

## Scope and Interdependencies (updated)

### Introduction

1. Patients, clinicians and the public have been asked to advise on what services and conditions should be included in the scope of the new review. NHS England proposed three categories (in scope; out of scope; to be determined).
2. Over 50 responses were received and the feedback is recorded below. The comments below are not exhaustive and Members should refer to the full original responses as provided.
3. It was apparent from the responses received that not enough explanation had been given to respondents which had led to some misunderstanding of the concept of scope. Despite this, the responses received were relevant and helpful.
4. At the Board Task and Finish Group it was proposed that the question of scope was not simply a question of 'in scope' or 'not in scope' but was rather more of a spectrum. In response to this helpful observation and to assist Members in their deliberations, four categories are now proposed. NHS England plans to engage with all four categories as appropriate:
  - a) The congenital heart disease service
    - The standards for this service will be developed as part of the new review of congenital heart disease services.
  - b) Patients with conditions that are not congenital heart disease, but receive their care wholly or mainly from congenital heart services
    - The service for these conditions will not be reviewed as part of the new review of congenital heart disease services, but the standards being developed may address aspects of the service.
  - c) Services that are not congenital heart disease services but which congenital heart disease patients may use as part of the congenital heart disease pathway.
    - The standards for these services will not be reviewed as part of the new review of congenital heart disease services. Any impact on these services will be considered prior to decisions being taken and during implementation. The use of these services by congenital heart disease patients to these services will be considered by the review.
  - d) Services that are not part of the congenital heart disease pathway, but that are reliant on clinical support or backup from CHD specialists.

- The standards for these services will not be reviewed as part of the new review of congenital heart disease services. Any impact on these services will be considered prior to decisions being taken and during implementation.

## In scope

5. A number of services were originally listed as potentially being in scope. Respondents agreed. Some asked that the categories be further clarified. Services that were considered to be within scope were:
  - a) Improving the quality of care of people with suspected or diagnosed congenital heart disease along the whole patient pathway:
    - Fetal diagnosis of congenital heart disease.
    - Pre-natal care (including care of women whose unborn child has suspected or confirmed congenital heart disease).
    - Care for children and young people.
    - Transition from children's services to adult services.
    - Care for adults.
    - End of life care
  - b) Care and support for families suffering bereavement and / or poor outcomes from surgery or other intervention for congenital heart disease.
  - c) The review covers all care for congenital heart disease commissioned by the NHS for people living in England.
6. Guy's and St Thomas' NHS Foundation Trust stated: *'We are fully supportive of all the aspects listed as being within the scope of the review enabling a complete view of the service for patients with congenital heart disease from antenatal diagnosis through childhood and transition into adulthood and including support of the family.'*
7. A cross party group of Parliamentarians wrote: *'it makes no sense to exclude Scottish congenital heart surgery services from the scope of this Review. We remain one United Kingdom and if services can be coordinated cross-border between Northern Ireland and the Irish Republic, why cannot this be so within our own country? The NHS Constitution gives patients the right to make choices over their healthcare; that right should become a reality for congenital heart disease people living in the far north of England through access to Scottish services as it is for those in the South.'*

## Out of scope

8. NHS England set out a number of services which it considered to be out of scope of the new review of congenital heart disease services. Responses to these services are set out below.

**Neonatal, paediatric and adult intensive care unit (ICU) services and transport and retrieval services.**

9. A number of respondents have recommended that neonatal, paediatric and adult intensive care unit (ICU) services and transport and retrieval services should be within the scope of the review.
10. The Children's Heart Surgery Fund stated: *'It makes no sense to exclude travel and access from the scope of this review and would fly in the face of the Health Secretary's affirmation that the new Review would take full account of the IRP report.'*
11. Leicestershire HOSC stated that it *'is concerned that the document does not include the following as "in Scope": ECMO Services, Paediatric Intensive Care Services. We believe that the Independent Reconfiguration Panel's report at recommendations Six and Eleven would point to these two services as being "in Scope".'*

