

SUBMISSION TO

JOINT LEICESTERSHIRE AND RUTLAND HEALTH SCRUTINY
COMMITTEE FOR ITS INQUIRY INTO

THE PROPOSED DECOMMISSIONING OF LEVEL ONE
SERVICES FROM THE EAST MIDLANDS CONGENITAL HEART
CENTRE

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DR SALLY RUANE

HEALTH POLICY RESEARCH UNIT
DE MONTFORT UNIVERSITY
LEICESTER

Is the stated wish of NHS England to close the East Midlands Congenital Heart Centre as a Centre of specialist surgery and interventional cardiology on the basis of the number of procedures undertaken by surgeons justified by the evidence?

Dr Sally Ruane¹

Introduction and Background

The provision of congenital heart disease (CHD) services which are prescribed specialised services has been a contentious matter for some years. Several reviews of congenital heart disease services have taken place since the 2001 report of the public inquiry into concerns about the care of children receiving complex cardiac surgery at the Bristol Royal Infirmary between 1984 and 1995.

The *Safe and Sustainable* review was launched by the Department of Health in 2008. At the end of that review, in July 2012, a joint committee of Primary Care Trusts (JCPCT) made a series of decisions on the future of children's congenital heart services in England including a decision to reduce the number of centres providing children's heart surgery from ten to seven. This resulted in two separate challenges and the Secretary of State asked the Independent Reconfiguration Panel (IRP) to consider the JCPCT findings. The IRP reported² critically and the process was halted. Responsibility was transferred to the newly created NHS England which is solely responsible for commissioning congenital heart disease services. Several investigations, separate from the Safe and Sustainable review, were also initiated. It was the view of NHS England that these repeated investigations and reviews had fostered an unhelpful competitiveness among providers, reduced the confidence of some patient groups as to the integrity of the process and left participants exhausted and frustrated³.

In July 2015, the NHS England Board, produced its own report on the future of congenital heart services in England⁴. The report noted that the period between 2000 and 2010 had seen a significant improvement in outcomes⁵, comparing well internationally. It cited NICOR's then most recent report⁶ which, using a risk adjustment model, found that overall centre

¹Dr Ruane works in the Health Policy Research Unit at De Montfort University.

² IRP (2013) Advice on safe and sustainable proposals for children's congenital heart services.

³ NHS England Board (2015) New Congenital Heart Disease Review: Final Report. July

⁴ NHS England Board (2015) New Congenital Heart Disease Review: Final Report. July

⁵ Brown et al, Trends in 30-day mortality rate and case mix for paediatric cardiac surgery in the UK between 2000 and 2010, *Open Heart* 2015;2: doi:10.1136/openhrt-2014-000157. This analysis of the ten year trend in 30 day mortality showed that while the number of procedures performed in the UK increased during that decade, raw 30-day mortality rate for paediatric cardiac surgical episodes in the UK fell from 4.3% in 2000 to 2.6% in 2009/2010.

⁶ National Congenital Heart Disease Audit Report 2011-2014, NICOR, 2015

survival rates in the UK are statistically either as predicted or better than predicted with particular improvement in survival in the most recent 18 months of the period.

Following a process of consultation with clinicians and patients, the July 2015 report set out agreed new standards and service specifications for CHD services, which would be applied across England and which providers would need to meet. The NHS England Board agreed a go-live date of April 2016 to begin implementation of the new standards, embedded in contracts with providers, with a standard-specific timetable giving up to five years to achieve full compliance. In July 2016, NHS England announced its intention to decommission Level 1 services from the East Midlands Congenital Heart Centre at Glenfield Hospital, part of University of Leicester Hospitals Trust.

A summary of the process undertaken by NHS England to arrive at its judgement can be found in the NHS England paper⁷ submitted to the Leicester City Health and Wellbeing Board for its meeting in August 2016⁸. The paper was authored by Will Huxter, then NHS England SRO for the Congenital Heart Disease Review, and Regional Director of Specialised Commissioning (London) and set out for the purposes of the Health and Wellbeing Board, which is attended by both elected councillors and members of the public, the written explanation for NHS England's announcement. Mr Huxter, along with colleague Dr Linehan, attended the meeting in person, to explain NHS England's view and to answer questions put to him.

The decision in July 2015 was that providers would have until 2021 to reach full compliance with all specified standards but with earlier deadlines for some of these standards. The July 2015 agreement was that compliance with the 125 annual procedures per surgeon standard would be measured via a three year average. This was taken by providers to be a three year period, beginning from April 2016 (ie measured between April 2016 and March 2019). If the understanding of providers was correct, the August paper appears to imply that, in December 2015, at a meeting of the NHS England's Executive Group, a decision had been taken to alter the timescale for measuring compliance. Now achieving the 125 annual procedures per surgeon standard would be measured retrospectively rather than averaged over a three year period from April 2016. Providers which were not by April 2016 undertaking 125 procedures per surgeon were required to demonstrate how they would be doing so by April 2017.

The provider proposals for providing congenital heart services according to the newly agreed standards were submitted in October 2015 and were assessed by a 'commissioner led panel'. The panel considered that "taken together, provider proposals did not provide a national solution [sic]; and giving more time would not yield a different outcome; and that developing a national solution would require significant support and direction from NHS England"⁹. The NHS England Executive Group accepted this assessment from the commissioner led panel. Stepping up its 'direction' of the service, it agreed that action should be taken to ensure compliance with the 'April 2016' standards. The Specialised Services Commissioning Committee (of NHS England) endorsed this approach when it met in February 2016.

