Improving risk adjustment in the PRAiS (Partial Risk Adjustment in Surgery) model for mortality after paediatric cardiac surgery and improving public understanding of its use in monitoring outcomes

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Scientific summary

The PRAiS model for mortality after paediatric cardiac surgery

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Scientific summary

Background

In a previous National Institute for Health Research (NIHR) Health Services and Delivery Research project, we developed a risk model for 30-day mortality after children's heart surgery. The PRAiS (Partial Risk Adjustment in Surgery) model incorporates information on the procedure performed, diagnosis, age, weight and comorbidity. A comorbidity is any other health problem a patient has alongside their cardiac condition (e.g. prematurity or genetic abnormalities). Because of issues around the completeness and quality of the data set used for the model development, our treatment of comorbidity had to be simplistic.

Clinical teams are now using software that implements the PRAiS model to monitor outcomes on a regular basis; the National Institute of Cardiovascular Outcomes Research (NICOR) uses it in its audit work, and NHS England has adopted the use of the model as a quality standard.

The availability of PRAiS triggered events that resulted in the temporary suspension of surgery at one unit and a consequent drive to improve data completeness at all units. The media scrutiny and public anger that surrounded this service suspension illustrated the need for additional public resources to support the appropriate interpretation of outcome data.

Aims and objectives

- Aim 1: improve the PRAiS risk model for 30-day mortality following paediatric cardiac surgery by incorporating more detailed information about comorbid conditions.
- Aim 2: develop, test and disseminate online resources for families affected by congenital heart disease in children, and for the public and the media, to facilitate the appropriate interpretation of published mortality data following paediatric cardiac surgery.

The objectives to achieve aim 1 were:

- to revisit, with better data, the potential for using, within PRAiS, comorbidity groups devised during the original study (1.1)
- to modify or refine these comorbidity groups and explore options for changing our handling of procedure and diagnostic data (1.2).

We would then:

- explore trade-offs between the detail used for procedural, diagnostic and comorbidity information within PRAiS while maintaining a robust calibration (1.3)
- calibrate a new version of the PRAiS risk model, after deciding on the final risk factors (1.4)
- update the PRAiS software as necessary (1.5).

The objectives to achieve aim 2 were:

- to confirm the presentations of mortality data in national audit (2.1)
- to coproduce, with users, a web tool to facilitate the interpretation of mortality outcomes (2.2)
- to perform a mixed-methods evaluation of the web tool to improve the final version (2.3)
- to disseminate the final web tool and evaluate the final tool (2.4).

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Aim 1: update of the PRAiS risk model for 30-day mortality – methods

Data

Since 2000, quality assurance in paediatric cardiac surgery in the UK has been underpinned by the National Congenital Heart Disease Audit (NCHDA), which is managed by NICOR. Mandatory data submissions to NCHDA are requested every 3 months, and survival status is provided by the hospitals and through independent information from the Office for National Statistics (ONS), in which records are linked using NHS numbers. We received a data set of pseudonymised records from NCHDA in April 2015 that included all paediatric cardiac procedures performed in the UK and Ireland from January 2009 to April 2014. We removed all records in which the patient was aged > 16 years at the time of the procedure, all records in which the procedure was performed prior to April 2009, any records relating to non-cardiac procedures, any records relating to non-surgical or minor procedures and any records relating to procedures performed at Oxford's John Radcliffe Hospital, which stopped performing paediatric cardiac surgery in 2010. Our data set then contained 22,917 surgical interventions. All model development was carried out using this data set ('the main data set').

In February 2016, NCHDA provided us with a further year of validated data, comprising procedures performed between April 2014 and March 2015 ('the validation data set'). We had not expected to receive these additional data and, at this late stage in the model development process, it was decided that this data set would be used as an external prospective validation set for the model developed using the April 2009–March 2014 data set. Following the removal of records as per the main data set, the validation data set contained a further 4436 surgical interventions.

Unit of analysis and outcome measure

The unit of analysis was a '30-day episode'. For each patient, an episode started with their first surgical procedure. Any further surgical procedures that the same patient underwent within 30 days of this first procedure were not included in the model development. The next surgical procedure recorded for the same patient > 30 days after the first surgical procedure was treated as the start of a new 30-day episode. The outcome measure for each episode was death within 30 days of the start of that episode.

