Extraordinary NICOR Congenital contributors meeting
Wednesday May 22nd 2013
12.30 – 14.30
Meeting Room: 2nd Floor: HRM7-9
Hilton Metropole Hotel, Edgware Road, London W2 1JU
Notes

Attendees (Database Managers):	
Thomas Witter	Guy's Hospital
Carolyne Boyles	Southampton General Hospital
Katie King	Southampton General Hospital
Sheila Jamieson	Freeman Hospital
Phil Kimberley	Royal Brompton Hospital
Andre Ring	Harley Street Clinic
John Stickley	Diana Princess of Wales Children's Hospital
Jose Velasquez	Bristol Royal Hospital for Children
Kerry Morgan	Alder Hey Hospital
Rae Samson	Royal Hospital for Sick Children
Attendees (Clinicians):	
Chris Austin	Royal Victoria Hospital
Lars Nolke	Our Lady's Children's Hospital
Asif Hasan	Freeman Hospital
Andrew Parry	Bristol Royal Hospital for Children
Andrew Tometzki	Bristol Royal Hospital for Children
John Sullivan	Freeman Hospital
Lee Ferguson	Freeman Hospital
Prem Venugopal	Alder Hey Hospital
Andrew Sands	Royal Victoria Hospital
Atilio Lotto	Glenfield Hospital
Kevin Watterson	Leeds General Infirmary
Osama Jaber	Leeds General Infirmary
David Anderson	Guy's Hospital
Owen Miller	Guy's Hospital
Victor Tsang	Great Ormond Street Hospital for Children
Fiona Wilcoxon	Leeds General Infirmary
George Ballard	Leeds General Infirmary
Michael Lavrsen	Southampton General Hospital
Peter Barry	Glenfield Hospital
Trevor Richens	Southampton General Hospital
Nihal Weerasena	Leeds General Infirmary
Andreas Hoschtitzky	Alder Hey Children's Hospital Liverpool UK
Audit Steering Group members	
Rodney Franklin	NICOR Congenital Clinical Lead - Chair
Chuck Mclean	Chair SCTS Congenital Database Subcommittee
Kate Brown	Lead for Research and Outcomes
Kate English	BCCA ACHD representative
Lin Denne	Data Validation Officer
Tracy Whittaker	NICOR Congenital Project Manager
Owen Nicholas	NICOR Senior Analyst

1. Welcome, introduction and Background

RF provided an update on the current status of the audit and the current focus of presenting outcome data and funnel plot methodology. The presentation also described the current process for notifying potential outliers. The main criticisms levied at the audit are:

- the length of time taken to publish the data due to inherent delays whilst the data is validated
- the delay in reaching 1 year survival data so that in hospital and not just 30 day mortality are presented
- the inability and perceived unwillingness to provide whole Centre mortality assessment, i.e. SMRs, knowing that 24% of procedures are currently not captured in analyses. The reason for this was explained as a lack of suitable risk adjustment methodology. SMRs published by Prof Jarman (Dr Foster) using HES data were shown to be unrepresentative of actual performance due to poor risk adjustment and data quality. However there is a clear need to address this as a priority development for NICOR Congenital.

RF reminded those present that the January 2013 Stakeholders meeting had agreed to:

- The use and distribution of Partial Risk Adjustment in Surgery (PRAiS) software mediated Variable Life Adjusted Displays (VLADs) to all units for in house monitoring of surgical outcomes. These were subsequently funded by Safe and Sustainable programme (£30k). The role out began in April 2013 with Leeds being the first new recipient.
- The use of PRAiS to calculate whole Centre SMRs in a controlled manner, with planned feed back to the Centres prior to publication at today's extraordinary Contributors meeting.

RF then provided a detailed summary of the events and surrounding data quality issues relating to the premature disclosure of the initial PRAiS SMR software run to NHS England on 27/28 March 2013, which resulted in the suspension of congenital surgical activity at Leeds General Infirmary (LGI). NHS England directed NICOR to reanalyze the data with once the complete LGI 2011/12 data had been received on April 5th. All centers were within safety limits on the second analysis, based on data available as of 5th April and LGI were given permission to resume activity by NHS England. All centers were simultaneously asked to check and resubmit PRAiS related data fields by April 29th. RF presented the results of DCs data quality assessment and cleaning, which on the whole were very good. However a major data discrepancy was still apparent due to disproportionately low comorbidity submissions from Bristol and Southampton. The planed recalibration of the PRAiS software based on the updated data, as well as subsequent SMR calculation, will therefore be).

2. NICOR in house governance changes

An extraordinary NICOR Congenital Steering Group meeting was held on May 7th to discuss the LGI disclosure. John Deanfield, director of NICOR, acknowledged that governance arrangements and standard operating procedures need to be improved. UCL has initiated an internal review of NICOR governance. It aims to identify & fill gaps in policies and Standard Operating Procedures within and across audits. The review is also likely to recommend establishing Memoranda of Understanding between NICOR & specialist societies.