⁷ W Huxter (2016) NHS England's proposals for congenital heart disease services at University Hospitals of Leicester NHS Trust. Paper presented to the Leicester City Health and Wellbeing Board meeting on 18 August Paper C page 17 -

<http://www.cabinet.leicester.gov.uk:8071/documents/g7459/Public%20reports%20pack%20Thursday%2018-Aug-2016%2016.00%20Health%20and%20Wellbeing%20Board.pdf?T=10>

⁸ This meeting can be viewed online at <https://leicester.public-i.tv/core/portal/webcasts>

⁹ Huxter, 2016

The meeting of the NHS England Executive Group took place in December 2015 at around the same time as a new policy initiative, the Sustainability and Transformation Plans (STPs), were announced. STPs are plans, developed in secret and enforced in specified geographical patches, to secure substantial cuts and service restructuring to reduce the cost of health care provision to reflect the diminishing share of the GDP allocated to the NHS. STPs point to a marked shift towards centralised top-down control in the health service. With a provider deficit of £3.7bn (Gainsbury, 2016) by the end of 2015/16 and the development of STPs during the spring and summer of 2016, some considered the announcement in July 2016 of NHS England's intention to terminate specialised surgery at three congenital heart centres across England as a cost-cutting exercise. Concerns expressed in the summer of 2016 about the budget pressures faced by NHS England and the cost of commissioning specialised services by the Public Accounts Committee¹⁰ may have reinforced this suspicion. This report does not set out to evaluate this claim but notes that it was vigorously denied by Will Huxter at the Health and Wellbeing Board meeting in Leicester in August 2016.

Assessing standards in congenital heart centres in 2016

Instead Will Huxter's paper emphasised that the commissioner led panel had singled out some standards as "particularly important determinants of service quality and safety:

- All surgeons should be part of a team of at least four, with on-call commitment no worse than 1:3 from April 2016 and that each surgeon must undertake at least 125 operations per year. From April 2021 the aim is a minimum 1:4 rota.
- Surgery must be delivered from sites with the required service interdependencies."

A process to assess compliance with 24 selected standards was launched by NHS England in January 2016 (notably ahead of the Specialised Services Commissioning Committee endorsement). These 24 standards were described as those "most closely and directly linked to measurable outcomes (including the surgical and interdependency standards previously highlighted by SSCC) and to effective systems for monitoring and improving quality and safety"¹¹. The process of assessment not only sought to assess compliance with the April 2016 standards but also took into account – or speculated upon – the ability of providers to reach the 2021 standards.

This marked a change in the previous understanding with providers. First, at least some of the standards to be reached by April 2019 now had to be reached by April 2017. Second, an assessment was being made, a provisional assessment but nonetheless an assessment, of the anticipated compliance with April 2021 standards as early as April 2016.

Will Huxter's paper emphasises that the panels assessing compliance were asked to focus on whether standards were being met and, if not, would be met, rather than make policy recommendations for NHS England. "The driver for this work has been to ensure delivery of the standards."

¹⁰ Public Accounts Committee (2016) NHS Specialised Services, House of Commons

¹¹ W Huxter (2016) NHS England's proposals for congenital heart disease services at University Hospitals of Leicester NHS Trust. Paper presented to the Leicester City Health and Wellbeing Board meeting on 18 August.

NHS England’s 2016 assessment of standards in the East Midlands Congenital Heart Centre

NHS England found:

“a) Surgical activity

University Hospitals of Leicester reported a caseload of 331 procedures for 2015-16, an increase of 55 procedures compared with 2014-15. This is insufficient for three surgeons to meet the current minimum activity requirement of 125 cases per surgeon per year. The full standards (effective from 2021) require a team of four surgeons rather than three, and that there was felt to be no realistic prospect of Leicester increasing activity during this period to a level that would allow these requirements to be met.

b) Interventional cardiology rota

The Trust did not demonstrate that they have implemented a 1 in 3 interventional cardiologist rota.

c) Access to specialist services

The Trust does not have access to 24/7 bedside paediatric gastroenterology or paediatric nephrology.

The Trust does not have vascular and interventional radiology services on site.”

As a result of this assessment process, in July 2016 NHS England announced its intention to cease commissioning level 1 services (highly specialised diagnostics and care including all surgery and most interventional cardiology).

The purpose of this report

In the months that followed NHS England’s announcement that they were minded to decommission level 1 services from the East Midlands Congenital Heart Centre, it became clear that the primary and ultimately only concern of NHS England was the number of procedures being performed by each surgeon and the likelihood that there would be sufficient patient need to ensure 125 procedures were performed by each surgeon once four surgeons were in place. While respectful of the University Hospitals of Leicester NHS Trust’s commitment to fulfil the 125 procedures per surgeon standard, this report assesses the evidence underpinning NHS England’s focus on the relationship between the volume of procedures performed and the quality outcomes of care as the basis for its policy intentions.

In order to do this, this report draws on the rapid review synthesis undertaken by Ms Janette Turner and colleagues¹² (known hereafter as ‘the review’ or ‘the Turner review’). The Turner review was commissioned by NHS England to inform them in their ongoing service review

¹² Janette Turner, Louise Preston, Andrew Booth, Colin O’Keeffe, Fiona Campbell, Amrita Jesurasa, Katy Cooper, and Elizabeth Goyder (2014) What evidence is there for a relationship between organisational features and patient outcomes in congenital heart disease services? A rapid review. *Health Services and Delivery Research*, No. 2.43

http://www.journalslibrary.nihr.ac.uk/_data/assets/pdf_file/0017/130085/FullReport-hsdr02430.pdf

A database search for more recent research has not revealed evidence which challenges the Turner et al conclusions.

regarding how these congenital heart services in England should be best organised. The Turner review reassessed and updated the evidence base (an earlier evidence review had been undertaken by Ewart in 2009¹³) to examine what evidence there is for a relationship between organisational features and patient outcomes in congenital heart disease (CHD) services. Turner's rapid review focusses in particular on the evidence regarding the volume of procedures undertaken either by institutions or by individual surgeons and on the evidence regarding the proximity of specialist services and what the effects of volume and proximity are on outcomes, including both mortality and complications. In other words, Turner's review contains the evidence base for the judgements NHS England is making.

