What evidence is there for a relationship between organisational features and patient outcomes in congenital heart disease services? A rapid review

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Scientific summary

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Background

This rapid evidence synthesis 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 service review about how these services should be best organised. Prior work for the service review referred to a 2009 literature review which confirmed a relationship between volume and patient outcomes in CHD and highlighted the contributory effects of other system and process factors to this relationship. This rapid evidence synthesis has reassessed and updated the evidence base to examine what evidence there is for a relationship between organisational features and patient outcomes in CHD services.

Objectives

This rapid review focuses on two key organisational features: volume and proximity. The rationale for this is based on the hypothesis that there may be a relationship between the volume of CHD procedures (both by institution and by surgeon) and patient outcomes and the clinical conjecture that reconfiguration which includes the colocation (or increased proximity) of specialist services may be related to better patient outcomes. The research questions also reflect the view that mediating factors influence the relationship between patient outcomes and volume and proximity.

The research questions are as follows:

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

Methods

The rapid review was undertaken in 12 weeks. Our review aimed to identify key evidence of relevance to the review question and to extract and synthesise this evidence in a transparent and reproducible manner. A range of search methods was used to identify English-language, peer-reviewed evidence from 2003 to 2014 to address the research questions. Search methods included database searches, citation searches, evidence from topic experts and scrutiny of reference lists from key reviews and included evidence. Assessment of the search results according to the inclusion and exclusion criteria was undertaken by one reviewer and a 10% random sample checked by a second reviewer according to a predefined set of inclusion and exclusion criteria. Data extraction was undertaken in Microsoft Excel (2010, Microsoft Corporation, Redmond, WA, USA) using a purpose-specific data extraction form developed iteratively and tested extensively for this rapid review. Formal quality assessment was not undertaken; instead the usefulness of included studies to answering the review question and the generic and study-specific limitations reported by study authors were critically assessed. Data were extracted and then tabulated in Microsoft Word (2010, Microsoft Corporation, Redmond, WA, USA). Owing to both the clinical and methodological heterogeneity of the included studies, a meta-analysis was not undertaken.

Results

A total of 39 studies were included in the review. Our database searches identified 2256 references, from which 19 papers were included in the review. Supplementary search methods were used extensively. An additional 20 papers included in the review were identified via citation searching (two papers), reference lists of published reviews (15 papers) and reference lists of included papers (three papers).

No UK-based studies were identified and 36 out of the 39 studies (92%) included outcomes only for paediatric patients. Of the 39 included studies, 32 (82%) investigated the relationship between volume and mortality and seven (18%) the relationships between other service factors and outcome or between volume and non-mortality outcomes. Eighteen of the 32 studies investigating the volume–mortality relationship included all CHD conditions and 14 focused on specific single or complex conditions and procedures. Thirty-one of the 37 studies (84%) that used mortality as the primary outcome measured in-hospital mortality. Only 10 (27%) of the included studies measured mortality after discharge from hospital. Thirty-five studies (90%) were from the USA, 92% were multicentre studies and all were retrospective observational studies.

Overall, we have found that although the evidence does demonstrate a relationship between volume and outcome in the majority of studies, this relationship is not consistent. Studies on single conditions or procedures were more likely to identify an effect of volume on mortality but these were focused on high-risk conditions, such as hypoplastic left heart syndrome, and procedures, for example the Norwood procedure. Even within these highly selected groups there was considerable variation in effect depending on procedure type and individual centre performance. It is possible that, for example, surgeon volume may be as important as centre volume for these complex cases. This updated and extended review confirms a pattern of studies supporting the existence of a volume and outcome relationship.

The findings from studies that did consider broader CHD populations were more equivocal. In some studies in which an effect was identified, the effect was weak or demonstrable for only specific subgroups of patients. Overall, there was no clear indication that the evidence for the volume and mortality relationship was substantially stronger than the evidence for a no effect relationship in this group. The findings further highlight the complex relationship between volume and outcome and the range of other factors, which also have an effect. Some of these, such as condition severity, are well established but the effect of association of processes, systems and individual clinical effects on outcome remain unknown.

We also included evidence from three studies on adult CHD, of which one, which included patients receiving a transplant for a range of conditions in addition to CHD, was of limited value. The other two studies explored the effect of surgeon type in relation to outcome. Both studies found that adult CHD patients had better outcomes when operated on by paediatric surgeons in specialist children's centres.

We found limited evidence on the effects of proximity of other services on mortality or the impact of volume on non-mortality outcomes. There appears to be relatively little evidence from studies that attempt to measure the effect of related processes on outcome and this is an area for future development.

Some key themes emerged from our analysis.

