News: The Safe and Sustainable Review of Children’s Heart Services

Suspended After an Independent Panel Found That the Decision Was Based on a “Flawed Analysis”

The restructuring of children’s heart surgery in England and Wales has been suspended because an independent panel found that the decision was based on a “flawed analysis.”

The Safe and Sustainable Review of Children’s Heart Services (see http://circ.ahajournals.org/content/126/15/f85 and http://circ.ahajournals.org/content/127/15/f85) aimed to create fewer and larger centres offering paediatric cardiac surgery by decreasing the current 10 centres to 7. The review looked at the existing provision of child cardiac surgery centres and future requirements to improve the service to patients, improve clinical outcomes, and best deliver surgical expertise to National Health Service (NHS) patients. Throughout the Safe and Sustainable Review, the consensus has been that a restructure is needed, but the decision about which centres should stop offering services and which should be expanded has been subject to widespread disagreement.

In July 2012, the Joint Committee of Primary Care Trusts (JCPCT) announced that the 3 child heart surgery centres set for closure were Leeds General Infirmary, Leeds; East Midlands Congenital Heart Centre, Glenfield Hospital, Leicester (see http://circ.ahajournals.org/content/122/8/f43); and the Royal Brompton Hospital, London. These centres then became the focus of campaigns and court action to save them.

Meanwhile, the 7 centres chosen to continue to offer the service—Great Ormond Street, London; Evelina Children’s Hospital, London; Newcastle Freeman Hospital, Newcastle; Birmingham Children’s Hospital; Alder Hey Children’s Hospital, Liverpool; The Royal Children’s Hospital, Bristol; and Southampton General Hospital, Southampton—began to make preparations for the implementation of the new network by 2014.

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Awards: British Cardiovascular Society Young Research Workers Prize

Recipients of the British Cardiovascular Society Young Research Workers Prize describe the research that led to the award.
On March 27, 2013, A Judge Formally Quashed the Decision to Stop Children’s Heart Surgery at Leeds General Infirmary

The Safe and Sustainable Review process found itself before the courts in England in early 2013 when the Save Our Surgery Group, which was set up to campaign to keep child heart surgery in Leeds, challenged the JCPCT decision. On March 7, 2013, the High Court ruled that the consultation over changes to children’s heart surgery was unfair and legally flawed after hearing that as part of the NHS review process, each hospital was visited by a panel of experts and given a score based on its performance. However, the JCPCT also produced “subscores” measuring the quality of service under various criteria but had not disclosed them to the consultees.

On March 27, 2013, the court reconvened, and the judge formally quashed the decision to stop children’s heart surgery at Leeds General Infirmary. The matter was further complicated when, within 1 day of that hearing, Sir Bruce and senior managers from the Care Quality Commission visited the Leeds hospital and ordered it to immediately stop children’s heart surgery after receiving data suggesting a higher mortality rate than the national average. Operations were suspended for several days in April 2013 but were allowed to resume after an investigation revealed the mortality data were flawed.

“Flawed Analysis of Incomplete Proposals and Their Health Impact, Leaving Too Many Questions About Sustainability Answered and to Be Dealt with as Implementation Risks”

As a result of the controversy and campaigns resulting from the JCPCT’s decision, the Secretary of State for Health, the Right Honourable Jeremy Hunt, asked the Independent Reconfiguration Panel, to assess the decision. The Panel was established in 2003 to provide advice to the Secretary of State for Health on contested proposals for health service change in England. Mr Hunt asked the Panel whether it thought the proposals would enable the provision of “safe, sustainable and accessible services” and if not, why not.

The Independent Reconfiguration Panel concluded, “Overall, the Panel is of the opinion that the proposals for change, as presented, fall short of achieving this aim.” It explained that the JCPCT’s decision was “based on flawed analysis of incomplete proposals and their health impact, leaving too many questions about sustainability unanswered and to be dealt with as implementation risks.”

The chair of the Panel, former consultant surgeon Lord Bernard Ribeiro, FRCS, FACS said, “Throughout our review, people told us that being listened to was something they valued. We have listened to a wide cross-section of individuals and organisations during recent months, giving us the opportunity to meet and hear from many parents, children, frontline staff, local charities, and volunteers involved in these services. The focus of this review and the Panel’s advice is fundamentally about the long-term future and best interests of children with congenital heart disease.

“The critical factor to consider, in the Panel’s view, is that engagement of all interested parties is the key to achieving improvements for patients and families without unnecessary delay. There is now a real opportunity to involve patients, the public, and other stakeholders in taking work forward as set out in the Panel’s recommendations.”