The Turner review addressed the following questions:

- 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)?

The Turner review represents the most up to date and thorough review of good quality research that exists in the English language in this area. A detailed description of its methodology can be found in the review.

The Turner review's extensive literature search resulted in the inclusion of:

- 39 studies¹⁴ in total
- 32 /39 of the studies investigated the relationship between volume and mortality
- 18 of the 32 studies investigating the volume–mortality relationship included all congenital heart conditions
- 14 of the 32 studies investigating the volume-mortality relationship focused on specific single or complex conditions and procedures
- 7/39 investigated the relationships between other service factors and outcome or between volume and non-mortality outcomes
- 31 of the 37 studies that used mortality as the primary outcome measured in-hospital mortality.
- 10 of the included studies measured mortality after discharge from hospital.
- 35 /39 studies were from the USA
- 0 studies were from the UK.
- 92% were multicentre studies and all were retrospective observational studies.

For the 14 studies involving specific conditions or procedures, these were mainly complex conditions, such as:

¹³ Ewart H.(2009)The Relation Between Volume and Outcome in Paediatric Cardiac Surgery Oxford: Public Health Resource Unit

¹⁴ Individual studies may be referred to by author in the footnotes in this report. Full bibliographic details of individual studies can be found in the J Turner et al (2014) review http://www.journalslibrary.nihr.ac.uk/_data/assets/pdf_file/0017/130085/FullReport-hsdr02430.pdf

- hypoplastic left heart syndrome (HLHS), pulmonary atresia and/or procedures including the Norwood procedure, arterial switch operation (ASO), transposition of great arteries (TGA) and Blalock–Taussig shunt procedure (BTSP) (10/14);
- heart transplant (2/14);
- ventricular septal defect (VSD) repair cases only (1/14); and
- ventricular assist devices (VADs) only (1/14).

The relationship between the number of procedures undertaken by Centres and mortality among patients

The Turner review found 19 studies which examined the relationship between the number or volume of cases or procedures per institution or centre (volume) and mortality vis a vis all CHD conditions (outcome).

The review found that many studies report a relationship between volume and mortality but that this is often not a simple one. A study might find that volume was related to in-hospital mortality but not to post-discharge mortality; or a relationship between volume and high risk cases but not low risk cases. A study might find that a relationship existed between volume and mortality but that the relationship was diminished or completely absent when the highest volume provider was removed from the analysis. A study might find that the incidence of complications in different centres did not differ by volume but that large centres enjoyed a lower death rate among patients with complications. A study might find that there was a relationship between mortality and volume of adult cases in a centre but not between mortality and volume of all cases in the centre. A number of studies found that the effect of volume on mortality declined over time with a lesser impact in the most recent periods. Several studies found no relationship between volume and outcome.

The Turner review found 14 studies investigating a volume - mortality relationship focused on a specific condition or conditions. Even in these studies of specific complex and rare condition and associated procedures (9/14) where overall the evidence for a relationship between volume of cases and outcomes was stronger, this relationship was not straightforward. One study of hypoplastic left heart syndrome found a relationship between volume and mortality in stage 1 palliation but not stage 2 while another found a stronger relationship in stage 1 but variable effects in stages 2 and 3. Another study examined the effect of volume on mortality for five conditions and procedures but found a relationship for only one. Four out of six studies on the Norwood procedure found an association between volume and mortality but two others found no association. The sole study examining predictors for mortality in the Blalock-Taussig shunt procedure found condition severity and weight the main predictors with no relationship between volume and mortality.

The relationship of volume of cases per surgeon and mortality

Only four of the included studies of specific conditions and procedures included a measure of volume per surgeon. As these studies focussed on complex conditions and procedures, a relationship between surgeon volume and mortality could be expected as, by definition, these cases require particularly high expertise. Even here, though, the picture is complex. Two¹⁵ of the four studies found no relationship between volume of Norwood procedures per surgeon

¹⁵ Checcia et al; Tabbutt et al

and mortality. One of these¹⁶ acknowledged that the numbers involved were so small that establishing a link was problematic. The other of these¹⁷ found that surgeon volume did have an effect on morbidity and length of stay. The third study¹⁸ examined the relationship between surgeon volume and mortality in four conditions / procedures but found a relationship between surgeon volume and mortality for only one of these – there was a relationship between surgeon volume and mortality among TGA patients but there was no relationship between surgeon volume and mortality for PAIVS, the Norwood procedure and IAA. By contrast the fourth¹⁹ did find a relationship between volume of cases per surgeon and mortality for the Norwood procedure²⁰.

Checchia et al, from data collected between January 1998 and December 2001, found a relationship between centre volume and mortality but not between surgeon volume and mortality. The Norwood procedure is rare with a total of 801 Norwood procedures across 29 institutions over a four year period and as only two surgeons (and 4 institutions) in all 29 centres performed more than one Norwood procedure a month, the authors considered that the numbers may have been too small to detect a surgeon volume mortality relationship. They emphasise the importance of good protocols and care plans within each centre as the chief means of improving outcomes.

