Safe and Sustainable
Paediatric Congenital Cardiac Services

NHS

Specialised Services

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Dear Councillor Mulherin

Thank you for your letter of 7 September 2011 and for an opportunity to clarify the issues that you have raised.

Regarding your comment about how options have been developed, I would like to refer you to the detailed pre-consultation business case as evidence of the degree of analysis and consideration that has been applied by the JCPCT in its deliberations.

In response to your specific questions:

1. No centres have been included in options solely on the grounds of 'population', but rather on the grounds of high caseloads and the ability of other surgical centres to assume these caseloads were surgical centres with high caseloads to be removed from potential configuration options (population levels are of course a good indicator of a caseload in any individual centre but are not in themselves sufficiently informative to evaluate potential configuration options).

For example, Birmingham Children's Hospital has been included in all options because the JCPCT concluded that its very high caseload (555 surgical procedures) could not reasonably be met by other surgical centres taking into account existing caseloads at other centres and reasonable travel times. Similarly, the JCPCT concluded that the combined caseload for the London centres (around 1,250 surgical procedures covering London, South East and Eastern England) could not be reasonably met by one surgical centre in London, or by other surgical centres outside of London were there to be no surgical centre in London.

By contrast, Leeds Teaching Hospitals NHS Trust has a relatively low caseload (316 surgical procedures in 2009/10, and 336 in 2010/11). The JCPCT's analysis did not suggest that other surgical centres in potential configuration options would struggle to assume the Leeds caseload were the Leeds centre removed from potential configuration options.

In your letter you refer to Alder Hey Children's Hospital. This centre was not included in all options on the grounds solely of its own caseload (400 surgical procedures) but because the retention of Alder Hey was a reasonable recommendation after applying the following two working principles:

i. The population and caseload suggests a need for two surgical centres in the North of England, as there is insufficient forecast activity to reasonably suggest the retention of three centres
ii. A potential option that comprised the Freeman Hospital and Leeds Teaching Hospital NHS Trust (at the exclusion of Alder Hey Children's Hospital) would not be viable as for both centres to achieve a minimum of 400 surgical procedures (as required by the Safe and Sustainable standards) would require significantly unreasonable changes to patient flows and clinical networks.

Because of this, only options which included Liverpool and Leeds or Liverpool and Newcastle were considered.

You also refer in your letter to the surgical centre in Bristol, but this centre has not been included in configuration options on the grounds of population or caseload.

2. I am advised that Leeds Teaching Hospitals NHS Trust received the maximum score of 'excellent' for current co-location of services, and a very high score for how those services could continue to be delivered in the event of an increased caseload. These high scores reflect the provision of on-site services that you describe in your letter. However, the Trust was also assessed against its ability to meet other quality standards and when considered in the round, the Trust received the second lowest score of all eleven surgical centres.

3. Professor Sir Ian Kennedy's panel advised that none of the current surgical units have developed networks that fully comply with the *Safe and Sustainable* standards, but the panel acknowledged the strength of the current network in Yorkshire and Humber by assessing it as 'strong'. However, the panel also identified a number of gaps in compliance and as such the network was not described as 'exemplary'. As I describe above, the Trust was assessed

against a number of different standards and the cumulative conclusions of the panel led to Leeds Teaching Hospital being awarded the second lowest score.

4. It is not correct that 'all surgical centres are theoretically capable of delivering the nationally commissioned Extra Corporeal Membrane Oxygenation (ECMO) service'. During the assessment process, all centres were asked whether they would be able to provide nationally commissioned services, including ECMO for children with severe respiratory failure. Leeds Teaching Hospitals NHS Trust submitted an application to deliver ECMO services but the application was declined as the panel was not confident that the Trust had demonstrated that it had the appropriate skills and infrastructure to deliver respiratory ECMO for children.

5. Travel and access was considered as part of the options appraisal process, although the parents and clinicians with whom we consulted on the matter recommended that it receive the lowest of the criteria used for arriving at the final options for consultation. The model of care that we describe in the consultation document proposes to reduce travel times for the many families who currently travel long distances to receive treatment by bringing non-interventional assessment and follow-on care closer to the homes of children with congenital heart disease by establishing these services in local hospitals. All of the options for consultation also ensure that the children in Yorkshire and the Humber can be reached by a specialist retrieval time in compliance with the standards around emergency retrieval times set by the Paediatric Intensive Care Society (PICS).

6. The detailed breakdown of scores will be made available once the JCPCT has concluded its deliberations. This is because the JCPCT members agreed last year that they did not wish to see the detailed breakdown of scores while they continued their work. Scrutiny committee members and other stakeholders have therefore received the same level of detail that has been shared with the JCPCT members themselves.

