Rapid Evidence Synthesis Proposal - What evidence is there on how organisational features affect patient outcomes in congenital heart disease services?

Background: This proposal has been written in response to a request by NHS England to further examine the evidence around the delivery of congenital heart disease (CHD) services. The purpose of the evidence synthesis is to support the ongoing review about how these services should be best organised.

Services for children with CHD have been the subject of scrutiny for a number of years. In 2012, following an extensive review as part of the "Safe and Sustainable" work programme, a series of recommendations were made for the re-configuration of cardiac services for this patient group (NHS Specialised services, 2012). The recommendations of "Safe and Sustainable" were challenged and were subsequently the subject of a Judicial Review (JR) and an Independent Reconfiguration Panel (IRP) who concluded that the processes of the review were flawed. Consequently service reconfiguration was not implemented. These services are subject to a new review which will consider the whole lifetime pathway for CHD.

The JR and IRP (IRP 2013) identified a number of issues of concern with the "Safe and Sustainable" process including the use and interpretation of the existing evidence base on delivery of surgical services for CHD and patient outcome. In particular they questioned the reliance on evidence around the relationship between volume of cases and outcomes. A 2009 literature review (Ewart, 2009) had examined this evidence in detail and, although confirming the existence of a relationship between volume and outcome, also cautioned that this relationship alone was not sufficient to make recommendations on the size of units needed as the effects of other contributory system and process factors to this relationship were unclear in the published literature.

Rapid review process: This is a rapid evidence synthesis which needs to be completed within a very short timeframe to produce a review which is relevant and timely. Therefore rapid review methods will be used to ensure the efficient identification and synthesis of the most relevant evidence. The review will not attempt to identify all relevant evidence or to search exhaustively for all evidence that meets the inclusion criteria, although the proposed searching approach aims to identify the key evidence. Similarly the data extraction and

quality assessment will focus on the most critical information for evidence synthesis rather than aiming to exhaustively extract and critique all the available information in individual papers. Given time and resource constraints, and the need to work in a transparent and reproducible manner, our review will focus on identifying and synthesising the key evidence as described below.

Purpose of review: The purpose of this literature review is to examine what evidence there is on how organisational features affect patient outcomes in congenital heart disease services.

Review questions: The literature review can be more specifically framed to focus on two key organisational features. The rationale for this is based on the existing, evidence-based, consensus that there may be a relationship between the volume of CHD procedures and patient outcomes and the clinical consensus that reconfiguration which includes the co-location (or increased proximity) of specialist services may be related to better patient outcomes. The questions are as follows:

1a. 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?

1b. How are patient outcomes influenced by proximity to/colocation with other specialist clinical services (e.g. co-location of services such as specialist cardiac paediatric intensive care)?

Scope: Clearly there is enormous scope to both search for and review related evidence as the subject area incorporates several different dimensions. The literature review will focus on evidence from CHD services for children and adults as this will be the most relevant. Evidence from other paediatric surgical services and evidence from general adult cardiac services may also be relevant to CHD services. Where there is limited evidence from the CHD literature, the review will potentially consider the wider literature on these other clinically similar services as feasible and where relevant. Appendix 1 sets out our proposed conceptual framework to guide the review process.

This framework will allow us to:

- Define the scope of the search strategy
- Define inclusion and exclusion criteria to specify what types of studies will be included in the final report
- Construct summary tables of all included studies to present key information and findings
- Synthesise the evidence from the included studies

The report will not appraise the evidence in terms of how future services should be provided or make recommendations about service configuration.

Methods:

Search – Our initial approach will be to develop a search strategy based on the search strategy of Ewart et al (2009) with some modifications in order to capture a wider evidence base around the other explanatory factors (see conceptual framework) and a wider range of interventions (both adult and paediatric surgical and interventional cardiology services), within the time constraints of a rapid review. The search strategy is structured relevant terms as follows:

- Population = adults and children receiving treatment for congenital heart disease
- Intervention = organisational factors (based on volume and proximity)
- Outcomes = mortality, complications and related outcomes

The databases that will be searched are: MEDLINE, EMBASE, Cochrane Library, Web of Science (Science Citation Index and Social Science Citation Index) and CINAHL.