Tabbutt et al, from data collected between May 2005 and July 2008, found no relationship between surgeon volume and mortality. They did find a relationship between surgeon volume and length of stay and morbidity (such as renal failure, longer time to first extubation, and duration of ventilation sepsis) although this was one of several risk factors, the others being genetic abnormality, centre volume, open sternum and post Norwood operations. Tabbutt et al found lower birth weight, genetic abnormality, ECMO for failure to separate from CPB, and open sternum to be independent risk factors for 30-day and hospital mortality.

Karamlou et al, analysed 2421 cases falling into one of four groups (transposition of the great arteries [TGA], Norwood, interrupted aortic arch [IAA], and pulmonary atresia with intact ventricular septum [PAIVS]) in which surgery took place between 1987 and 2000 in 33 centres. Surgeon level data was available for two of these, TGA and the Norwood procedure and surgeon experience was measured in terms of five domains which included total number of the specific procedure performed by the surgeon and the number of years over which the surgeon performed that procedure. They found that increased surgeon experience was associated with improved mortality for TGA but has no effect on the outcomes following the Norwood procedure. Karamlou et al concluded “Survival of neonates with complex

¹⁶ Checcia, P. et al (2005) The effect of surgical case volume on outcome after the Norwood procedure, *The Journal of Thoracic and Cardiovascular Surgery*. 129:754–9

¹⁷ Tabbutt, S. et al (2012) Risk factors for hospital morbidity and mortality after the Norwood procedure: A report from the Pediatric Heart Network Single Ventricle Reconstruction trial, *The Journal of Thoracic and Cardiovascular Surgery* Volume 144, Number 4, 882-895

¹⁸ Karamlou, T. et al (2010) Lesion-specific outcomes in neonates undergoing congenital heart surgery are related predominantly to patient and management factors rather than institution or surgeon experience: A Congenital Heart Surgeons Society Study, *The Journal of Thoracic and Cardiovascular Surgery* c Volume 139, Number 3, 569-577

¹⁹ Hornik, C. et al (2012) Relative Impact of Surgeon and Center Volume on Early Mortality After the Norwood Operation, *Ann Thoracic Surgery*, 93:1992–8

²⁰ A further study published after the Turner review, and based on more recent data (2004-2013) found no relationship between numbers of procedures performed per surgeon and a range of outcomes. B Anderson et al (2016) The Norwood operation: Relative effects of surgeon and institutional volumes on outcomes and resource utilization, *Cardiology in the Young*, Vol 26, 683-692

congenital heart disease is influenced more by patient and management factors than by institution or surgeon experience. Institutional excellence in managing some diagnostic groups does not indicate similar performance for all diagnostic groups. Weighted risk-adjusted comparisons could provide a mechanism to improve results in institutions with less than optimal outcomes.”

Hornik et al examined data from a more recent period: 2,555 patients undergoing Norwood procedures between 2000 and 2009 in 53 centres, operated upon by 111 surgeons. A high volume surgeon was defined as performing more than ten procedures a year and a low volume surgeon was defined as performing fewer than five. They found that lower surgeon volume was consistently associated with higher mortality regardless of whether the surgeon worked in a low volume, medium volume or high volume centre. They noted that surgeon volume effect on mortality was more modest in paediatric cardiac surgery than it appears to be in adult cardiac surgery.

Hornik et al point to limitations in the other studies. The study by Checchia et al drew on administrative data relying on International Classification of Diseases, 9th revision (ICD-9) diagnosis and procedure codes. However, there is no ICD-9 code for the Norwood operation, such that a combination of other codes must be used, the accuracy of which is unknown. Hornik et al observe that the Karamlou et al analysis was based on the number of patients from each Congenital Heart Surgeons Society centre voluntarily enrolled in a cohort of patients with aortic atresia or stenosis undergoing the Norwood operation, rather than the overall number of patients at each centre undergoing the Norwood operation. Hornik et al’s study has the advantage of containing more recent data and including all patients in the centres receiving the Norwood surgery.

Besides the regionalisation of paediatric heart surgery, Hornik et al suggest other strategies to improve outcomes and reduce variation could include the development and implementation of quality improvement initiatives. They note that few studies have evaluated centre or surgeon characteristics that might form the basis of such initiatives although they acknowledge that their own analysis of the impact of a cardiac specific rather than general paediatric intensive care unit found the former did not lead to better outcomes than the latter²¹ (and see below). They suggest that research of other factors beyond structure alone is needed. These factors include training and availability of personnel, composition of the care team, use of standardized management protocols, and mechanisms to improve timely recognition and treatment of complications. Hornik et al propose that initiatives supporting enhanced mentoring by the senior or high-volume surgeon, or establishing a constant surgeon of record for Norwood operations, could be 2 potential mechanisms that may reduce variation and improve outcome.

Evidence of the impact of volume on non-mortality outcomes

Only a small number of studies could be found addressing the impact of volume on outcomes other than mortality.

