

## Monitoring outcomes after paediatric heart surgery with PRAiS: background, interpretation and caveats

### Background

PRAiS (Partial Risk Adjustment in Surgery) is a new risk model that can be used to estimate the risk of death within 30 days of a primary paediatric cardiac surgical procedure. It uses risk factors based on CCAD specific procedure, age, weight and a patient's recorded diagnoses and co-morbidities. The original risk model has been published in Crowe et al 2012<sup>1</sup> and was developed on a random 70% subset of ten years' of UK national audit data and used the 2010 CCAD specific procedure algorithm. It was validated in the remaining 30% of the national data set which had not been used for model development. The pilot study in 3 UK centres reported this month in Heart<sup>2</sup> used this version of the risk model.

The PRAiS risk model has now been updated by recalibrating the model parameters on the updated 2009-2012 CCAD data set using the May 2013 CCAD specific procedure algorithm. We note that this recalibrated version has not been tested in a pristine data set, but that only the value of the model parameters has changed and not the risk factors included. As with any risk model, its performance among later data cannot be guaranteed.

### Using risk adjustment in looking at mortality data

The P in PRAiS stands for partial and this needs to be remembered when interpreting any analysis of PRAiS-adjusted data. Inevitably, some factors associated with risk of 30-day mortality are not accounted for (how many we don't know) and others are not accounted for fully. Extreme prematurity is an example - within the model it has the same effect on estimated risk as non-extreme prematurity. Using PRAiS within a centre, one can assume that case-mix (in terms of factors unaccounted for) is relatively stable and that medium-long term changes (say a rise in the proportion of patients with extreme prematurity) would be recognised and understood by the local clinical team. If comparing PRAiS-adjusted outcomes between centres, one needs to recognise that case-mix in terms of factors unaccounted for in the model may differ.

Essentially, although partial risk-adjustment makes for fairer comparisons, it doesn't make comparisons fair.

### Comparisons

However fair or unfair, comparisons do have a role to play in quality assurance and quality improvement. In most areas of healthcare there are no absolute standards and so feedback in terms of outcomes has to rely on the relative standards of "how are we doing compared to last year?" and "how are we doing compared to the place down the road?"

If comparisons are made in the spirit of improvement and with an understanding of the caveats, there is valuable learning to be had that could lead to improved outcomes.

### Statistical tests

The PRAiS software, which generates Variable Life-Adjusted Display charts, does not incorporate statistical tests of significance. Our concern about conducting statistical tests in routine monitoring is that, within the clinical research paradigm, doing so magically transforms these data (which can be checked, discussed, explored, learned from) into evidence (which must be revered and acted upon). There is a risk of complacency when there is not a "statistically significant" effect and a risk of over-reaction when there is. The approach that was taken by Queensland Health in Australia in their quality improvement programme was to set quite a low threshold for a statistical "alert" so that most programmes had the odd alert every now and then with the result that any stigma attached soon faded. Importantly this was coupled with a sensible protocol for response.

<sup>1</sup> Crowe S, Brown KL, Pagel C, Muthialu N, Cunningham D, Gibbs J, et al. Development of a diagnosis- and procedure-based risk model for 30-day outcome after pediatric cardiac surgery. *J. Thorac. Cardiovasc. Surg.* 2012 Jul 17;

<sup>2</sup> Pagel C, Utlely M, Crowe S, Witter T, Anderson D, Samson R, et al. Real time monitoring of risk-adjusted paediatric cardiac surgery outcomes using variable life-adjusted display: implementation in three UK centres. *Heart Br. Card. Soc.* 2013 Apr 5;