Data cleaning

Considerable effort was required to prepare the data set for analysis. This data cleaning process included identifying and removing duplicate records, identifying and removing records in which a 30-day life status could not be derived, and allocating a mean weight for age to records that had missing or anomalous weights.

Model development and candidate risk factors

The analysts worked closely with an expert panel of clinical and data management representatives from five specialist UK hospitals. Our iterative model-building process informed the grouping of procedural, diagnostic and comorbidity information into groups that both demonstrated excellent statistical performance and had clinical face validity.

The starting point for including additional comorbidity information was the four groupings of comorbidities devised during the development of PRAiS 1:

1. acquired comorbidity
2. congenital non-Down syndrome comorbidity
3. prematurity
4. Down syndrome.

Other additional risk factors that were common in the data set, and several categories of acquired heart conditions not directly related to a patient's primary congenital cardiac diagnosis, were also considered.

Two additional groups of additional risk factors were developed by the expert panel: additional cardiac risk factor and a severity of illness indictor.

Possible methods of incorporating these groups were discussed by the expert panel. The treatment of comorbidities and other additional risk factors needed to be clinically meaningful, robust in use and not open to 'gaming' in prospective use. The methods considered included simple indicators for each group of comorbidities and additional risk factors, a count of the number of instances of each group, a simple count of non-duplicate European Paediatric Cardiac Coding comorbidity codes and common combinations of risk factors.

In PRAiS 1, age and weight were both included as continuous linear variables, with additional discrete age bands. The relationship between age, weight and mortality is non-linear, so we explored better ways to account for this non-linearity than the use of categorical age bands.

The existing groupings of procedural and diagnostic information were also assessed. As the number of parameters used by comorbidity information was set to increase, the number of risk model parameters used by other information needed to decrease to maintain model robustness and to avoid overfitting. The analytical team worked with the expert panel to identify broader groupings of specific procedure and diagnosis categories based on the risk associated with a procedure and diagnosis, and the age at which the procedures occurred.

Model development followed an iterative process of clinical discussion of risk factors with the expert panel, multivariable logistic regression, and the assessment of performance under 25 × 5 cross-validation. The performance of competing models was measured using the Akaike information criterion of the model, the area under the receiving operator characteristic (AUROC) curve and calibration results in the cross-validation test sets and by exploring model performance in distinct population subgroups defined by risk factor.

Once the final model had been selected in the 2009–14 data set, it was then further assessed on the 2014–15 data set using the AUROC curve and calibration results.

Aim 1: update of the PRAiS risk model for 30-day mortality – results

The cleaned main data set comprised 21,838 30-day surgical episodes, of which 539 episodes resulted in death within 30 days (a mortality rate of 2.5%).

The PRAiS 2 risk model

The final risk model, decided on jointly by the clinical and analytical teams, was a logistic regression model with the following variables:

- age (included as $a \times age + b\sqrt{age}$)
- weight (included as $c \times weight + d\sqrt{weight}$)
- 16 specific procedure groupings
- procedure type (bypass or non-bypass/hybrid)
- 11 diagnosis groupings
- univentricular heart attribute (indicator variable)
- presence of a recorded congenital comorbidity
- presence of a recorded acquired comorbidity
- presence of a recorded severity of illness indicator
- presence of a recorded additional cardiac risk factor
- indicator variable for whether or not an episode occurred pre 2013.

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This last variable was introduced to account for decreasing mortality over time and to ensure relevance for prospective use of the risk model.

Evaluation of the risk model

Under cross-validation

The model tested in each fold of the 25 × 5 cross-validation had a median AUROC curve of 0.83, showing excellent discrimination (perfect discrimination: AUROC curve = 1). There was little evidence of overfitting, with a median calibration slope of 0.92 (perfect calibration = 1) and a median calibration intercept of –0.23 (perfect calibration intercept = 0).

In the external validation set

The 2014–15 data set, which was used as an external data set, contained a further 4207 30-day surgical episodes, of which 97 resulted in death within 30 days (mortality rate of 2.3% overall).

When the model was tested in the 2014–15 data, its AUROC curve was 0.86 [95% confidence interval (CI) 0.83 to 0.89], its calibration slope was 1.01 (95% CI 0.83 to 1.18) and its calibration intercept was 0.11 (95% CI –0.45 to 0.67). The total number of observed deaths was 97, compared with the 89 predicted.