²¹ Burstein DS, Jacobs JP, Li JS, et al. Care models and associated outcomes in congenital heart surgery. *Pediatrics* 2011; 127:e1482–9. Scheurer M, Gauvreau K, Laussen PC, Mayer JE, Atz AM, Newburger JW. The impact of a designated cardiac intensive care unit on outcomes after the Norwood procedure. *J Am Coll Cardiol* 2011;57:E405

One study²² found higher-volume centres had higher complication rates but lowest-volume centres had higher mortality rates. They acknowledged that this may be a consequence of better reporting of complications in high-volume centres but also suggested that better mortality outcome, despite higher complication rates in high-volume centres, may be because high-volume centres are better at managing and rescuing patients with complications. A second study found a relationship with a reduced rate of one particular complication (chylothorax) in the highest-volume centres compared with other centres. However, this study also observed that some low-volume centres had comparable complication rates to high volume centres, again highlighting variability between centres. Two studies²³ found lower complication rates in high volume centres following the Norwood procedure. On the other hand, three other studies²⁴ found no association between volume and complication rates. Two studies²⁵ found that low-volume centres were associated with longer lengths of stay.

What size should centres be?

The Turner review found that most relevant studies did not analyse volume as a continuous variable and few researchers went so far as to suggest what an optimum size for a specialist paediatric heart surgery centre should be. Turner and colleagues state that the scatterplots showing volume against mortality offered some studies gave rise to no obvious threshold for centre volume. One study²⁶ suggested that a reasonable threshold for referral of children requiring the Norwood procedure is centres doing at least 20 procedures a year and 10 procedures a year for ASO.

Turner and colleagues consider the suggestions of their predecessor as reviewer of the evidence base in congenital heart surgery:

“The review by Ewart considered the data presented by Welke *et al.* and suggested a possible threshold of 200–250 cases per year. Welke *et al.* clearly expressed the view that *volume is likely to be a surrogate for the processes and characteristics of care systems that produce outcomes and that centre-specific quality measures would be more informative than volume thresholds.* Pasquali *et al.* and Vinocur concurred with this view and suggested that service design decisions should be guided by a range of individual centre performance measures and not volume. There are consistent and clear messages within the literature we have reviewed about the danger of viewing volume in isolation. Furthermore, included studies also caution concerning the likely, but as yet poorly understood, interaction of volume with the numerous other clinical and structural dimensions that contribute to delivering high-quality services and, hence, good outcomes. Finally, questions still remain concerning what volume should be the item of consideration: is it whole-service volume, complex procedure volume or individual surgeon volume that should direct decisions?”

²² Benavidez *et al.*

²³ Tabbutt *et al.* and Davies *et al.*

²⁴ Burstein *et al.*, Berry *et al.* and Pasquali *et al.*

²⁵ Karamlou *et al.* and Davies *et al.*

²⁶ Hirsch *et al.*

Reflecting on the evidence base

Turner and colleagues conclude:

“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. Instead there is a mixed picture with both effect and no effect being reported.”

Even in studies of specific conditions/procedures where an association between volume and outcome was more likely to be detected (than in studies involving all CHD conditions), the

“findings were not unequivocal as even within these highly selected groups there was considerable variation in effect depending on procedure type and individual centre performance”.

In the studies of wider patient groups, the findings were more equivocal and mixed and there was no clear indication in some studies that evidence of the effect of volume of cases on mortality was stronger than the evidence of no effect.

The Turner review built upon that conducted by Ewart²⁷ in 2009. According to Turner and colleagues, Ewart’s review

“concluded that, while the evidence did suggest there is a relationship between volume and outcome, it is likely that volume is a surrogate marker that encompasses other processes and system factors, the effects of which are unknown”.

Turner and colleagues included the seven studies examined by Ewart but expanded their review to include more recent literature. This more recent literature, too, underlines the complexity of the relationship between volume and outcome and offers

“evidence that this is unlikely to be a simple, independent and purely directly causal relationship. The effect of volume on outcome relative to the effect of other, as yet undetermined, health system factors remains a complex and unresolved research question”.

The conclusions drawn by Turner and colleagues are not dissimilar to those drawn by the authors of earlier systematic reviews²⁸ of volume-outcome studies across a wide range of procedures outside paediatric heart surgery. These researchers, like Turner and colleagues, cautioned that the policy implications of existing research could not be simply inferred and that the complexity of findings pointed to the need for further research, including research of a qualitative nature. A number of shortcomings in existing research up until the early twenty first century added to the difficulty for policy makers in interpreting research evidence. A

²⁷ Ewart H.(2009)The Relation Between Volume and Outcome in Paediatric Cardiac Surgery Oxford: Public Health Resource Unit.

²⁸ Fergusson B., Posnett, J. and Sheldon T. (1997) *Concentration and Choice in the Provision of Hospital Services*, Report 8 of the NHS Centre for Reviews and Dissemination, University of York; Halm E., Lee C., and Chassin M. (2002) ‘Is volume related to outcome in health care? A systematic review and methodological critique of the literature’, *Annals of Internal Medicine*, 137: 511-520

number of observations based on the research of that wider range of procedures are relevant when trying to draw policy conclusions in relation to children's heart surgery and particularly when trying to justify concentration of care into fewer, bigger centres.

In the volumes outcomes literature more widely, there are very few studies which examine the relationship between volume and outcome by surgeon rather than by centre. This applies also in the case of paediatric heart surgery where only four of the included studies in the Turner review measured this and those that did arrived at mixed and contradictory findings. Not only is the evidence base for an association between surgeon volume and mortality unclear and contradictory but there is no evidence for the figure of 125. However, the failure of EMCHC surgeons to perform 125 operations each during 2015/16 has been, and is being, used by NHS England as a principal justification for its intention to decommission services from the Centre.

