

<b>Institution:</b> University College London (UCL)		
<b>Unit of Assessment:</b> 10 - Mathematical Sciences		
<b>Title of case study:</b> Communicating and improving children's heart surgery outcomes in the UK, Ireland, and the USA.		
<b>Period when the underpinning research was undertaken:</b> 2010 - 2019		
<b>Details of staff conducting the underpinning research from the submitting unit:</b>		
<b>Name(s):</b>	<b>Role(s) (e.g. job title):</b>	<b>Period(s) employed by submitting HEI:</b>
Professor Christina Pagel	Professor of Operational Research	2005-present
Professor Sonya Crowe	Associate Professor of Operational Research	2009-present
Professor Martin Utley	Professor of Operational Research	1996-present
Dr Libby Rogers	Research Associate	2015-2017
Dr Luca Grieco	Senior Research Associate	2014 - present
<b>Period when the claimed impact occurred:</b> August 2013 – present		
<b>Is this case study continued from a case study submitted in 2014?</b> Y		
<b>1. Summary of the impact</b> (indicative maximum 100 words)		
<p>Professor Pagel's group at the UCL Clinical Operational Research Unit (CORU) has developed models and tools that have transformed monitoring of mortality and complications following children's heart surgery. CORU's research influenced national standards for improving the quality of care, improved quality assurance at hospital units dedicated to congenital heart disease and enhanced national reporting in the UK. In this way, CORU's research has contributed to improved survival. Professor Pagel's research and development of a website on surgical survival data in children with CHD has improved public understanding on children's heart surgery outcomes in the UK. It also provided an inspiration for societies in the USA to build an online portal to help parents access and interpret survival outcomes after heart surgery there.</p>		
<b>2. Underpinning research</b> (indicative maximum 500 words)		
<p>Congenital Heart Disease (CHD) affects 1% of babies worldwide and is the most common birth defect in the UK, with 4000 surgeries performed each year. This surgery saves and transforms lives but comes with risks of serious complications and death, making outcomes following surgery highly scrutinised by clinicians, regulators, commissioners and the media. CORU's Operational Research in CHD comprises a unique combination of statistical model building, data visualisation, software development, and innovative methods for incorporating multiple perspectives on priorities for improvement and the collection and communication of data. The programme of three interlinked research projects (RPs) described in this section was conducted in step with the evolving priorities and needs of the clinical community, families, service commissioners and regulators.</p>		
<b><u>RP1. Tools for monitoring survival and complications following surgery</u></b>		
<p>Different children with CHD have different risk profiles. Hence, simply reporting raw survival statistics potentially penalises hospitals that take on the most complex cases. Before CORU's work, hospitals, audit bodies, regulators and commissioners were unable to account for this variability when monitoring surgical outcomes or benchmarking performance.</p>		

In 2010/11, CORU developed the “Partial Risk Adjustment in Surgery” (PRAiS) model for 30-day survival following paediatric cardiac surgery (**R1**). This was the first risk model in CHD to incorporate the nature of each child’s heart defect (diagnosis) and if the child had any other health problem (comorbidity). These innovations required detailed iterative analysis with expert clinicians to establish a manageable hierarchy of diagnostic groups and to decide which comorbidities to include in an indicator variable. In 2013, CORU developed software to implement PRAiS that enabled hospitals and the national CHD audit body (NCHDA) to generate graphical summaries of risk-adjusted survival over time (**R2**). Using the software, hospitals could, for the first time, check that their survival rate was commensurate with national expectations by comparing it to the range predicted by PRAiS. In 2015/6, CORU significantly upgraded the model and software with more detailed information about comorbidities and severity of illness in response to the improvement in survival and data collection that followed the 2013 introduction of PRAiS (**R3**). The research used statistical methods trusted by the clinical community, such as logistic regression and validation in pristine test-data, to enhance the prospects of its adoption.

In 2014-18, CORU collaborated with a broader set of clinicians to select and define complications following surgery suitable for routine monitoring. CORU augmented the nominal group technique with robust voting methods to incorporate the perspective of CHD patients and their families in decisions on what to measure, before embarking on the world’s first prospective study of post-operative complications in CHD surgery (**R4**). This established the rate of each complication in UK practice and identified risk factors for complications.