15 Recommendations to Enable Sustainable Improvements for the Services and Learning for Future National Commissioning of Health Services

The Independent Reconfiguration Panel found that the proposals for children’s services were undermined by the lack of coordination with the review of adult services and said that the opportunity must be taken to address the criticism of separate reviews by bringing them together to ensure the best possible services for patients. It set out 15 recommendations to enable sustainable improvements for the services and learning for future national commissioning of health services.

The Panel considered that patients should receive congenital heart surgery and interventional cardiology from teams with at least 4 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.

It added that the current service, any proposed options for change, and the function, form, activities, and location of specialist surgical centres, children’s cardiology centres, district children’s cardiology services, outreach clinics, and retrieval services must be modelled and its affordability retested; and that NHS England should ensure that a clear programme of action is implemented to improve antenatal detection rates to the highest possible standard.

Another recommendation was that further capacity analysis should consider recent and predicted increases in activity, and that NHS England (which took over responsibility for the process from the JCPCT under a reorganisation of the NHS in April 2013) must establish a systematic, transparent, authoritative, and continuous stream of data and information about the performance of congenital heart services. In working with relevant professional associations, it should also put in place the means to continuously review the pattern of activity and optimise outcomes for the more rare, innovative, and complex procedures.

The Panel wants NHS England to reflect on the criticisms of the JCPCT’s assessment of quality, learn the lessons to avoid similar situations in its future commissioning of specialist services, and develop a strategic framework for commissioning that reflects the complex interdependencies between specialised services provision and population needs. It said, “The Panel’s advice addresses the weaknesses in the original proposals but it is not a mandate for either the status quo or going back over all the ground in the past 5 years. There is a case for change that commands wide understanding and support, and there are opportunities to create better services for patients. The challenge for NHS England is to determine how to move forward as quickly and effectively as possible.”
Responses to the Independent Reconfiguration Panel Report from Hospitals Facing Closure

Leeds General Infirmary
Sharon Cheng, from the Save Our Surgery group in Leeds, says the Independent Reconfiguration Panel report shows that the campaigners were right to challenge the decision. “If we had not taken this action, implementation would have gone ahead, and patients and families in our region would have been left with a far worse service than they currently receive,” she says.

Leeds Teaching Hospitals NHS Trust, which runs Leeds General Infirmary, says it hopes to have the opportunity to be involved in discussions with the Secretary of State and NHS England in the coming weeks about how best to take the review forward, but in the meantime, its clinical teams are “anxious to continue to provide an excellent service to patients.”

East Midlands Congenital Heart Centre
Aidan Bolger, MBBS, MRCP, lead cardiologist at East Midlands Congenital Heart Centre, Glenfield Hospital, also welcomes the decision to suspend the review. “The review was supposed to create a national network of surgical centres that were safe and sustainable. Now we, along with our colleagues in the other trusts and NHS England, will work together to make that a reality using the right evidence, common sense, and always with what is best for patients at the forefront of our minds,” he says.

The Royal Brompton Hospital
The Royal Brompton and Harefield NHS Foundation Trust says the Independent Reconfiguration Panel decision would go “some way towards restoring” the faith of families and patients in the NHS. “They have never been able to understand how one of the best performing and largest units in the country was destined for closure, especially when statistics showed that the population in London and the South East is growing much faster than had previously been thought, and demand for children’s heart surgery is increasing,” a hospital statement says.

The Brompton believes that the most appropriate solution is for children’s cardiac services to be delivered through a 3-centre network in London, which would give access to the best expertise through close collaborative working.

Responses from Other Stakeholders

The Government
Secretary of State for Health, Mr Hunt said, “This is clearly a serious criticism of the Safe and Sustainable process. I therefore accept the Panel’s recommendation that the proposals cannot go ahead in their current form, and I am suspending the review.” Meanwhile, Mr Hunt emphasises that the original argument for improving care is unchanged.

University Hospital Southampton
Michael Marsh, MRCP, FRCPCH, medical director at University Hospital Southampton, says that his unit will “continue to thrive and provide children from across the south of England with a high-quality, high-performing service that will continue to grow and expand over the coming weeks and months,” and he looks forward to helping NHS England “complete the reconfiguration process.”

Royal College of Surgeons
Royal College of Surgeons President Professor Norman Williams, FRCS, FMedSci, expresses disappointment at the suspension of the plans. He says, “The Royal College of Surgeons has been calling for changes to surgical services for children with complex heart conditions for many years. As the body that advances standards in surgery, we want to see plans put in place that will create a sustainable model for excellent care in the future and improve both service delivery and training of surgeons in a highly complex field. A wealth of evidence indicates that concentrating specialist surgical services into fewer, larger centres of excellence can improve outcomes and make services more sustainable.”

NHS England
NHS England has promised to lead a rethink of plans to improve children’s heart surgery in England over the next few weeks. Sir Bruce Keogh says that NHS England will study the recommendations in full to learn from them and adds, “We will institute a new process that recognises the strong case for redesigning services to meet the demands of the future whilst addressing the legitimate concerns in our local communities.”