In much of the volumes outcomes literature, there are methodological weaknesses which limit the usefulness of specific studies or studies in aggregate for policy makers. It is difficult to assess the extent of this problem with the studies included in the Turner review as the authors did not conduct a formal assessment of quality. Certainly, Turner and colleagues note that almost all the studies are from the USA. They are all retrospective and uncontrolled and many rely on routine administrative data which can be influenced and distorted by a range of factors, including by the billing context. Equally serious are the problems with the statistical techniques undertaken in some volume outcome research. These, which include treating volume as a discrete rather than continuous variable, have been criticised²⁹. Turner and colleagues note that fewer than half of the included studies analysed volume as a continuous variable (14/35 relevant studies). Additionally, the lack of consistency across the literature in what is counted as a small, medium or large centre also poses problems in drawing conclusions. These shortcomings potentially limit the usefulness of the data for UK policy makers.

Bedevilling the volumes outcomes literature, the question of causation is unresolved. Any demonstrated association between volumes and outcomes does not tell us what the underlying causal mechanisms are. Volume is a structural feature; it does not 'cause' a lower mortality rate. It is usually taken as a statistical pointer to the common sense notion that 'practice makes perfect', that the repeated performance of a procedure allows learning to take place by an individual surgeon and within the centre. However, we must note the observation among those reviewing the wider literature, echoed in some of the studies reported by Turner and colleagues, that even where significant volume outcome associations exist there are low volume hospitals that produce good outcomes and high volume hospitals that produce poor outcomes³⁰ and that hospitals and surgeons with similar volumes can have very different outcomes. These findings signal that causation is complex. Further, even where a surgeon demonstrates a high level of technical expertise in one complex procedure, it cannot be assumed that this will translate into a high level of expertise in other procedures.

²⁹ See D Byrne and K Yang (2008) Conceptual & statistical problems in exploring the relationship among volume, outcome & context in relation to the organisation of secondary & tertiary health provision: An issue of causal inference in non-experimental research, *Radical Statistics*, Issue 96; Halm et al (2002) 'Is volume related to outcome in health care? A systematic review and methodological critique of the literature', *Annals of Internal Medicine*, 137: 511-520

³⁰ For instance, Halm, E., Lee, C. and Chassin, M. (2002) 'Is Volume Related to Outcome in Health Care? A Systematic Review and Methodological Critique of the Literature' *Annals of Internal Medicine*, 137 511-520

Causation in health care does not take the form of a simple chain of events but instead is complex and contingent. Any association indicated in the statistical analysis should be at best a *starting* point not the end point when it comes to inferring policy significance. The quantitative studies need to be complemented by research, including qualitative research, into both hospital and practitioner level characteristics and practices such as staffing levels, models and processes of care, protocols and the consistency of their implementation, staff morale, the quality of nursing care and so forth. It may be that the best policy response is not to concentrate but to identify care practices which are particularly efficacious and to transfer these to other centres. At present, as Turner and colleagues point out, there is little research on effect of processes and systems on outcomes.

Many of the factors contributing to outcomes are not related to volume of cases per se. Several studies found other factors to be more significant than volume in influencing mortality, including age, weight and the riskiness of the procedure. Turner and colleagues note that their review revealed a wide range of patient, demographic and service factors that also have an impact on outcome. They add “the most influential risk factor for mortality by far is the severity of the condition and the associated surgical complexity needed to treat that condition”. Some of the studies reviewed by Turner demonstrated that outcomes had improved over time despite the profile of cases becoming more complex and that that performance gaps tended to narrow over time as improved protocols and procedures become established³¹, weakening the influence of volume on outcome. It follows that studies based on old data, and several of the studies reviewed by Turner and colleagues fall into this category, are likely to have limited policy relevance today. It should be noted that the most recent data relating to the number of procedures per surgeon and the outcome of care reported in the Turner et al review are already 8 years old.

The view of this report is not that these methodological shortcomings negate the overall finding that in paediatric surgery there is a relationship between volume and outcome. It does however concur with the views of Turner and colleagues and those of earlier researchers into the volume outcome relationship that this relationship, where it exists, is complex, is only one of a range of factors influencing outcome and should be seen as an indicator of other variables which themselves should be investigated.

Conclusions

As a result of the April 2016 standard requiring at least three surgeons to be performing at least 125 procedures a year, NHS England has effectively badged the EMCHC as too small. The further standard that each centre is performing at least 500 procedures per year by 2021 also leads NHS England to conclude that the EMCHC is too small to provide high quality care. However, there are a number of ways in which this judgement is not evidence based.

First, existing evidence does not constitute a basis from which relevant policy decisions in the UK today can be inferred. None of the studies in the Turner review were investigations of UK centres and the Turner review notes that several studies entailed investigating very small centres (some centres were performing only 20 procedures per year and even smaller numbers of cases could be involved in studies of specific rare and complex conditions). UK paediatric heart surgery has already been regionalised in the UK and the benefits of larger

³¹ See L Durairaj et al (2005) *ibid* for an excellent discussion of some of the issues involved in drawing out policy significance

volumes for complex cases have been realised. The relevance of research into very small centres is of little relevance, if any, to decision making in health systems in which services have already been regionalised. Some of the studies included in the Turner review were of US centres which had not been regionalised in this way.

Second, where a volumes outcomes relationship is demonstrated to exist, this tends to be true only on the average: that is, some larger centres may perform less well than average while some smaller centres may produce average or better than average outcomes. The Turner review reported several studies which had identified variation in the outcomes of centres of comparable sizes. This clearly points to the existence of other factors, including centre specific characteristics which themselves exercise influence on the quality of care given. It is evident that the EMCHC, with no deaths in 2015/16, at the time of NHS England's announcement, had among the best mortality outcomes in the country. It is too early to make comparative statements on mortality within thirty days for 2016/17 as the national data are not available. However, it appears the EMCHC compares well in relation to outcomes measured in terms of complications³².