### **RP2. Understanding children’s heart surgery outcomes**

In parallel to **RP1**, Professor Pagel designed and led an innovative study to develop a website to help families and the public access and interpret the published data (**R5**). This combined her expertise in statistical modelling, graphical displays and software development with psychology experiments and co-design prototyping. Working with charities, families of children who had undergone surgery, clinicians, journalists, members of the public and other academics, Professor Pagel developed content explaining how the NHS collects and analyses survival data in CHD, iteratively adapting text in response to feedback from the co-design process. This ensured that, for the first time, the survival data were presented using displays and language chosen by and tested with key audiences.

### **RP3. Targeting services to improve care for babies with CHD outside hospitals**

Previous research had not addressed concerns over levels of out-of-hospital mortality among babies with CHD, the variable provision of services at and following discharge from hospital, or the barriers to care experienced by some families.

In 2013-15, CORU worked with clinicians to establish the magnitude of adverse outcomes facing babies with CHD in the year after discharge from hospital, doing this by linking and analysing two national audit datasets for the first time (**R6**). CORU innovatively combined soft systems methodology and classification and regression tree analysis to help an expert group including patient representatives target recommendations for service improvements to specific groups of infants based on their profile of risk (**R6**).

### **3. References to the research** (indicative maximum of six references)

R1. **Crowe S**, Brown KL, **Pagel C**, Muthialu N, Cunningham D, Gibbs J, Bull C, Franklin R, **Utlely M**, Tsang VT (2012) Development of a diagnosis- and procedure-based risk model for 30-day outcome after pediatric cardiac surgery. *Journal of Thoracic and Cardiovascular Surgery*, 145:1270-8, 2013 doi:10.1016/j.jtcvs.2012.06.023

R2. **Pagel C**, **Utlely M**, **Crowe S**, Witter T, Anderson D, Samson R, McLean A, Banks V, Tsang V, Brown K (2013). Real time monitoring of risk-adjusted paediatric cardiac surgery outcomes using Variable Life Adjusted Display: implementation in three UK centres. *Heart*, 99(19) doi:10.1136/heartjnl-2013-303671

R3. **Rogers L**, Brown KL, Franklin RC, Ambler G, Anderson D, Barron DJ, **Crowe S**, English K, Stickley J, Tibby S, Tsang V, **Utley M**, Witter T, **Pagel C** (2017). Improving Risk Adjustment for Mortality After Pediatric Cardiac Surgery: The UK PRAiS2 Model. *Annals of Thoracic Surgery*, 104(1):211-219 doi:10.1016/j.athoracsur.2016.12.014

R4. Brown KL, Ridout D, **Pagel C**, Wray J, Anderson D, Barron DJ, Cassdiy J, Davis PJ, Rodrigues W, Stoica S, Tibby S, **Utley M**, Tsang V. (2019) Incidence and risk factors for important early morbidities with paediatric cardiac surgery. *The Journal of Thoracic and Cardiovascular Surgery*, pii:S0022-5223(19)31166-3. doi:10.1016/j.jtcvs.2019.03.139

R5. **Pagel C**, Jesper E, Thomas J, Blackshaw E, Rakow T, Pearson M, Spiegelhalter D. (2017). Understanding Children's Heart Surgery Data: (2016) A Cross-Disciplinary Approach to Codevelop a Website. *Annals of Thoracic Surgery*, doi:10.1016/j.athoracsur.2016.11.080, 2017

R6. **Crowe S**, Brown K, Tregay J, Wray J, Knowles R, Ridout DA, Bull C, **Utley M**. (2017) Combining qualitative and quantitative operational research methods to inform quality improvement in pathways that span multiple settings. *BMJ Qual Saf*, 26(8):641-652. doi:10.1136/bmjqs-2016-005636

#### 4. Details of the impact (indicative maximum 750 words)

NHS England commissions surgical centres and other services for children with CHD centrally. The following are crucial to this commissioning framework: the service standards set in contracts; the quality dashboards used to assess performance on a quarterly basis; and financial incentives for the provision of specific services. CORU's research transformed how local clinicians and national regulators monitor CHD surgical outcomes, and how these outcomes are reported in national audit. It resulted in funding for new services, increased the quality and accessibility of outcome data, and improved public understanding of this complex and highly emotive topic. The OR [Operational Research] Society recognised the "significant impact on the lives of children with congenital heart disease" when awarding CORU the 2019 Lyn Thomas Impact Medal for "the academic OR research which best demonstrates both novelty and real-world impact" (**S1**).