**Other interdependent clinical services (for example other tertiary paediatric services).**

12. Great Ormond Street Hospital for Children NHS Foundation Trust stated: *'It is important that the necessary interdependencies are included in the review (currently out of scope – Section 7, item 5). It is crucial that there is urgent 24/7 access to many other specialities, in particular for in-patient hospital care (e.g. ENT, general surgery, ICU, anaesthesia, neurology, respiratory medicine, nephrology, haematology, etc).'*
13. One respondent stated<sup>1</sup>: *'Any major reorganisation of congenital cardiac services, that does not include the impact and on-going effects on other allied tertiary specialities is almost bound to be flawed, and likely to lead to unintended consequences if not appropriately factored into any decision-making.'*

**Local maternity services.**

14. Central Manchester University Hospitals NHS Foundation Trust wrote: *'We believe that the provision of complex or specialised maternity services for women with congenital cardiac disease requires more detailed consideration and is paramount. Whilst adults with congenital cardiac disease are within the scope of the review, local maternity services are not. It is important to consider the sub-set of women who are pregnant and require specialist obstetric care, either because of maternal cardiac disease or foetal cardiac disease. In our experience, care for such women is not always available locally, and effective care for this cohort is vital in ensuring a positive outcome for mother and baby. The co-location of obstetrician, paediatric cardiologist and surgeon provides the best access for mother and child, creates the service with optimum opportunity for favourable outcome, and minimises the risks of separation. As such, services for this group of women should be considered within the scope of the review.'*

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<sup>1</sup> Where respondents appeared to be writing in a personal capacity as opposed to on behalf of a group or organisation, their responses have been anonymised.

15. Bristol Congenital Heart Unit wrote: *'The current proposal for Scope does not make clear the plans for cardiac obstetric services. We are unclear about the meaning of "local maternity services". Comprehensive cardiac obstetric services are an essential component of an adult congenital heart service. However, most cardiac obstetric clinics cater for both congenital and acquired heart disease in pregnant women. It would be helpful to clarify plans to cover this aspect of care. In our view cardiac obstetric services should be part of the review.'*

**Some general comments on the 'out of scope' section were received:**

16. Guy's and St Thomas' NHS Foundation Trust wrote: *'We recognise the need for the boundaries to the services included in the review and would agree that those listed as being out of scope are not the primary focus of this particular review. We would however like to stress the importance of interdependencies within both children's and adult services. High quality neonatal, paediatric and adult intensive care, transport and retrieval services are essential to ensure a high quality Congenital Cardiology and Cardiac Surgery service. Adults with congenital heart disease require the full range of medical, surgical and obstetric services and the interdependency of other tertiary Paediatric services has been well established. The review process will need to consider how these important linkages and their impact on the quality of Congenital Cardiac Services are taken into account.'*
17. One respondent stated: *'All three excluded issues strike me as entirely central to arguments about the whole life pathway and the standards of patient care. In the absence of reasoned justification, the most likely explanation seems to be that some of your preferred "winners" do rather badly on these assessments, which are therefore being discounted and ignored.'*
18. Leicester City Council wrote: *'The excluded services, those not intrinsically linked to the treatment of congenital heart disease itself, as in the out of scope list, but which are used by patients with congenital heart disease or related to services for them, require robust pathways for access. Thus detail of the managed linkages to be made in the course of the review with these services is to be welcomed.'*
19. A cross party group of Parliamentarians wrote: *'By excluding intensive care, neonatal and maternity services from the scope of this review, we are concerned that this would repeat the mistake of the Safe and Sustainable Review (as attested by the Save Our Surgery judicial review outcome) by effectively disregarding the value of gold-standard co-located services to quality congenital heart services. As clinicians told the IRP: "co-location with specialist children's services [is] as significant to the quality of service as the size of the team and scale of the activity of the specialist surgical centre."*
20. The Chair of the Joint Health Overview and Scrutiny Committee (Yorkshire and the Humber) wrote: *'There are concerns that service areas such as neonatal, paediatric and adult intensive care unit services and local maternity services are currently deemed to be outside the scope of the review. Such matters were intrinsic elements of the Safe and Sustainable Review and are referenced within the associated standards documents... It also seems illogical to exclude transport and retrieval services as part of a national service review that aims to deliver a national service to national standards. Transport and retrieval services will be vital elements of the service into the future – particularly if the*

*outcome of the review results in fewer surgical centres. There will need to be clear and consistent standards for transfers and retrievals.'*

### **To be determined**

21. A number of services were identified whose inclusion in scope was to be determined. Responses are set out below.

#### **Children, young people and adults with congenital heart arrhythmias.**

22. Respondents recommended that children, young people and adults with congenital heart arrhythmias should be included in the scope of the review.
23. One respondent wrote: *'It is vitally important that services for children, young people and adults with congenital heart arrhythmias are in scope for the review. Management of rhythm disturbances is an essential element of the Congenital Heart Disease pathway.'*

#### **Children and young people with acquired heart disease.**

24. Respondents recommended that children and young people with acquired heart disease should be included in the scope of the review.