Third, the evidence base for a relationship between surgeon volume and outcome is particularly scant and what little there is offers only a mixed picture. There is no evidence for a figure of 125, an observation made in the IRP's report³³ to the Secretary of State in 2013, which drew attention to the fact that previous reviews had suggested lower figures (see Appendix 1, extract from the Independent Reconfiguration Panel report, para 4.12.12). When the NHS England review of congenital heart services in 2016 misused the research evidence and cited the Turner et al review to back its 125 procedures per surgeon figure, Ms Turner stated publicly that her review had not identified this figure or any other figure as a minimum. She re-stated the review's conclusion that the picture is complex and that factors besides volume are significant in shaping the outcomes of care³⁴.

Fourth, there is no evidence base for the 500 figure for the volume of procedures to be performed by a centre as whole. The IRP report in 2013 also made this point. Turner and colleagues believe it is not yet clear whether the volume outcome effect is more significant at a surgeon level rather than a centre level since there is inadequate evidence from which to draw a conclusion.

NHS England has declared its intention to close the EMCHC as a surgical centre despite admitting that the Centre is giving 'excellent care'³⁵. NHS England may have got into this paradoxical position because it has focussed exclusively on inputs (the standards). The claim by Will Huxter that the standards prioritised for the 2016 assessment were those most closely associated with outcomes should therefore be interpreted with care since at least some standards set do not reflect the evidence.

³² See National Institute for Cardiovascular Outcomes Research – Congenital Heart Disease Audit website. Also preliminary analysis of 2016/17 data.

³³ IRP (2013) Advice on safe and sustainable proposals for children's congenital heart services. See especially pages 50-52, reproduced in Appendix 1 below

³⁴ Cited in E Oxford (2016) Questions raised over NHS England's use of heart surgery research, Health service Journal 12th August

³⁵ Dr G Linehan, NHS England, oral statement, Health and Wellbeing Board meeting, Leicester, 18th August 2016

What must be remembered is that the standards – as inputs - are a means to an end and not an end in themselves. Their purpose is to help secure good outcomes. The EMCHC already delivers good outcomes and the Care Quality Commission rated the Centre as ‘Good’ overall with ‘Outstanding’ in effectiveness. However, NHS England has failed to give due weight to this fact. The good outcomes provided by EMCHC reflect a range of factors which contribute to outcomes. The importance of these other factors has been overlooked by NHS England in its overly narrow and rather mechanistic focus on volume.

By focussing on standards instead of outcomes, NHS England appears to have made the same mistake as Joint Committee of Primary Care Trusts in the Safe and Sustainable Review in establishing standards which are not sufficiently based on the evidence and which, as a result, lose the confidence of parents and the wider public.

Changes in recent years which have seen not only the regionalisation of congenital heart surgery but also the identification and rolling out across Centres of good practice have improved performance across the country. In many respects these developments supersede the findings of the studies reviewed by Turner and colleagues. The Turner review itself makes this point.

Volume is a surrogate measure for other characteristics or variables which need investigating. Although the literature warns explicitly against a policy of viewing volume in isolation this is effectively what NHS England have done by holding up volume of procedures per surgeon as their focus of concern. Despite the scant evidence for the 125 figure, NHS England proposes to up-end services, closing the East Midlands Congenital Heart Centre and transferring existing patients and diverting prospective patients elsewhere as if the risk to patients and families of this substantial upheaval is negligible.

Ultimately it is to good outcomes that clinicians, managers, policy makers and patients aspire. EMCHC produces good outcomes. The question is not whether it is performing enough procedures to produce good outcomes – clearly it is performing enough procedures as the outcomes are already good. In the current context, given that outcomes across specialist children’s heart surgery providers compare well internationally, it is more useful from a policy point of view to start with a focus on outcomes and to work backwards to understanding what ‘causes’ these. This would allow NHS England to try to understand how EMCHC achieves its good outcomes and even whether any lessons can be learnt about best practice from EMCHC which can be rolled out to other centres in the country if necessary. Additionally, because of these other factors, it is possible to see that Centres could achieve good outcomes consistently despite not reaching a particular volume of cases.

Were NHS England stepping in to close a failing Centre, it would find a degree of sympathy among the public. However, it is difficult for patients, carers and public, not to mention clinicians and managers working in the affected Centre, to comprehend the wish of those running the NHS to close a highly successful unit.

Appendix 1

Extract from The Independent Reconfiguration Panel's report³⁶ 2013

4.12.12 From the documentary evidence submitted, the Panel found that the thresholds for minimum critical mass recommended by the Kennedy Report, Munro Report and the European Association for Cardio-Thoracic Surgery²² were substantially lower than 400-500 cases per surgical centre. The Kennedy Report suggested that paediatric congenital heart surgeons should perform a minimum of between 40 and 50 open-heart operations a year. The Munro report recommended that *“surgical centres should have a minimum of three paediatric cardiac surgeons performing a minimum of 300 paediatric surgical procedures per annum, on average, sensibly distributed between the surgeons to avoid occasional practice”*. The EACTS report concluded that *“there are no data in the scientific literature of an exact cut-off point between what is a too small, adequate or optimal case load and indeed it seems impossible to ensure such points as so much of medical service is dependent on the local culture and circumstances”*. The Report went on to recommend the optimal overall activity should be over 250 patients operated per year and each surgeon should perform 126 cardiac surgical procedures on adults or children.

