The Application of a Mortality Risk Model to Adjust for Case Mix in Paediatric Cardiac Surgery for the United Kingdom using the Central Cardiac Audit Database

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TITLE:

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AIMS:

To establish whether a risk model can be developed that is fit for the purpose of adjusting for case mix severity during routine monitoring of outcomes for paediatric cardiac surgery in the United Kingdom (UK).

OBJECTIVES:

Our objectives are as follows.

1)   To test an existing risk model based on the RACHS-1 score and patient age, derived from outcomes at one centre (GOSH), to the CCAD data from all centres across the UK.

2)   To understand the contribution that diagnostic information can make to risk estimation and monitoring of outcomes, establish whether information concerning co-morbidities can contribute to improved methods of risk estimation and, if indicated and possible, revise the existing risk model such that it is suitable for use at other centres and by CCAD.

3)   To examine the implications of reporting mortality outcomes by diagnosis as well as by procedure category.

4)	To disseminate our findings and any risk models and monitoring tools developed to UK centres and to the CCAD so that it can consider how best to share the information with stake holders including via its "public portal" web pages.

STATEMENT OF RESEARCH QUESTIONS:

It has been recognised for some time that it is important and valuable to monitor outcomes in cardiac surgery and that to do so fairly and effectively, one needs to risk-stratify the case load of each unit. Analytical methods for doing this are well advanced for adult cardiac surgery and the use of graphical techniques to display risk-adjusted outcome charts is now a commonly used part of the quality assurance process. Currently no process for routine risk adjustment for paediatric cardiac surgery exists. Such methods have been suggested for paediatric cardiac surgery but as yet these have not been subjected to rigorous testing using large multi-site data sets and this is necessary before the methods are introduced into routine use. Support is sought for a multi disciplinary clinical group with expertise on outcomes in paediatric cardiac practice, to work with the team of mathematicians behind many of the techniques used in outcome monitoring for adult cardiac surgery. Working with the Central Cardiac Audit Database, we will use the data to investigate the robustness of risk scoring across different centres with a view to establishing the feasibility of routine outcome monitoring methods in paediatric cardiac surgery. This will include exploring the addition of diagnosis and co-morbidity information to existing risk models and the implications of reporting outcomes by both diagnosis and procedure. The proposed study is not a trial or an experiment based on formal hypothesis testing. Rather, the hypothesis that motivates the study is that the use of case-mix adjustment in the routine monitoring of outcomes for congenital heart surgery would improve quality assurance processes and the information available to surgeons and carers. The work will establish whether a risk-model can be found that is fit for this purpose.

BACKGROUND:

Progress in risk stratification for paediatric congenital heart surgery
It has long been accepted [1] that risk stratification of adult cardiac surgery patients is an essential part of the audit process which reduces the prospect of unfair assessment of outcomes attributed to a surgeon or team whose mortality rate is relatively high simply because it reflects patients that were inherently higher risk. In addition, various methods have been developed to help in the analysis and interpretation of risk stratified data [2-6].

Achieving something similar for paediatric congenital heart surgery is clearly desirable, but is challenging, due to the great diversity of the patient population in terms of the diagnoses, indications for surgery, the operation performed, age at operation and other factors [7]. At present, mandatory data submissions are requested every three months to CCAD from

hospitals performing cardiac surgery in the UK, including details about the patient and the operation performed. CCAD later independently checks the patients' survival status with the Office of National Statistics and therefore patient identifiers including the NHS number are provided to CCAD, which holds exemption under section 60 of the Health and Social Care Act 2001.

Even before much had been published on risk scoring systems for congenital surgery, simple monitoring methods had been discussed [5]; however since then there have been advances in this field. With respect to the operation performed, there exists an internationally accepted classification scheme called RACHS-1 [8], by which 79 different types of operation are grouped into 6 categories ranked in order of increasing risk, as perceived by clinicians. The RACHS-1 scheme appears to be useful as a basis for forecasting risk [7], has been validated in a range of contexts and as of November 2009 has been cited in 214 scholarly articles. There is also a scoring system known as ARISTOTLE [9] for grading the complexity of operations, although it has been shown that the RACHS-1 scoring system is better suited for stratifying risk [10]. Recently two large databases in North America and Europe were used to develop an empirically based tool for monitoring mortality after congenital heart surgery, which appears to perform well [11]. However, this tool was developed using voluntary data submissions and is based on the survival status at hospital discharge, which may differ significantly to the outcome at 30 days.