1. There are a range of factors which influence mortality in CHD, and centre volume is only one of them. Our data extraction identified 67 different variables used to adjust for risk in the included studies and the most influential risk factor for mortality is the severity of the condition.
2. Medicine moves forward, and clinical advances, training, increasing expertise and changes in service provision mean outcomes for CHD have also changed over time. Five studies that analysed data over long time periods (approximately 10 years) measured changes in mortality over time and found that, irrespective of other factors including volume, mortality decreased over this time period.

This occurred despite increasing complexity, thus attesting to ongoing clinical improvement. This means the relevance of findings from historical data to contemporary services needs to be carefully considered.

3. Although aggregated data may show a difference in mortality rates between low- and high-volume centres, such aggregation may mask between-centre variation. Several included studies identified variation between centres, with some low- or medium-volume centres performing equally as well as those with high volume. Such variation indicates that individual centre effects relating to training, management protocols, expertise and availability of services are also likely to influence outcomes.
4. The evidence base available to guide UK decisions on service design and configuration for CHD is dominated by retrospective studies conducted within the USA, and many of the studies have analysed centres with very small case numbers. The extent to which the reported findings are generalisable and relevant to the UK setting is, therefore, limited. The organisation of services in the USA is very different to the UK and other countries where there has already been a degree of centralisation of CHD services. With centralisation comes a corresponding increase in volume, as more cases are concentrated in fewer centres. It remains unclear whether the impact of volume on outcome is largely a consequence of higher-volume units organising and providing a complex service with all the 'right' components, or whether it remains an independent factor directly related to the advantages of dealing with a larger number of cases. The lack of any UK studies to contribute to the review indicates a serious gap in evidence relevant to service provision in the NHS.
5. Despite the growing number of studies, few have suggested what the optimum size of a CHD centre in terms of volume should be. Fewer than half of the included studies analysed volume as a continuous variable which would provide the most robust evidence from which to consider volume thresholds.

Limitations

This was a rapid review with limited second sifting and a modified quality appraisal that followed standard methods to ensure that it was transparent and reproducible.

Many authors of studies included in the review take great care to point out the methodological limitations of their studies and caution against overinterpretation of their findings. Included studies are predominantly retrospective and observational in nature. Such design features make it very problematic when trying to establish a direct inverse relationship of cause (volume) to effect (mortality). All but five of the included studies used routine data sets as the source data including administrative, registry and voluntary data sets. With this comes consequent risks to data quality such as completeness, accuracy and selection bias. These sources also lack the data on key clinical and service-related processes needed to explain the associated effects of factors other than volume on outcome. The insights gained from study reports of a single condition or surgical procedure are important for an understanding of those conditions. Typically such reports bear little relation to overall surgical volume and, therefore, provide a limited contribution to the evidence that relates to optimal volumes for entire CHD services.

It is increasingly recognised that certain methods of investigation and analysis are unsuited to investigation of the volume/outcome question. Even though considerable advances in methodological approaches (e.g. complexity stratification) continue to be made, questions about the optimal configuration for volume/outcome debate remain unlikely to be resolved within the foreseeable future. This seems particularly the case given the absence of a comprehensive and accurate national database that provides sufficient information to account for risk, complexity and the effects of clinical care and service-related processes.

Conclusions

We have conducted a rapid review of the evidence on the relationship between volume and outcome and between other service factors and outcome for CHD. Overall, we found a substantial number of studies reporting a positive relationship between volume and outcome, particularly for highly complex cases. However, the complexity of the evidence requires careful interpretation. A mixed picture emerged from the 39 included studies, which increases our understanding of the complexity of this relationship and highlights variation in both methods and findings across individual studies, the potential effects of a range of other factors that may interact with volume and influence outcome and the methodological limitations imposed by the research approaches taken. Interpreting the evidence is particularly challenging because of a lack of information on clinical and service-related processes in the literature. This lack of information means that the volume–outcome relationship is difficult to disentangle from other clinical and service-related processes and outcomes.

A clear evidence gap remains to be addressed with regard to better understanding of the relationships between the wide range of organisational factors in CHD services, how these can potentially predict a number of outcomes of relevance to patients and families, and the causal pathways between organisational factors and outcomes. It is these questions that need to be answered and this requires the development of comprehensive, high-quality clinical and administrative databases which collect information on a range of organisational factors and outcomes related to quality of care. There is scope to expand the existing National Institute for Cardiovascular Outcomes Research (NICOR) database to capture more of this information. There is a clear need to conduct robust UK-based studies; an enhanced database could then be used to conduct observational studies of the relationship between organisational factors, including volume, and outcomes that would have direct relevance to the NHS. Future research efforts directed to these tasks would be of considerable benefit to improving patient care for CHD.

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