#### **Research informed national standards for improving the quality of care:**

In July 2015, NHS England published recommendations for an improved model of CHD care in the "New Congenital Heart Disease Review" (**S2**). CORU's research on the development of online resources for interpreting survival data (**RP2**) and measuring surgical complications (**RP1**) was discussed in detail and formed the basis for recommendations. In addition, the review acknowledged the improvements in data quality resulting directly from implementation of PRAiS model: "The PRAiS model (...) enabled meaningful analysis to be performed on 30-days mortality. The development of PRAiS and improvement in data quality has led to a high level of confidence in the 30-day mortality information produced" (**S2**).

Subsequently, NHS England published new "Congenital Heart Disease Standards & Specifications" in May 2016. These stipulate the use of PRAiS software by hospitals in monthly reviews of their outcomes: "The Network will (...) review dashboard metrics including PRAiS mediated variable life adjusted display plots (VLAD) outcomes and unplanned re-interventions, discussion of mortality, morbidity, adverse events and resultant action plans" (**S3**). In addition, they specified quality metrics for a national dashboard to help prevent premature deaths that included the use of PRAiS and the measurement of post-surgery complications (**S3**). Since 2016, these metrics have been submitted quarterly to the NHS Congenital Heart Paediatrics Specialised Services Quality Dashboard (SSQD) used to monitor service quality and support improvements. In the two years to September 2019, the inclusion of complication data based on **RP1** led to seven instances of hospitals being identified as outliers by the NHS England Quality Surveillance Team (**S5**). Subsequently,

these hospitals had to account for high complication rates and detail the measures put in place for improvement.

CORU's research on targeting improvements (**RP3**) directly informed commissioning of CHD services. Specifically, recommendations from this research were implemented by NHS England setting standards on: 1) the information that should accompany children if their care is transferred between services; 2) the employment of more cardiac liaison nurses; 3) each child having a named cardiac liaison nurse; and 4) on the need for regular review of deaths outside hospital by staff working in primary, secondary, tertiary and community care (**S5**).

Another recommendation of the research prompted NHS England to introduce, within the Commissioning for Quality and Innovation (CQUIN) framework, financial incentives for the development of home monitoring services for children with just one functioning ventricle. This resulted in the provision of this beneficial service across centres in England that perform cardiac surgery in UK children (**S5**).

#### **Improved quality assurance of CHD programmes:**

The PRAiS software (**R2**) was adopted by the NCHDA and by all 13 hospitals in the UK and Ireland performing children's heart surgery within one year of its release in March 2013 (purchased through UCL Business at GBP3,000 per licence). CORU's updated model and software, PRAiS2 (**R3**), were adopted by NCHDA and the 13 hospitals within two weeks of its release in June 2016.

Death rates have fallen from 2.5% in 2010-2013 to 1.5% in 2016-2019 (**S4**) equating to 40-50 fewer children dying within 30 days of surgery each year. While attributing this improvement to any one factor is not possible, transparency of outcome data is widely recognised as a precondition for, and a key driver of, sustained quality improvement in healthcare. The former Chair of NHS England's congenital heart services clinical reference group acknowledged "The risk-adjustment for case-mix, user-friendly front-end to the software and the intuitive presentation format have engendered a renewed focus of attention on performance and outcomes throughout provider units. Monthly review of outcomes using these metrics has been a major contributor to enhanced clinical governance, engendered a culture of service review and improvement and in turn improved surgical outcomes." (**S5**)

In April 2015, following CORU's extensive programme of patient and user engagement, NCHDA adopted seven of the nine complications CORU had recommended for measurement in **R4** for national routine collection (**S4**), including two particularly driven by parental needs. Prior to CORU's research, the incidence and impact of these complications was unknown. Data from all UK centres on these complications were reported for the first time in NCHDA's 2017-18 report (published in 2019), which acknowledged that monitoring them "offer[s] important data (...) of value to parents, the clinicians at the centres undertaking the operations and specialist commissioners" (**S6**).