Importantly, the literature and our own work to date focus on outcomes and risks according to the procedure(s) that patients have undergone, augmented by patient-specific information such as age and weight. Currently, no use is made of information concerning the nature of the heart defect nor of any co-morbidities that the patient has. Whilst in many areas of surgery there is a one-to-one mapping between diagnosis and surgical intervention, this is not the case in paediatric congenital heart surgery. Some procedures are performed for a number of diagnoses, which undermines the extent to which the procedures performed by a surgeon or within a unit accurately reflects case-mix. Similarly, the same heart defect may be managed using different surgical interventions, with the choice of intervention reflecting other aspects of the patient's condition (age, weight, co-morbidities, severity of symptoms) but also with scope for there to be differences in surgical strategy between units based on local experience and, potentially, on a different balance being struck between long term objectives and short-term risks. An understanding of this complex issue is essential to determining whether and how diagnostic information may be usefully combined with information concerning the procedures performed in methods for risk-stratification.

Appropriateness of the project team

Work led by the first applicant has resulted in the development of a predictive model of risk for paediatric cardiac surgery based on the RACHS-1 classification and age at operation [12]. This risk model has been developed using only data concerning patients that had surgery at Great Ormond Street Hospital (GOSH). One of the main motivations for this research proposal is to establish the extent to which this risk model is appropriate for use with data concerning patients of other hospitals; it is conceivable that, due to differences in the nature of the patients seen and the surgical strategies employed, the relationships between RACHS-1 classification, age and risk may differ at other centres.

The second applicant has trained in health services research, having undertaken the MSc in public health with health services research focus at the London School of Hygiene and Tropical Medicine in 2007. She has since taken on the role of clinical outcomes lead for cardiothoracic services at GOSH where she has worked with the CCAD to improve the data quality of cardiac surgery procedure records at GOSH and has functioned as an external assessor for CCAD at other institutions.

The third applicant is based with CCAD and has been the original project manager for the cardiac audits, since CCAD was founded in 1996. He has both technical training with a PHD and a clinical background in cardiac electrophysiology, a combination, which facilitates the liaison between the clinical leads of the national audits and the technical staff in CCAD who build the applications. His responsibilities to date have included the analysis of the data and generation of the tables and funnel plots which are shown on the Congenital Public Portal (www.ccad.org.uk/congenital).

The fourth, fifth and sixth applicants work at the Clinical Operational Research Unit (CORU), which is an academic group that applies mathematical and statistical modelling methods to a wide range of clinical problems. The unit has particular research interests related to cardiology and cardiac surgery [see, for example 2, 4, 5, 6, 11]. In collaboration with Professor Tom Treasure (now an honorary member of the unit), CORU helped to develop a simple graphical method (known as VLAD) that can be used to chart mortality outcomes in adult cardiac surgery for a unit or individual surgeon, taking due account of the risk stratification of caseload [2]. This method is used extensively and has become a standard analysis tool in the audit of adult cardiac surgery. CORU has also been active in

methodological research associated with risk scores and outcomes assessment, being the first to use so called 'funnel plots' for assessing outcomes in cardiac surgery [14], having developed novel methods for assessing risk scoring systems [15] and having collaborated with the development of a risk scoring system for adult thoracic surgery [16]. There have been previous successful collaborations between CORU and Great Ormond Street Hospital including work on outcomes [5, 11, 14], safety [13] and hospital operation [17, 18].

The project team will be assisted by a research fellow with skills in data analysis, mathematical modelling and inter-disciplinary collaborative work with clinical teams. The project goes well beyond formulaic data analysis. It is necessary for those involved in data analyses to be familiar with the operation of a paediatric cardiac surgery centre, to gain an appreciation of the surgical nomenclature, the context in which data are collected and also to have an appreciation of the ways in which outcomes monitoring can be used to promote good practice. Such a "hands-on" approach to analytical work within clinical research is a hallmark of CORU's methodology and will be facilitated by the make up of the project team.