#### **Children and young people with inherited heart disease.**

25. The majority of respondents to this service supported its inclusion within the scope of the review.
26. One respondent recommended that children and young people with inherited heart disease should be excluded from scope, 'except [for] a reference to include relationships to genetic services'.

#### **Adults with inherited heart disease.**

27. A number of respondents supported including adults with inherited heart disease within the scope of the review; a smaller number recommended that adults with inherited heart disease be excluded from scope.
28. One respondent recommended that adults with inherited heart disease should be excluded from scope, 'except [for] a reference to include relationships to genetic services'.
29. One respondent stated: *'My proposal to include adults with inherited cardiac disease might seem controversial and I do not wish to suggest that all such services need to be within a congenital heart centre. However, where the potential care of a child with cardiac disease is involved (as will be the case where an inherited cardiac condition is diagnosed in*



*parent/sibling etc) then I believe the review needs to take a view and provide standards etc.'*

### **Cardiac extra corporeal membrane oxygenation (ECMO) for children and young people.**

30. Respondents to this category supported the inclusion of cardiac ECMO for children and young people.
31. The Evelina Children's Heart Organisation stated: "*...for surgery on the more complex conditions (transplant included) cardiac ECMO is absolutely intrinsic and vital.*"
32. Leicester City Council stated: "*We would support the inclusion of ECMO from the outset, as from the evidence we took during our scrutiny process it is apparent that ECMO is an essential part of the treatment of congenital heart disease in children.'*"
33. One respondent wrote: "*ECMO and complex tracheal surgery services are closely inter-linked with cardiac surgery (i.e. must be able to provide cardiac ECMO if undertaking cardiac surgery; and complex tracheal surgery requires bypass capability). While any decision about these services may therefore "follow" the decision on configuration of cardiac surgical services, this dependence and the order of decision-making needs to be clear in the review.'*"
34. One respondent stated that it would be "*better termed Mechanical Circulatory Support (MCS) as this term covers ECMO and all other forms of support which are not mentioned (e.g. VAD).'*"

### **Respiratory ECMO for children and young people.**

35. Many respondents supported including respiratory ECMO for children and young people within the scope of the review, however a smaller number disagreed and said that it should be excluded from scope.
36. Leicester City Council stated: "*We would support the inclusion of ECMO from the outset, as from the evidence we took during our scrutiny process it is apparent that ECMO is an essential part of the treatment of congenital heart disease in children.'*"
37. One respondent stated: "*The scope MUST include respiratory ECMO, Tracheal Surgery and Cardiothoracic transplantation as these are inherent components of delivering congenital heart services. None can be delivered without complete dependence on paediatric cardiac surgery services. To exclude them from the review would fail to acknowledge the essential interdependence of these services.'*"
38. Children's Heart Surgery Fund stated: "*We note that the role of respiratory ECMO and heart transplant services in the scope of the review is to be determined. We would warn the new Review against repeating the mistake of its predecessor by overemphasising the importance of the location of existing heart transplant and extracorporeal membrane oxygenation (ECMO) services. We believe that neither is central to the determination of the location of the provision of paediatric cardiac services and whilst we appreciate the*

*need for them to be considered, we believe that the Review should abide by the IRP's Recommendation 11 that "decisions about the future of cardiothoracic transplant and respiratory ECMO should be contingent on the final proposals for congenital heart services."*

### **Cardiac extracorporeal life support (ECLS) for adults.**

39. Many respondents supported including ECLS for adults within the scope of the review, however a small number disagreed and said that it should be excluded from scope.
40. One respondent stated that it would be *'better termed Mechanical Circulatory Support (MCS) as this term covers ECMO and all other forms of support which are not mentioned (e.g. VAD).'*
41. East Midlands Congenital Heart Service stated: *'This needs to be more clearly defined; if in the context of ECPR (resuscitation) then no, if in the context of providing post operative cardiac support then this is mandatory to support any ACHD surgical programme in the same way as for a paediatric service.'*

