Birmingham) serving the W Midlands; and 'EMBRACE' (Leeds & Sheffield) serving Yorkshire & Humberside. London already has two large, amalgamated transport services, CATS & STRS. This leaves Newcastle, Leicester, Nottingham, Southampton, Oxford, Bristol & Cardiff as un-amalgamated unit-based services. The JCPCT's proposal for Congenital Heart Networks across England supports the case to form further acute transport groupings in the future. Experience of setting up the other amalgamated services shows that this needs to be financially supported.

5.2.5 The matter of transfer of children back from the surgical centre was discussed at the Steering Group. It was suggested that retrieval services should be commissioned in such a way that 'repatriating' children back to local services should be part of the contract with both the retrieval service and ambulance providers.

5.3 Potential impact on workforce

5.3.1 The Steering Group is aware that some respondents have suggested during consultation that potential impacts on the NHS workforce must be identified and assessed by the JCPCT as part of the process for agreeing a final configuration option. However, the Steering Group agrees with the JCPCT's position as set out in the consultation document, which is that the potential impact of reconfiguration on the workforce cannot be determined with confidence before the JCPCT has made a final decision and, as such, should not be a consideration in the JCPCT's process for agreeing a final decision. Rather, this is an issue for implementation, and it will be important for the Congenital Heart Networks and commissioners to identify and resource education and training requirements, particularly for nurses.

6 The following sections of this report provide the Steering Group's response to submissions made to the JCPCT during consultation and on which the JCPCT has sought clinical advice from the Steering Group.

6.1 Rare and complex procedures

6.1.1 A number of respondents have suggested that the delivery of 'rare and complex' surgical procedures should be restricted to a very small number of designated surgical units, reflecting a recommendation in the report of the Bristol Inquiry in 2001.

6.1.2 Steering Group members advise the JCPCT that 'rare and complex' procedures are not currently defined; in any event they would not advise that rare and complex procedures are restricted to a smaller number of centres. Steering Group members do not consider that reconfiguration poses particular risks for rare diagnoses and they advise that the impact of reconfiguration to the delivery of rare and complex procedures can be managed within appropriate clinical governance frameworks. This is because Steering Group members are reassured that the relevant concerns set out in the Bristol report in 2001 can be safely addressed by the larger, expert surgical centres proposed by the JCPCT; a rigorous clinical governance framework across the national congenital heart network (with the active participation of commissioners, providers, professional associations and lay organisations) will enable a safe service planning for rare and complex procedures across the network.

6.2 Nationally commissioned services

6.2.1 The JCPCT has received opposing evidence about the significance that the JCPCT should attach to the current location of the nationally commissioned services.

6.2.2 Steering Group members advise the JCPCT that the recommendations of the separate expert panel that reported on nationally commissioned services in 2010 remain valid. While the re-location of a nationally commissioned service presents some potential risks, these risks can, in the view of the Steering Group, be managed.

6.3 Analysis of mortality data

6.3.1 It has been put to the JCPCT during consultation that Professor Spiegelhalter's analysis of mortality data (which was published following the separate review of the paediatric cardiac surgical service at the John Radcliffe Hospital in 2010) should be applied by the JCPCT to differentiate between high quality and low quality surgical units.

6.3.2 The Steering Group's previous advice was that owing to a low national caseload and difficulties in adjusting for complexity, mortality outcomes should not be used to identify potential configuration options. As such, mortality outcomes have not been analysed by the JCPCT[1] or played any part in the development of configuration options.

6.3.3 The Steering Group does not advise the JCPCT to apply an analysis of mortality data in the future process for agreeing a configuration option for the reasons previously explained.

END

[1] Except for the limited purpose of receiving Mr Pollock's report in response to the publication of Professor Spiegelhalter's analysis in December 2010

Appendix A
Proposed additional standards

Background

In full term babies the *ductus arteriosus (arterial duct*) usually closes naturally within the first few days of life. In babies born prematurely it may remain open ('patent') resulting in extra blood flow through the lungs – this may delay / prevent weaning from the ventilator. It is the practice to refer these babies for surgical ligation of their patent *ductus arteriosus* (PDA). These babies are cared for in the Neonatal Intensive Care Unit / Special Care Baby Unit and the practice in some centres has been for the neonatal team to transfer the baby to the surgical centre for operation. With larger surgical teams in the Specialist Cardiac Surgical centres, alternative pathways may be developed.

	Designation Standard	Measures	Compatible Evidence Base	Status
A29	As the sole exception to the *Safe and Sustainable* standards which stipulate that heart surgery on children must be performed in a designated Specialist Surgical Centre it is permissible for neonates with *patent ductus arteriosus* (PDA) to receive surgical ligation in the referring neonatal intensive care unit (level 3) provided that the visiting surgical team is despatched from a designated Specialist Surgical Centre and is suitably equipped in terms of staff and equipment.	Written protocols	Gould D et al (2003) 'A comparison of on-site and off-site Patent Ductus Arteriosus ligation in premature infants', Pediatrics Vol 112, 6	**Mandatory**
A30	It will be for each Congenital Heart Network to determine whether this arrangement is optimal (rather than transferring the neonate to the Specialist Surgical Centre) according to local circumstances, including a consideration of clinical governance and local transport issues.	Written protocols		**Mandatory**
A31	All Congenital Heart Networks must have clear protocols that address the provision of surgical ligation for neonates with PDA.	Written protocols		**Mandatory**

Background

A number of participants at consultation events sought reassurance that surgical centres will continue to be audited against the standards once the designation process has concluded. This proposed standard does not stipulate a timetable for future audits (that is for the commissioning body to stipulate outside of the standards document) but it does ensure that the standards themselves and the outcome of future audits are widely publicised.

	Designation Standard	**Measures**	**Compatible Evidence Base**	**Status**
E14	Specialist Surgical Centres must make parents and carers aware of the *Safe and Sustainable* standards and the outcome of audits of compliance. As a minimum this will include publishing the *Safe and Sustainable* standards on the centre's website and informing parents of their existence in first appointment letters and other relevant literature.	Patient / parent literature Compliance audits	National Service Framework for Children, Young People and Maternity Services (2003 and as modified).	**Mandatory**