Monitoring outcomes in congenital heart surgery

As already discussed, charts of outcomes that take preoperative risk factors into account have been developed for use in adult cardiac surgery to display a surgeon's overall outcomes and to highlight any disturbing trends [2,6]. These charts are called Variable Life Adjusted Displays, or VLAD charts, which is their commonly used acronym. Members of the project team have been instrumental in establishing the technical feasibility of constructing VLAD charts relating to paediatric congenital heart surgery [12]. One such VLAD chart is shown in Figure 1. Here, successive operations are plotted on the horizontal axis and the jagged graph shown in bold gives a running tally of how much better (or worse) outcomes have been compared to what would be expected using a risk model. Systematic descent of this curve indicates possible cause for concern, the coloured regions indicating the chance that departure from the horizontal could be a chance coincidence. In this example, the VLAD curve rises, which indicates better than expected outcomes.
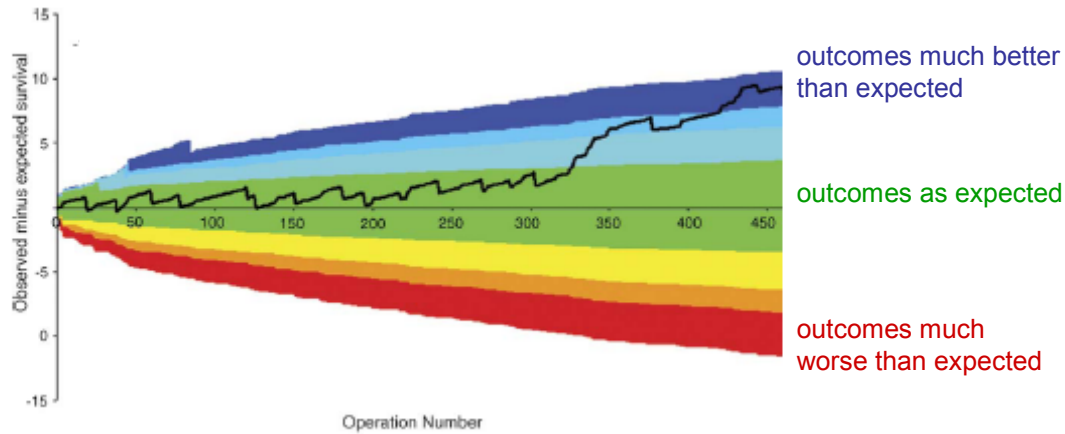
Figure 1: **An example of a Variable Life Adjusted Display (VLAD) Chart.**

Before such methods are introduced into common use for paediatric cardiac surgery, there is a need to test both the underlying risk model and the monitoring methods to ensure that they are not misleading. The project team have begun this process by assessing the accuracy of the risk model across the range of risk, using data from a single unit (GOSH). As shown in figure 2, we have established that, among the Great Ormond Street data used in the construction of the model, the risk model performs well for predicted risks over 3%, under-estimates risk for predicted risks in the range 2%-3% and over-estimates risk for patients with a predicted risk less than 2%. These features of the risk model do not significantly undermine its use in monitoring outcomes at GOSH [19] but the question arises as to whether such features could bias comparisons between centres with markedly different case mix.
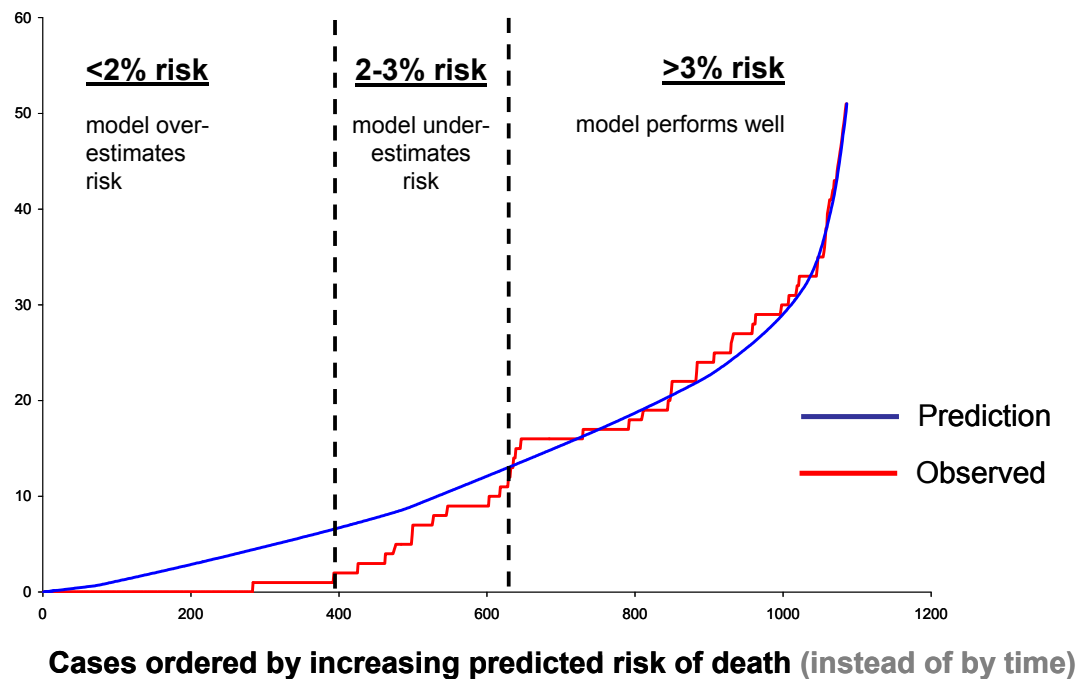
Cumulative deaths