4.12.14 The Panel noted that the final report from the Public Health Resource Unit, in response to the question set in the brief: *“Do the findings of the review allow the generation of evidence based recommendations for the minimum volume of paediatric surgical activity for individual procedures, individual surgeons and/or individual surgical units, stratified by the age of the patient?”* stated: *“Whilst confirming the association between volume and outcome in paediatric cardiac surgery, the papers reviewed do not provide sufficient evidence to make firm recommendations regarding the cut off point for minimum volume of activity for paediatric cardiac procedures overall or for specific high complexity procedures at either institutional or surgeon level. Neither is it possible to stratify optimal volume by age of the patient. It is important to remember that volume is, in effect, a surrogate marker which subsumes a wide range of process and system characteristics which have yet to be identified or analysed for their association to outcome.”*

4.12.15 The Panel also noted that the report stated that *“in those studies expressing volume as a continuous variable no statistically significant inflection points were identified. This makes it difficult to make categorical recommendations on volume. The Bazzani study used a volume of 75 cases as the cut off between low and high volume and showed an association with outcome that may not have been statistically significant. Two Welke studies (2008, 2009) taken together suggest that a volume of over 250 cases per annum may be optimal”*.²⁴

4.12.16 The Panel noted that the PCBC, consultation document and decision-making business case were silent on the facts that the Kennedy, Munro and EACT reports had recommended substantially lower thresholds than were being suggested by the NHS.

4.12.17 The Panel noted that the consultation document and DMBC do not indicate the lower thresholds suggested by the literature review. They do however acknowledge that *“Whilst confirming an association between volume and outcome in paediatric cardiac surgery the*

³⁶ IRP (2013) Advice on safe and sustainable proposals for children's congenital heart services. P50-52

JCPCT has acknowledged that the scientific papers reviewed do not provide sufficient evidence to make firm recommendations regarding the cut-off point for minimum volume of activity for paediatric cardiac procedures overall, or for specific procedures at an institutional level. The standards are therefore based on the consensus of the professional societies, which in turn are based on the available evidence”.

5.4 The JCPCT’s case for “larger surgical centres”

5.4.1 The Panel reviewed the JCPCT’s case for change and sought views from all parties. The case for “larger surgical centres” for children’s heart surgery is presented by its proponents as incontrovertible – a principle that “*everyone has signed up to*”. What the Panel heard was less straightforward. The case for larger centres relies on two key arguments:

- The relationship between volume of cases per centre and per surgeon and better outcomes for patients
- Larger teams are more sustainable and hence provide higher quality services

5.4.2 The relationship between volume and outcome

In clinical medicine, it is observed that there is generally a positive association between doing more of something and getting better results for patients. For some specialty services, there is clear evidence for a strong positive relationship between volume of procedures and outcomes achieved. The Panel reviewed the relevant published literature for congenital heart disease and took evidence from clinicians on this issue. Whilst there is some evidence of a positive relationship between volume of procedures and outcome at lower numbers per centre, for the current surgical centres in England and the proposed minimum of 400 procedures per centre, the evidence is that there is no significant positive relationship between increases in volume and expected outcomes.

5.4.3 The Panel found that the proposed standard of a minimum number of procedures per surgeon was initially set at 100 paediatric procedures, in addition to any adult caseload. However, the final standard moved away from setting the number of procedures per surgeon, to requiring each surgical centre to undertake a minimum of 400 and preferably 500 paediatric surgical procedures “*sensibly distributed between all four cardiac surgeons*”. This was in recognition that most surgeons undertake adult practice and the balance of adult and paediatric work tends to change over the surgeon’s career with the proportion of adult work increasing over time.

5.4.4 Some evidence suggests a more positive impact of volume on outcomes for relatively rare and complex procedures to treat, for example, hypoplastic left heart syndrome. This suggests either larger centres as proposed or concentrating such procedures in fewer centres. The Panel noted that much larger centres such as in Boston, USA were implementing surgical sub-specialisation to improve outcomes further.

5.4.5 The Panel was concerned that in presenting the case for change in the consultation document and the DMBC, the NHS failed to indicate that the evidence of a link between volume and outcome, and experience of rationalisation of services internationally, related to a much lower threshold of activity per centre than the standard of 400 cases per centre proposed. There was also a failure to explain that the Kennedy and Munro reports had suggested significantly lower thresholds per surgeon and per centre. The Panel met many well-informed parents as well as clinicians and HOSC members who had diligently read all the referenced material in the consultation document and DMBC. This failure to set information in context was at the heart of feelings reported to the Panel by some parents, HOSCs and clinicians that the process lacked transparency and used information selectively.

Larger teams

5.4.6 The Panel found widespread support for the standard of at least four full-time surgeons per team. This has a range of benefits such as aiding recruitment and retention of staff, supporting sub-specialisation, mentoring, collaborative working on complex cases, cover for planned and unplanned absence, training, research and audit. A number of clinicians also highlighted the relationship between stable teams and high quality services. The importance of the wider team of specialists who are involved in the care of children with CHD, was also highlighted to the Panel by many who felt that the implications for these professions had not been sufficiently addressed by the proposals.

5.4.7 Patients relying on a specialist service expect experienced, skilled staff to be available round the clock to provide all the care that may be required. The Panel agrees that achieving this in a sustainable way requires a minimum of four full-time consultant surgeons in each team and a volume of procedures sufficient to develop and maintain the skills of surgeons, cardiologists and other personnel in providing a high quality, comprehensive service.

5.4.8 Recommendation Two

Patients should receive congenital heart surgery and interventional cardiology from teams with at least four full-time consultant congenital heart surgeons and appropriate numbers of other specialist staff to sustain a comprehensive range of interventions, round the clock care, training and research.