In addition to the database search as outlined above, we will also undertake the following to identify key evidence for the review:

- Liaison with topic experts.
- Citation searching on papers included in Ewart (2009) and other key papers identified by topic experts.

- Scrutiny of reference lists of included primary studies and relevant systematic reviews.
- Scrutiny of recent reviews of services and guideline documents for relevant peer reviewed evidence.

Inclusion and Exclusion Criteria – the evidence included in the review will be restricted to quantitative studies to ensure it addresses the key review questions and outcomes of interest. This is likely to be observational evidence; however there may be evidence from trials. The included evidence will be restricted to OECD countries only to ensure relative health system comparability. We will only include peer reviewed evidence published in order to ensure we are synthesising evidence which has already undergone methodological and expert scrutiny. We will limit the included evidence on the relationship between volume and outcome in paediatric cardiac surgery to 2009-2014 as evidence prior to 2009 is available in the Ewart review (Ewart 2009), which has undergone scrutiny through its inclusion in the "Safe and Sustainable" work programme. Other evidence will be included if published 2003-2014 in English to ensure the most recent relevant evidence is prioritised within the constraints of the rapid review process.

The inclusion criteria can be summarised as follows:

Population = adults and children undergoing treatment for congenital heart disease.
Intervention = the organisation of treatment based on at least one of the following: volume of activity and/or proximity to/co-location with other related services. Only studies including either volume or proximity factors will meet the inclusion criteria of the review.
Comparator = other methods of organisation of treatment (only studies with a comparator group will be included)
Outcome = patient outcomes. Studies reporting process outcomes will only be included if they report at least one patient outcome.

Data Extraction – Formal data extraction of included papers will be undertaken and will include both the explanatory factors outlined in the conceptual framework and any other factors identified by included studies, as well as patient outcomes. This may include data on:

Patient factors: Age of the patient casemix, range of the patient casemix.

Organisation: volume of activity (institutional volume and staff volume), specialisation (adult/children/both), sub specialisation (nature and complexity of procedures), size of specialist unit (number of staff, number of beds etc.), proximity to/co-location with other specialist clinical services, hospital/surgeon/nursing workloads, the health system that organisations operate in, timing of procedures and hospital/surgeon/nursing training/experience.

Outcomes: mortality, life expectancy, morbidity, quality of life, complications of treatment; and possibly processes such as length of stay and unplanned readmission rates. Data on process outcomes will only be extracted from studies which report at least one patient outcome. We anticipate that outcomes will be reported using measures such as relative risks, odds ratios and mean differences. Where possible, given the time and resource limitations, these will be reported, alongside confidence intervals. We will also check which way around the data is reported in terms of a) the intervention and comparator (for example high versus low volume and vice versa) and b) the outcome (for example mortality or survival). Where possible, outcomes will be converted so that they are all in the same direction for both of the above factors.

Quality Assessment - Rather than using a standard checklist approach, instead, the focus will be on an assessment of the overall quality and relevance of the evidence included in the review. The assessment of relevance will be made based on a number of factors which may include the study type, the country in which the research was undertaken, whether the research is single centre or multi centre, whether it included more than one procedure/intervention. The assessment of quality will be based on study type and other key factors. This process of quality and relevance assessment will allow readers of the rapid evidence synthesis to make an assessment of the hierarchy of relevance and quality of evidence included in the review.

Timelines:
Draft Proposal – 15 January 2014
Final Proposal – 24 January 2014
First draft report – 1 April 2014

Review Team:

Elizabeth Goyder	Colin O'Keeffe
Andrew Booth	Fiona Campbell
Janette Turner	Katy Cooper
Louise Preston	Amrita Jesurasa