Figure 2 Comparing cumulative tallies of deaths compared to what would be expected given the risk model developed at Great Ormond Street Hospital

Current NHS policy places increased weight on patient outcomes and quality improvement. Clearly one of the remits of a national audit database is to monitor outcomes and quality. The complexity in both diagnosis and procedure for congenital heart surgery has meant that this is currently not feasible. The main objective of this research project is to explore the feasibility of such routine monitoring.

NEED:

In the wake of the Bristol Royal Infirmary Inquiry where one centre experienced a number of excess deaths in children after cardiac surgery, there has been an emerging culture of audit and quality improvement in the NHS. The CCAD public web portal for paediatric heart surgery data was launched in 2007 and up to the end of 2008, 68,000 procedures have been submitted from throughout the UK. During this period, outcomes of paediatric cardiac surgery have become subjects of great interest to the clinical community, patient families and the public. Despite this, relatively little is known about risk-stratified mortality rates in this context, because the case mix for paediatric cardiac surgery is very complex. Currently no process for routine application of risk adjustment exists that addresses this complexity.

Therefore, despite effective mandatory national audit data collection, clinical teams and others do not have tools for monitoring risk-adjusted outcomes in a fair and robust way.

The CCAD organisation is strongly supportive of this research: the most recent CCAD national contributors' meeting, which includes patient family representation, and the CCAD Newsletter noted the deficiencies in access to data analysis as significant impediments to the audit program. The current approach taken by CCAD in terms of assessing and reporting patient outcomes is to evaluate 36 specific paediatric cardiac surgery procedure categories, summarising the number of deaths in each one for individual centres and comparing these between centres. There are two major problems with this system of evaluation: the number of procedures is large and the number of individual patients in each category, even across the whole country is relatively small and therefore the system is very unlikely to detect true differences in outcome in a timely fashion. The second is that the 36 specific procedure categories do not capture all of the operations performed (RACHS-1 identifies 79) and it excludes many operations that result in mortality, rendering those procedures relatively inaccessible to the monitoring system. For these reasons we currently lack the necessary insights into how to monitor and assess outcomes to ensure that optimal standards are maintained.

Outcome monitoring with appropriate risk adjustment is well advanced in adult cardiac surgery, which has been of clear benefit to the surgical profession in relation to its quest for improved quality assurance. There is evidence that since outcome monitoring in adult cardiac surgery became mandatory and routine, outcomes have improved and there has been no consequent negative effect in terms of centres turning away high risk cases, as was originally feared [20]. There were consequent benefits to patients and their families in terms of the quality of care and the improved information they received. It is hoped that new knowledge generated by the results of this proposed research will help to promote equivalent quality assurance and transfer of information in the paediatric cardiac surgical community in a sustainable way.