7. Despite the potential impacts to families to which you refer, it is important to note that the outcome of the recent public consultation was overwhelming support for the need for reconfiguration of services. The issues that you have described have been explored during options-appraisal process, as well as during the consultation. Patients, their families and carers, clinicians and the public have told us about this during engagement events, undertaken while the options were developed, as well as at the consultation events, and responses to the consultation. Focus groups with young people and their families were run to explore these issues in depth. A Health Impact Assessment has been undertaken by an independent expert third party to explore, assess and analyse the positive and negative

impacts resulting from the proposed changes , and the measures to enhance and mitigate these, on patients and the public with particular emphasis on the vulnerable groups. Locally, workshops were run by an independent third party in Leeds, Bradford and Kirklees to assess impacts of the proposed changes on vulnerable groups. The *HIA Scoping Report*, *Key Emerging Findings from Phases 1&2*, and the *HIA Interim Report* have been published and shared with HOSCs and LINKs. The JCPCT will consider the independent final HIA Report, as well as the independent qualitative report from Ipsos Mori. Additionally, the Safe and Sustainable standards provide for improved facilities for families in the designated surgical centres, including family accommodation.

8. The NHS is reviewing the provision of congenital cardiac services via two separate but related reviews. The view of experts, endorsed by the Steering Group in December 2008 and by the SCG Directors Group in 2009, was that the immediate concerns around safety and sustainability related to the paediatric element of the service. The process for the designation of adult congenital services will proceed in 2011 with reference to the separate standards that have been developed by a separate expert group and which were published in 2009.

9. Any adult congenital heart surgery is over and above the 3600 procedures for children (u16s). The current number of operations on adults is less than 870 p.a. (CCAD), so approximately 20% of the national caseload on congenital heart surgery is adult. This is likely to grow at a faster rate than children's surgery given that more children are surviving into adulthood. Nevertheless the analysis that has been undertaken to date suggests that no centre will be overwhelmed by this additional activity. The HOSC should be aware that as a separate exercise a review of adult congenital heart surgery is being undertaken which will conclude where this surgery will take place and will have the benefit of the conclusions of the paediatric heart surgery review to support it.

10. The review has assessed the impact of inter-dependent services and their sustainability. This is outlined in both the pre-consultation business case and the consultation document. The JCPCT will now consider evidence around inter-dependent services (including paediatric intensive care services) that has been submitted during consultation before making a final decision.

11. Please see Annex A.

12. The remit of the review is services in England and Wales. Responsibility for the NHS in Northern Ireland rests with the devolved administration in Northern Ireland. However, the

secretariat publicised the consultation and encouraged the population of Northern Ireland to take part in the consultation via advertisements in local newspapers in Northern Ireland.

13. I understand that EMBRACE has presented to the JCPCT and to the OSC an analysis of potential retrieval times relevant to Yorkshire and the Humber. Furthermore, ambulance services were invited to sit on the Safe and Sustainable Steering Group and the separate group that developed the quality standards. They are also represented on the Health Impact Assessment Steering Group. The Health Impact Assessment has taken into account the impact of the proposed changes on the provision of ambulance services. Retrieval times have been considered and analysed. The proposed times for retrieval comply with the Paediatric Intensive Care Society (PICS) guidelines. The proposed Safe and Sustainable clinical standards include a mandatory requirement that there must be 'an appropriate mechanism for arranging retrieval and timely repatriation of patients'.

14. The JCPCT recognises that improved training processes will need to be put in place for clinical staff and the independent expert panel, chaired by Professor Sir Ian Kennedy, has also concluded that 'the succession planning for surgeons must be a key consideration for the future delivery of paediatric cardiac service.' The professional associations representing surgical, medical and nursing staff who sit on the steering group (which is chaired by the Director for Medical Education for England) and other experts with whom we have consulted (for example in the Deaneries) have advised that this is an issue for the implementation phase of the review rather than the assessment phase.

15. I am unsure as to what you mean by 'training records' and I would be grateful if you were to clarify your question so that I may provide an answer.

16. As I have explained previously, the scope of the review is services in England and Wales. The small number of cases that flow from Scotland and Northern Ireland to English surgical centres have been taken into account by this review. However, the catchment area for Newcastle does not include Scotland as the children's heart surgical unit in Glasgow is part of the Scottish devolved administration's responsibility and therefore outside the scope of the *Safe and Sustainable* review.

17. A review of the surgical centre in Glasgow is not within the remit of the JCPCT and I believe that NHS Scotland is best placed to answer your question.

Yours sincerely

Sir Neil McKay C.B.

Chair of the Joint Committee of PCTs

Annex A

Compliance of the *Safe and Sustainable* consultation with the *Code of Practice for Consultations*

Criterion 1
Formal consultation should take place at a stage when there is scope to influence the policy outcome.

The formal public consultation on the proposals to improve children's congenital heart services was launched at the time when no decisions have been made on the number or location of the surgical centres, nor on the proposed standards and model of care, and the consultation has provided an opportunity to shape the proposals, bring forward relevant evidence and to submit alternative options for the JCPCT's consideration.

Additionally, informal consultation took place in the early stages of the Safe and Sustainable Review.

Patients and the public were invited to give their comments on the proposed clinical standards via an extensive public engagement exercise in the autumn of 2009, which included a national stakeholder event in October 2009.