The model showed excelled performance, with no evidence of overfitting. We recalibrated the final model using 2009–15 data and updated the PRAiS software. This software has been released to all UK and Ireland centres and to the national audit body, and it is already in national use.

Aim 2: development of a public website – methods

This part of the project was a multidisciplinary effort with interwoven strands; it was led by CP (Mathematician), DS (Communication of Risk), TR (Experimental Psychology) and EJ of the charity Sense about Science (Communication of Evidence).

CP and DS were responsible for drafting material for the website and the animations, while MP (Cambridge) was the web developer. Sense about Science co-ordinated and facilitated four sets of two workshops, starting at the beginning of the project. One strand of workshops was for parents of children who had had heart surgery [recruited via the Children's Heart Federation (CHF)] and the other was for potential users, such as policy and media officers for Royal Colleges, NHS England and academic press. For parent recruitment, the CHF initially added a news item to its website and Facebook page (www.facebook.com) and forwarded responses to Sense about Science. Later, CHF also passed on details of other charities that could help [e.g. Little Hearts Matter (www.lhm.org.uk) and Tiny Tickers (www.tinytickers.org)] and these also posted news items on Facebook and newsletters. For workshops 2–4, we offered parents a range of dates and times. Each set of workshops recruited fresh participants so that we could ensure that we always had a fresh perspective on the material.

Participants received only minimal details about the project and were not required to read anything in advance. Workshops began with a brief background presentation and by establishing appropriate consent and permissions (e.g. with regard to recording). Next, participants were each given about 15 minutes to explore the website material on a laptop (workshop 2 onwards). It was made clear to parents that they were free to leave if they did not feel comfortable to continue. There then followed a facilitated discussion, the focus of which varied between workshops. We tested the understanding of concepts and plain-language explanations in all workshops. The participants were invited to provide feedback remotely on future iterations of the site (all accepted) and we incorporated their feedback on the near-final web material.

CP and MP attended almost all of the workshops, with other team members attending at least two each. Sense about Science led each workshop, with analysts in the position of silent observers unless there were

specific questions on content and web structure. Sense about Science provided reports and recommendations after each workshop. CP and MP worked closely together to update the content on the website and worked with an external animation company to produce the two website videos.

TR and EB ran two sets of three formal experiments each; the first set was in December 2015/January 2016 between the second and third rounds of workshops and the second set was in March 2016 before the final set of workshops. Each set explored further how people understood the presented statistics and some of the key sections of the new drafted material.

We also sent existing material for feedback to the CHF and the expert panel from aim 1 in November 2015, February 2016 and May 2016. In April 2016, we sent the near-final version of the website to all previous workshop participants, both for further feedback and to show the value of their previous participation. Sense about Science planned the website launch strategy.

Aim 2: development of a public website – results

The scope of the website increased substantially over the year as we moved from just trying to explain the existing national audit output to redesigning the way in which survival statistics were presented, providing a great deal of background information and signposting users to other resources (charities and support groups). As a direct consequence of the workshops and psychology experiments, we developed four key messages that were prominently displayed on the website and repeated throughout the site. The messages were as follows.

1. The 30-day survival rate after children's heart surgery is very high for all hospitals in the UK and Ireland, and is among the best in the world.
2. A higher survival rate does not imply a better hospital.
3. A hospital's predicted range of survival, calculated by a formula, depends on the particular children treated at that hospital. So, a hospital treating children with more complex medical problems will have a lower predicted range.
4. A hospital's survival rate should only be compared with its own predicted range. It is not valid to directly compare survival rates between hospitals.

Other key design changes that arose from user feedback were the creation of a very simple home page to aid navigation; the addition of explanations of key concepts, key terms and all levels of the data; the provision of a default display of individual hospital data rather than a table of all hospitals; and having sections about what the website can (and cannot) tell families of children with heart disease.

We produced an extensive website that provides interactive exploration of the data, explanatory animations and a wealth of background information. The website (http://childrensheartsurgery.info/) was launched in June 2016; it was very well received and was endorsed by major stakeholders.

Conclusions

We developed a better risk model and a website to explain the model's use in monitoring survival after children's heart surgery. A key theme throughout has been the importance of collaboration and coproduction.

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