This proposed project, which seeks to explore the feasibility of routine risk adjustment to paediatric cardiac surgery in the UK, is possible since a high quality national database now exists. The only way to effectively perform a project of this kind is to use a large national dataset such as the CCAD database in order to remove the biases associated with optional reporting of procedures such as occurs in other large databases [11] and avoid the case mix bias that may arise when using data from a single centre. Since patient mortality outcomes

are independently checked by CCAD with the Office of National Statistics, the chance of underreporting of poor outcomes, as has also been reported in a recent study from North American and European Databases [11], will be avoided. As stated, the project team includes a senior figure within the CCAD organisation and has put in ground work in this area over the previous few years as laid out in BACKGROUND. The project is in line with the mission of the HSR program since it seeks to apply a risk adjustment model to an existing national database, which is one of the stated areas of its remit. Furthermore, the proposed research complements current wider NHS policy in terms of quality improvement and the generation of quality accounts, since adjustment for case mix in paediatric cardiac surgery would increase the likelihood of such accounts being useful and interpretable.

METHODS

Preparatory work

The national dataset of paediatric cardiac surgery procedures (68,000 records) is currently being prepared for use in this programme of research by the CCAD and will be released to the analysts shortly. Over the period January to May 2010 inclusive, we will develop an algorithm to automate the classification of surgical procedures according to the RACHS-1 scheme. Additionally we will liaise with the CCAD to ensure that the analysts, who have already spent time familiarising themselves with the context of paediatric heart surgery, are fully conversant with the methods employed by CCAD in collating, "cleaning" and coding the data it receives from surgical units. We are not seeking funding for this preparatory work.

Data analysis and model development

Given the features of the performance of the current risk model that are evident using data from Great Ormond Street Hospital, it is inevitable that the development of a more refined model of peri-operative mortality risk will be warranted. A carefully designed analysis strategy will be used, subdividing data gathered into two sets – the development set and the test set. These sets will be compiled using a randomisation process to select of 70% of all data available at the outset of the project, stratified by centre and calendar year, to form the development set. The test data set (the remaining 30% of the available data) will not be used until the latter phases of the study and will play no part in risk model development. It is necessary to observe such a quarantine process to avoid the bias that inevitably results if the same data that are used to develop a risk model are used to test it, which almost always leads to overoptimistic test findings. We anticipate that some of the work on this section of

the project, developing the procedure based model may be complete by mid way through 2010.

Initial exploratory analyses

The development set will first be used as the basis for a number of exploratory analyses in order to learn more about pre-operative factors reported to CCAD that influence outcome and other issues associated with the development and use of risk scores. Since the development set is quarantined from the test set, however many analyses of this sort are performed, no accidental bias can be introduced to the final evaluation of the resultant risk model. Such preliminary analyses will include:

1. Identification of inter- and intra-centre differences in practice;
2. Identification of any time varying patterns of operative complexity (as assessed by the RACHS-1 score), predicted risk (assessed using the existing Great Ormond Street risk model) or outcome;
3. Examination of the sensitivity of risk scoring to the classification used within the RACHS-1 method;
4. Examination of outcomes by diagnosis, and any subsequent implications for use of risk models based only on procedure;

A particularly important topic for investigation concerns the treatment of data in cases where a patient has several procedures during the course of a single operation, several operations during a single episode of hospital care or several operations at different points in time in the management of single heart defect. This is not uncommon with patients who have congenital heart abnormalities. The usual manner in which such cases are used in risk scoring exercises is to assign the outcome to the procedure that has the highest complexity score however it is far from clear whether this is sound. We intend to examine this by examining outcomes for patients assigned to a given complexity score to see whether those having multiple procedures have a higher mortality than those who don't. This issue may partly be addressed by the exploration of risk adjustment based on diagnosis.

These issues will be addressed both by data analysis and by mathematical modelling, which has proved useful in this context [21].

Development of a more refined risk model

The next phase of analysis will be concerned with using the development data set in order to derive a risk model more refined that that presently available, better reflecting current practice across the UK. Development of a new risk model will have two phases, the first concerning the choice of risk factors to include from those routinely reported to CCAD, the second being one of calibration.