National Clinical Director for Cardiac Care for NHS England and consultant cardiologist Professor Huon Gray, MD, FRCP, says that he is pleased that the Independent Reconfiguration Panel “endorsed the case for children’s heart surgery and interventional cardiology to be provided only by well-resourced, specialist teams providing round the clock cover, and the use of national standards for commissioning the pathway of care.” However, he acknowledges that the Panel also raises some important issues, so changes cannot be implemented immediately.

NHS England has until the end of July 2013 to decide on the next step.

Mark Nicholls is a freelance medical journalist.
Awards: British Cardiovascular Society Young Research Workers Prize

Recognising Excellence Among Young Researchers Intending to Pursue a Career in Cardiovascular Clinical Medicine or Research

Recipients of the British Cardiovascular Society Young Research Workers Prize describe the research that led to the award to Jennifer Taylor, BSc, MSc, MPhil.

The Young Research Workers Prize of the British Cardiovascular Society (see http://circ.ahajournals.org/content/124/8/f43) recognises excellence among young researchers intending to pursue a career in cardiovascular clinical medicine or research. The annual prize of £1500 for the winner and £500 for the runners up is for research concerned with the cardiovascular system. It is open to any researcher, including those not medically qualified, and membership of the British Cardiovascular Society is not a requirement. Applicants must not have attained consultant status (or equivalent) at the time the research was performed. For clinicians, the research must have been completed before achieving a Certificate of Completion of Training in cardiology. For basic scientists, the research must have been performed within 10 years of their PhD award.

Entries can include previously published work but should not consist wholly of work already published in full paper form by the closing date for submissions. Applicants should submit an abstract together with a brief communication (≤1000 words), including an introduction, methods, results, and discussion. Up to 5 tables or figures and a maximum of 15 references can be included. Applicants should describe how much of the work they did themselves and the contribution and names of any collaborators.

Up to 5 finalists are chosen to present a 12-minute paper at the British Cardiovascular Society’s annual conference. Judging is conducted by the Academic and Research Committee, which is housed in the Education and Research Division of the British Cardiovascular Society, and the judges consider both the presentation and response to questions when deciding the winners.

The prizes are presented at the British Cardiovascular Society annual dinner, which is held during the annual conference, where finalists are guests of the Society.

Using a Scn5a+/– Mouse to Provide a Specific Genetic Model to Investigate Cellular Mechanisms of Its Arrhythmogenesis

Claire Martin, MA, MRCP, cardiology registrar, Bedford Hospital NHS Trust, Bedford, England, received the British Cardiovascular Society prize in 2012.

Ventricular arrhythmogenesis is a major cause of mortality worldwide. One important inherited cause is Brugada syndrome associated with loss of sodium channel function. Dr Martin says, “During my research for a PhD, I conducted a series of experiments using a Scn5a+/– mouse to provide a specific genetic model to investigate cellular mechanisms of its arrhythmogenesis.”

First, Dr Martin conducted in vivo experiments to show that the mouse model reproduces the clinical ECG features of Brugada syndrome, showing both ST elevation and ventricular tachycardia, as well as abnormalities of both conduction and repolarisation.1 Monophasic action potentials and bipolar electrograms in a whole-heart Langendorff-perfused system then demonstrated increased spatial and temporal heterogeneities in electrophysiological properties specifically involving the right ventricle of Scn5a+/– hearts.2–4 Dr Martin explored this further using a multielectrode mapping array to demonstrate lines of functional conduction block leading to reentrant circuits and ventricular...
tachycardia. She finally demonstrated the molecular mechanism for these right ventricular changes using reverse transcription polymerase chain reaction, Western blots, and functional ionic current analysis through a specific reduction in right ventricular expression of Na transport compared to K channels in the Scn5a+/- hearts producing both slowed conduction and repolarisation heterogeneity.

Dr Martin’s prize-winning research was carried out in the Physiological Lab, University of Cambridge, Cambridge, England, where she worked in the group of Professor Christopher Huang, MD, PhD, alongside the group of Andrew Grace, FRCP, PhD, in the Biochemistry Department. She also collaborated with several other centres: Cesare Terracciano, MD, PhD, and his group, Heart Science Centre, Imperial College London, London, on cardiac myocyte isolation and patch-clamp experiments; Professor Ming Lei, DPhil, and his group, Institute of Cardiovascular Sciences, University of Manchester, Manchester, England, on multi-electrode mapping experiments; Cristina Rada, PhD, and her group, Medical Research Council Lab of Molecular Biology, Cambridge, on Western blot experiments; and Nicola Brice, PhD, and her group at Takeda Cambridge Limited on reverse transcription polymerase chain reaction experiments.