### **Respiratory ECMO for adults.**

42. The majority of respondents to this service recommended that respiratory ECMO be excluded from the scope of the review, however a small number felt that it should be included within the scope of the review..
43. One respondent stated: *'adult respiratory ECMO functions completely independently of adult congenital heart disease and would not be relevant.'*

### **Complex tracheal surgery.**

44. Respondents supported the inclusion of complex tracheal surgery to the scope of the review. One respondent, however, questioned the relevance, stating: *'not clear how his relates'*.
45. One respondent stated: *"The scope MUST include respiratory ECMO, Tracheal Surgery and Cardiothoracic transplantation as these are inherent components of delivering congenital heart services. None can be delivered without complete dependence on paediatric cardiac surgery services. To exclude them from the review would fail to acknowledge the essential interdependence of these services.'*
46. Alder Hey Children's NHS Foundation Trust: *'ECMO and complex tracheal surgery services are closely inter-linked with cardiac surgery (i.e. must be able to provide cardiac ECMO if undertaking cardiac surgery; and complex tracheal surgery requires bypass capability). While any decision about these services may therefore "follow" the decision on configuration of cardiac surgical services, this dependence and the order of decision-making needs to be clear in the review.'*

**Heart transplant and bridge to transplant services for child and young person.**

47. Respondents supported the inclusion of heart transplant and bridge to transplant services for child and young people.
48. One respondent stated: *“The scope MUST include respiratory ECMO, Tracheal Surgery and Cardiothoracic transplantation as these are inherent components of delivering congenital heart services. None can be delivered without complete dependence on paediatric cardiac surgery services. To exclude them from the review would fail to acknowledge the essential interdependence of these services.”*

**Heart transplant for adults.**

49. Many respondents supported the inclusion of heart transplant for adults within the review, but some disagreed.
50. One respondent stated: *‘The item “heart transplant for adults” is wrongly worded and it should be worded “heart transplants for adults with congenital heart disease”. It is extremely important that this matter is included within the review.’*
51. One respondent recommended that this item *‘should say heart and lung transplantation (some patients will need both with congenital heart disease) – could use the term cardiothoracic transplantation.’*

**Other suggested areas for inclusion:**

52. A number of other areas to be included within the scope of the review were suggested by respondents as detailed below.
53. Birmingham Children’s Hospital wrote: *‘Networks of Care, and precisely what such Networks entail, are also fundamental to successful implementation, and patient and family experience, but are not mentioned. . . As for any Network to work in practice, consistent and coordinated retrieval and transport is crucial. Ideally we would Networks to at least be in the ‘to be determined’ section.’*
54. Great Ormond Street Hospital for Children NHS Foundation Trust stated: *‘it is important that research and innovation are included as part of the scope of the review. Research and innovation are crucial to continue to provide sustainable, quality care for congenital heart disease. The ability to carry out such research and innovation is an important interdependency. The creation of large, sustainable specialist congenital heart centres/networks has the potential to create centres in England that are competitive with the best in the rest of the world.’*
55. Newcastle Upon Tyne Hospitals NHS Foundation Trust stated: *‘It should also be part of the scope of this review to establish well defined clinical pathways with clear referral routes for more complex aspects of patient care, to ensure future provision of the following services:*
  - *Heart transplant for adult congenital patients.*



- Cardiac extracorporeal life support (ECLS) for adult congenital patients.
- Complex tracheal surgery.
- Cardiopulmonary transplant and bridge to transplant services for child and young person.

*However by the very nature these services they should be undertaken in a limited number of centres. These centres should have a well-established track record and expertise in provision of the above services, with not only excellent results but also have research and innovation as part of their remit.'*

56. One respondent commented: *'I think it would be valuable to clarify the position of the pregnant woman with congenital heart disease and whether this aspect of care is covered by the new review. Comprehensive cardiac obstetric services are an essential component of a fully functioning adult congenital heart service. However, most cardiac obstetric clinics cater for both congenital and acquired heart disease in pregnant women as well as covering the scope of women with arrhythmias and inherited cardiac conditions. It would be helpful for the review to clarify if it plans to cover this aspect of care. The current proposal for the scope of the review does not make it clear. In my view cardiac obstetric services should be part of this review.'*

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