Assessing the performance of the new risk model

The final stage of the analysis will be to use the test data set (previously quarantined from the analysts) to assess the performance of the risk model. Formal statistical testing will be carried out using the Hosmer Lemeshow test [22] and related statistical methods. In addition, analysis using the MADCAP method [14] will be performed to provide a visual guide to the performance of the risk model over the entire range of risk, [c.f. Figure 2].

Assessing the robustness of the routine monitoring of risk-adjusted outcomes

Having assessed the performance of the risk model, we will go on to establish whether its use in the routine monitoring of outcomes is robust. To this end a further set of data will be obtained from the CCAD covering the period since the start of the research project. These data will be used as test data for examining the performance of the monitoring tools developed to mimic the prospective monitoring of risk adjusted data at the level of individual units, enabling the analysts to establish the extent to which any features of the risk model may undermine the validity of its routine use. Importantly, this activity will also give some indication as to how often the risk model should be updated to reflect changes in the underlying risk of peri-operative mortality faced by paediatric congenital heart surgery patients in the UK.

Based on this final analysis, we will establish caveats to the interpretation of risk-adjusted outcome data that will be disseminated alongside tools for prospective monitoring of outcomes in paediatric congenital heart surgery.

Power Calculations

Access has been granted by the CCAD to available data concerning all congenital heart operations performed in UK sites during the period 2002-2008 inclusive and on an ongoing basis, the size of sample available to the research team (approximately 68,000 cases in the first instance) is ample for the purposes outlined.

CONTRIBUTION TO COLLECTIVE RESEARCH EFFORT AND RESEARCH UTILISATION

It is hoped that the main product of this research will be a risk model that is suitable for routine monitoring of outcomes, although it is possible that analysis will show that the complexity of congenital heart surgery is not adaptable to such routine monitoring. Although certain procedure based mortality rates are currently available, and are of interest for stake holders who may require information on a particular procedure, the overall performance of a cardiac programme cannot be monitored on the basis of a single procedure. We plan to offer graphical displays of results over time, which could be used to identify increases or decreases in the performance of the programme, thus rendering these more accessible to quality control. The output of our research would be better powered to detect problems arising in a programme at an earlier stage. We plan to work with key stake holders to ensure that our work is presented in a fashion which may be as easily interpreted as possible, including displaying the information on the CCAD public portal for all to see.

PLAN OF INVESTIGATION AND TIMETABLE

A timeline setting out the plan for achieving the aim of this project is shown below. Important milestones are shown by bold vertical lines indicating: the end of the model development period; the end of work establishing the feasibility of routine risk adjustment and the end of funded dissemination activity.

Activity	Jun 2010	Jul 2010	Aug 2010	Sep 2010	Oct 2010	Nov 2010	Dec 2010	Jan 2011	Feb 2011	Mar 2011	Apr 2011	May 2011
Test of previously developed RACHS and Age risk model on national data												
Explore the interaction between diagnosis, procedure and outcome in evaluating risk												
Develoment of a more refined risk model possibly incoporating diagnosis & co-morbidities												
Assessing performance of new risk model												
Explore the feasibiltiy of using the risk model in routine monitoring												
Prepare papers detailing research findings for submission to peer-reviewed journals												

APPROVAL BY ETHICS COMMITTEES

The CCAD database is exempt under section 60 of the Health and Social Care Act 2001, and as such is permitted to hold information relating to patients undergoing cardiac interventions in the UK. A data sharing agreement has been formed between the investigators based at the Clinical Operational Research Unit (CORU), University College London and the Information Centre for Health and Social Care, which sets out the conditions under which data may be transferred to CORU for the purposes of this research.

PROJECT MANAGEMENT

The project will be jointly managed by Dr Brown (at Great Ormond Street Hospital) and Professor Utley (at CORU) under the leadership of Mr Tsang. Formal progress meetings will be held monthly with the physical proximity of UCL and Great Ormond Street Hospital permitting frequent informal discussions concerning clinical and analytical issues as they arise during the course of the project. The analytical team hold honorary contracts at Great Ormond Street, which will enable them to gain essential insights concerning the context in which any risk-adjusted monitoring of outcomes will take place. The bulk of the analytical work will be conducted at CORU by a research fellow under the line-management of Dr Pagel.