Dr Martin currently works as a cardiology registrar at Bedford Hospital and has recently passed her PhD viva voce examination. She says, “I hope in the future to be able to use the insights that I have gained into the mechanisms of ventricular arrhythmogenesis in the mouse model in translational work in clinical studies. Specifically, I would like to use my work to refine risk stratification of Brugada syndrome, and to develop therapeutic targets for arrhythmia suppression in a disease for which only the proven treatment so far is cardioverter defibrillator implantation.”

**References**


Applying Genomic Approaches to Identify Genetic Determinants of Cardiovascular Disease, with a Focus on Inherited Cardiac Conditions and Cardiac Arrhythmia

James Ware, PhD, MRCP, Walport Clinical Lecturer in Cardiovascular Genomics, National Heart and Lung Institute, Imperial College London, National Institute for Health Research Royal Brompton Cardiovascular Biomedical Research Unit, London, England, received the British Cardiovascular Society prize in 2011 for work carried out during the early stages of his PhD.

Dr Ware was awarded a Wellcome Trust Clinical PhD Fellowship in 2008 and worked at Imperial College London under the supervision of Professor Stuart Cook, MRCP, PhD; Professor Tim Aitman, FRCP, DPhil, FMedSci; and Professor Nick Peters, MD, PhD, applying genomic approaches to identify genetic determinants of cardiovascular disease, with a focus on inherited cardiac conditions and cardiac arrhythmia.

Dr Ware started his PhD studying the genetic regulation of heart rate. He used linkage mapping to identify a new genetic locus controlling heart rate in a model organism and applied integrative genomics approaches to dissect the locus and identify a new candidate gene for the trait.

Dr Ware says, “This gene, encoding a cell adhesion molecule, has not previously been associated with cardiac function and may identify a new pathway for therapeutic modulation of heart rate.”

Dr Ware then moved into human genetics, developing next-generation sequencing approaches for molecular diagnostics and high-throughput sequencing studies in inherited cardiac conditions.

He also developed a computational approach to help determine whether new genetic variants identified in clinical diagnostic sequencing are pathogenic or benign. Dr Ware presented this work at the Heart Rhythm Society’s 33rd Annual Scientific Sessions in Boston, MA, in 2012.

**Dr Ware with Rachel Buchan, MSc, preparing samples for DNA sequencing in the lab at the National Institute for Health Research Royal Brompton Cardiovascular Biomedical Research Unit. Photo courtesy of Dr Ware.**
where he was runner up in the Young Investigator’s Award competition.

After a postdoctoral fellowship and a Fondation Leducq travel award to work in the lab of Professor Jon Seidman, PhD, and Professor Christine Seidman, MD, at Harvard Medical School, Boston, Dr Ware took up a clinical lectureship at Imperial College and the Royal Brompton Hospital in October 2012, where he is carrying out postdoctoral research in the lab of Professor Cook alongside higher specialist training in cardiology. He says, “I am currently studying the mechanisms of action and phenotypic consequences of titin variation in cardiomyopathy in collaboration with the Cook and Seidman labs.”

References

“We Demonstrated that IGFBP-1 Protects Against Atherosclerosis and Diabetes Mellitus by Reversing Insulin Resistance”
Adil Rajwani, MBChB, MRCP, PhD, cardiology registrar, University of Leeds, Leeds, England, received the British Cardiovascular Society prize in 2010.

Dr Rajwani’s research was conducted at the University of Leeds and was supported by the British Heart Foundation. He was supervised by Stephen Wheatcroft, FRCP, PhD, and Professor Mark Kearney, FRCP, DM, who have published extensively on the cellular associations of insulin resistance and cardiovascular disease, and in particular the interactions of the insulin/insulin-like growth factor (IGF)/IGF-binding protein (IGFBP) axis on these disease processes.

Dr Rajwani’s project examined the endogenous protein IGFBP-1, which regulates glucose metabolism. In population studies, low concentrations of IGFBP-1 are known to predict an increased cardiovascular risk, but little else was previously known about this association. In a murine model of atherosclerosis and in 2 models of insulin resistance (with low endogenous levels of IGFBP-1), transgenic overexpression of IGFBP-1 prevented the development of atherosclerosis and rescued glucose and blood pressure homeostasis. IGFBP-1 mediated these actions by restoring endothelial function and insulin sensitivity.

Dr Rajwani says, “When investigating the mechanisms underlying these novel findings, we demonstrated that IGFBP-1 independently upregulated endothelial synthesis of nitric oxide via a number of signalling intermediaries that are implicated in insulin signalling and insulin resistance.”

Since completing his PhD, Dr Rajwani has returned to clinical training as a cardiology registrar and is developing his research and clinical interests in cardiac imaging.

Reference

Jennifer Taylor is a freelance medical journalist.