Nine public engagement events were held in major cities across England between June and July 2010. The events were widely publicised in collaboration with local NHS commissioners, surgical centres and local interest groups. All events were well attended by parents, children, NHS staff, local scrutiny representatives and the media. At these events participants had the opportunity to put questions to a panel of experts. Written reports on the events were provided to the JCPCT so that the issues raised could be taken into account when developing criteria for the evaluation of options and in further development of the proposed clinical model of care.

From summer 2009 *Safe and Sustainable* has published a quarterly newsletter setting out background information, progress to date and future steps in the review process. A website provides background information and documents relating to the review, including detailed minutes of Steering Group meetings and Standards Working Group meetings and relevant reports. This enables the public to keep up to date with the process for the development of the draft standards and the review process.

In September 2010 the Office of Government Commerce undertook an independent review of the way in which the NSC Team had managed the *Safe and Sustainable* Review. The report was positive and the Review was particularly commended for "excellent clinician, patient and key stakeholder engagement". Similarly in September 2010 the National Clinical Advisory Team undertook an independent review of the clinical case for change driving the Review and the review was commended for the level of engagement with NHS staff and the public.

A number of briefings tailored to specific interest groups were published before and during the formal consultation. For example, in August and October 2010 every Health and Overview Scrutiny Committee in England and every Local Involvement Network in England were briefed about the Review. A briefing for every Member of Parliament was published in September 2010 which encouraged them and their constituents to take part in consultation events. In November 2010, a briefing was published for the Chief Executive of every local authority in England and in March 2011, for every General Practitioner in England.

Criterion 2

Consultation should normally last at least 12 weeks with consideration given to longer timescales where feasible and sensible

The consultation was launched on 1 March 2011 and ended on 1 July 2011. It lasted four months, one more month than the 12 weeks as recommended above. The consultation has been extended to over 7 months for Health and Overview and Scrutiny Committees (up to 5 October 2011).

Criterion 3

Consultation documents should be clear about the consultation process, what is being proposed, the scope to influence and the expected costs and benefits of the proposals.

Consultation literature has clearly explained the background for the need for change, the process followed to deliver options for consultation, and the process of consultation itself.

The outcome of the financial assessment is set out in the Pre-Consultation Business Case and Consultation Document. The benefits, as well as risks and proposed mitigation of risks associated with the proposed changes are outlined in the consultation documentation.

The outcome of the Health Impact Assessment was published in all key stages – in February 2011, the HIA Scoping Report was published, with Key emerging findings from Phases 1 and 2 published in June 2011 (during consultation, as set out in the guidance), and the Interim HIA Report was published in August 2011.

The response form included a mixture of open and closed questions, thus giving consultees an opportunity to express their views on issues not specifically addressed in the questions.

Criterion 4

Consultation exercises should be designed to be accessible to, and clearly targeted at, those people the exercise is intended to reach.

The consultation was targeted at different audiences. As many as 2,086 people attended 16 consultation events. These included three workshops specifically for young people, as well as a consultation document written for young people specifically. There were around 40 focus groups and workshops with parents, children, vulnerable groups, including BAME communities, supplemented by additional phone interviews and family interviews. The *Safe and Sustainable* review team has worked with clinicians, commissioners and voluntary sector to raise awareness of the consultation, in England, Wales, Scotland and Northern Ireland. During the consultation, the documentation was available in 12 languages: English, Welsh, Chinese, Polish, Hindi, Urdu, Gujarati, Punjabi, Bengali, Somali, Farsi and Arabic.

This resulted in more than 75,000 responses, making it one of the biggest consultations in the NHS. Around 20% of responses came from Black and Ethnic Minority (BAME) groups, and 10% from young people, a reflection of the high degree of awareness raised among these groups.

Criterion 5

Keeping the burden of consultation to a minimum is essential if consultations are to be effective and if consultees' buy-in to the process is to be obtained.

Safe and Sustainable has kept the burden of the consultation to a minimum by consulting at the formative stage. The consultation response form was available online and was user-friendly (for example, username or password was not required to respond to the questions).

Criterion 6

Consultation responses should be analysed carefully and clear feedback should be provided to participants following the consultation.

The consultation responses were analysed by Ipsos MORI, the independent expert third party, to ensure the analysis is independent and objective. The feedback was provided by publicising the outcome of the consultation in the national and local media, and on the *Safe and Sustainable* website. The responses that were received from organisations via letters or emails were published in full on the *Safe and Sustainable* website. The consultation documentation includes a high-level implementation plan. The response form includes the name of the Consultation Coordinator, to whom the consultees could submit comments about the consultation process.

Criterion 7

Officials running consultations should seek guidance in how to run an effective consultation exercise and share what they have learned from the experience.

A Consultation Coordinator was appointed and named in the consultation documentation as the person to contact with any queries or complaints regarding consultation process. Lessons learned are being shared within the organisation with those who are planning to consult.