SERVICE USERS AND PUBLIC INVOLVEMENT

The output from this study will be subjected to similar procedures to the data that are currently presented on the CCAD portal, which includes review by patient group representatives and other key stakeholders that are represented. Views will be sought on the interpretability and usefulness of the data and final presentation on the public portal will reflect this.

EXPERTISE AND JUSTIFICATION OF SUPPORT REQUIRED

The project team is a collaboration between clinicians, mathematicians with considerable experience of working with clinical data and the relevant national audit body (the Central Cardiac Audit Database), which combines:

1) Relevant clinical expertise developed working in the field of paediatric cardiac surgery (applicants 1 and 2) that is essential for successful completion of a complex project with direct clinical relevance such as this;

2) Data analysis and data management expertise (applicant 3) accrued by project management of the cardiac audit database for the previous 13 years from its inception;

3) Mathematical modelling and operational research expertise (applicants 4, 5 and 6) which has contributed to a range of projects in this area including the development of graphical monitoring tools used worldwide, the development of methods to evaluate the performance of risk models over the full spectrum of risk and the development of a risk model for use in monitoring outcomes of thoracic surgery.

The project team already have a successful track record of working together with a number of peer reviewed publications and presentations, most recently (Tsang V T, Brown K L, Synnergren M J, deLeval M R, Kang N, Gallivan S, Utley M, 'Monitoring risk-adjusted outcomes in congenital heart surgery: Does the appropriateness of a risk model change with time?', The Annals of Thoracic Surgery 87(2):584-587, 2009).

Work led by the first applicant Mr Tsang, who is an experienced cardiac surgeon, has resulted in the development of a predictive model of risk for paediatric cardiac surgery based on the RACHS-1 classification and age at operation. This applicant will supervise a more junior fellow in cardiac surgery, both on a part time basis, to provide clinical input for any procedure coding issues that may arise. The second applicant has trained in health services research, and has several years experience of data quality in relation to CCAD and will assist with clinical and data quality aspects of the work. Funding is sought for the first and second applicants and a cardiac surgical fellow, on a part time basis for one year to work on the clinical aspects of this project. The availability of diagnostic information and our plans to explore the potential use of this information make the success of this endeavor dependent on the clinical members of the team having sufficient, protected, time to work alongside the analytical team.

No funds are sought for the third applicant who is based with CCAD as the project manager and will function as the main link with this organisation.

The fourth, fifth and sixth applicants work at the Clinical Operational Research Unit (CORU), which is an academic group that applies mathematical and statistical modelling methods to a wide range of clinical problems and have been instrumental in developing monitoring tools for use in adult cardiac surgery. CORU's previous work on adult cardiac surgery audit contributed constructively to this area as may be seen from the publications list of related papers at the end of the full proposal attached in Appendix B. Funding is not sought for the team's preparatory work or for the contribution of Professor Gallivan and Dr Pagel; this will be funded from CORU's grant with the UK Department of Health Policy Research Programme. The project team will be assisted by a research fellow with skills in data analysis, mathematical modelling and inter-disciplinary collaborative work with clinical teams. Funding is sought for this research fellow for 7 months and for Professor Utley's contribution.

PLANNED OR ACTIVE RESEARCH GRANTS

2008 - 2011 *Cancer survivors and cancer survivorship: quantifying cancer prevalence and modelling its dynamics in England and the UK,* Macmillan Cancer Support (£172,000 over 3 years). Co-I Martin Utley

2006 - 2010 *The Clinical Operational Research Unit*, funded by the UK Department of Health Policy Research Programme (£2,400,000 over 5 years).
PI since March 2007 Martin Utley, PI Jan 2006 – March 2007 Steve Gallivan.

2006 - 2009 *Developing Evidence Based and Acceptable Stepped Care Systems in Mental Health Care: An Operational Research Project*, funded by the NHS Service Delivery and Organisation R&D Programme (£300,000 over 3 years). Co-I Steve Gallivan, Martin Utley

HISTORY OF PAST OR EXISTING NIHR PROGRAM RESEARCH

None.

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