Five hospitals have monitored complications with a further tool developed by CORU. Its application has increased understanding and enabled better data granularity as evidenced by a Clinical Nurse Specialist: "More frequently we need to use data visualisation tools like this to explain the complexity of the data. The automated slides are easy to use and understand and the fact that in essence we can drill down to see more specific data makes this a powerful and efficient tool for reviewing morbidity outcomes. This tool helps us a lot and is especially useful when trying to explain this sort of data to parents and young patients" (**S7**). The Clinical Lead of NCHDA acknowledged the impact of CORU's research: "CORU's research in the field of CHD has established state-of-the-art quality assurance metrics (...). The research work with CORU has been and will continue to be a major factor in why the NCHDA is regarded as an exemplar, both nationally and internationally, for outcomes analyses, quality assurance and targeted quality improvement initiatives in the field of paediatric and congenital cardiology" (**S4**).



**Improved public understanding on children's heart surgery outcomes:**

NCHDA's survival data on children's heart surgery is used by journalists, politicians, and the public to make difficult judgements about whether heart surgery is "safe". The Understanding Children's Heart Surgery Outcomes website developed by Prof Pagel (**R5**) launched in June 2016. The site has approximately 3500 users per year, consistent with it being widely used among parents of the 4000 children per year who have heart surgery in the British Isles. The website provides in-depth, state-of-the-art explanations for this sophisticated and complex form of outcomes analysis and is "highly regarded nationally by parent groups, NHSE, the CQC, individual centres and clinicians, as well as internationally, as an exemplar for public reporting of outcomes following CHD surgery" (**S4**). One parent acknowledged, "it [is] reassuring to know there is a site we can go to for impartial and trustworthy information. (...) I also now understand what the existing data on children's heart surgery can and can't tell us" (**S8**). The website was complimented in the national press and endorsed by major stakeholders including charities, clinical specialists and Royal Colleges (**S9**). An editorial in leading medical journal *The Lancet* commented that the website "does an excellent job of explaining what these statistics can and cannot tell parents and how they should be used" and that "many more areas of medicine requiring risk communication should take this initiative as a long overdue and most welcome example" (**S9**).

Prof Pagel's research for the website "had a strong influence on the development, functionality and success of our Hospital Navigator", an online portal developed by the Conquering CHD charity and the Society of Thoracic Surgeons to help parents access and interpret USA survival outcomes after heart surgery (**S10**). The design, language, and content of Hospital Navigator were inspired by Professor Pagel's work, which is "highly regarded and became recognised as best practice" (**S10**).

**5. Sources to corroborate the impact (indicative maximum of 10 references)**

- S1. The Operational Research Society announcement of Lyn Thomas Impact Medal 2019 corroborates the novelty and impact of the underpinning research in improving services for children with congenital heart disease.
- S2. NHS England New Congenital Heart Disease Review: Final report (published 23/07/2015) corroborates the recommendation for PRAiS application within NHS England.
- S3. "Congenital Heart Disease Standards & Specifications" (published 23/05/2016) corroborates the requirement that hospitals use of PRAiS software in monthly reviews of surgery outcomes and the influence of CORU research on other service standards.
- S4. Supporting statement from the Former Clinical Lead for NCHDA corroborates statements provided and that the underpinning research informed reporting and monitoring of postprocedural complications within 30 days of CHD surgery.
- S5. Supporting statement from the Chair (2015-19) of NHS England's congenital heart services clinical reference group corroborates the use of the CQUIN framework in England, the influence of CORU research on other service standards, and the role of PRAiS2 in improving outcomes.
- S6. National Congenital Heart Disease Audit (NCHDA) Report 2017-2018 corroborates benefits of using PRAiS software in reporting survival data and the value of reporting surgical complications.
- S7. Supporting statement from a clinical nurse specialist corroborates statement provided.
- S8. Guest post on Mumsnets blog (02/08/2016) corroborates statement provided.
- S9. Articles and blog posts in *The Guardian* (21/06/2016), *Lancet* (25/06/2016), Royal College of Surgeons (21/06/2016), Children's Heart Federation (date not provided) corroborate media coverage of "Understanding Children's Heart Surgery Outcomes" website and benefits of resources it provides.
- S10. Supporting statement from the Director of Programmes at Paediatric Congenital Heart Association (Conquering CHD) corroborates the influence of the "Understanding Children's Heart Surgery Outcomes" website on the "Hospital Navigator" website.