There will be a new NICOR organisational structure headed by an external Board with representatives from NHS England, CQC, BHF, lay rep and others to be determined. A new executive committee with three working sub-groups: risk & governance, communications, and data sharing information & IT is also to be formed.

3. Quality of newly submitted data

RF presented the results of DCs data quality assessment and cleaning, which on the whole were very good. There was no difference in mortality in the old records that were removed, compared to the records that remain. Procedure, weight and age are mandatory fields for the PRAiS analysis. Mandatory field data completeness for paediatric surgery is 99.96%. Overall 32% of records now have a 'significant' comorbidity entered. However a major data discrepancy was still apparent due to disproportionately low comorbidity submissions from Bristol and Southampton. The planned recalibration by CORU of the PRAiS software based on the updated data, as well as subsequent SMR calculation, will therefore be further delayed until these data submissions have been received (new deadline June 14th 2013). In addition there remain significantly more missing data for ACHD interventional cases which will need to be addressed by the ACHD standalone centres.

4. Mortality definitions

On behalf of DC, RF highlighted the challenges of assigning life status when ONS validation is not available for 30 day mortality. To date, life status has been assumed in these cases from the registered discharge status. This has been correct in 99.4% of cases but is incorrect when discharged alive early and died before 30 days. The steering group had agreed the following rules for processing data resubmissions:

- For England and Wales, accept discharge status as surrogate for 30 day status when ONS validation not available (non-NHS patients or NHS number change due to change in status such as adoption).
- For Scotland and Northern Ireland, accept discharge status as surrogate for 30 day status.
- Reject all records with key missing data (extremely few now).
- Use discharge status when life status in not validated
- Correct obvious errors only in coding
- Report corrections back to units for verification
- Include overseas patients

5. Partial Risk Adjustment in Surgery (PRAiS): methodology

5.1. KB summarized the rationale and development underpinning the PRAiS risk model. PRAiS was developed as a model to improve routine monitoring of surgical outcomes by clinical teams. It was not developed to estimate risk for individual prospective patients or to provide comparisons between surgeons or between centers. The model has been peer review published, including the successful 3 centre pilot study . The model has been recalibrated on 2007-2010 data and this version addresses the issue of the small under prediction of risk in very high risk cases.

5.2. Those present raised a number of questions and queries about the model and future direction:

- Other risk models recalibrate on an ongoing basis. In contrast, PRAiS is recalibrated on retrospective data as it is helpful for units to use the same data given the complexity of the case mix. Work is underway to recalibrate PRAiS on 2009/2012 data. Outcomes have been improving nationally since the model was developed using 2007-2009 data and may well continue to improve over time. Comorbidity data will also effect predictive risks. In this instance, the motivation for recalibrating the model so early is that CORU had anticipated a gradual change in data quality. The LGI incident and subsequent data checking by all centres of PRAiS relevant fields had led to a marked increase in comorbidity data. The group were supportive of using 2009/2012 data to recalibrate PRAIS and it was agreed to delay the final export to CORU until the outstanding two centers had checked the accuracy of comorbidity data.
- Asif Hasan mentioned that since PRAiS runs on the NICOR specific procedures there is a large group of 'not a specific procedure', whereas the STAT score (North American empiric model) has a larger number of procedures therein. KB agreed and said that this had been

addressed by adding diagnostic information including univentricular status into PRAiS. The performance and 'coverage' of the two models is similar, but PRAiS uses fields that are more familiar to UK audit.

- It was also suggested that it would be worth agreeing the criteria for future PRAiS updates.
- There was a call to extend outcome measures to morbidity. CMC highlighted the challenges surrounding developing a valid mortality measure and morbidity will be even more challenging. The SG are well aware of the need to take this forward in future and have already started this through the Research group with reoperations and neurological status. Victor Tsang mentioned that a new NIHR research project is commencing in several centres to look at morbidity measures and audit of this area.
- There was also some concern about how data would be presented and 'marketed'. CMc reported that consideration should be taken on opening the invite to the stakeholder meeting to include the press.

6. PRAiS and VLADS

6.1. KB demonstrated how PRAiS software produces VLAD charts that are useful for monitoring trends in outcomes and serves as a visual aid to gain an overall perspective on unit outcomes with respect to mortality, reoperations and caseload. All agreed that developing reliable morbidly measures, such as neurological status, would be challenging but needs to be built into future work.

7. STCS identification and response to surgical outliers: applicability to NICOR congenital

7.1. DB summarised how data, analysis and publications are handled in Adult Cardiac Surgery national audit. Data submission deadlines are on a quarterly basis and centers contacted if data is not submitted. Centers are asked to validate and confirm their data is correct before the analysis is published in the annual Blue Book. There is also a clear outlier policy with three bands (compared to the two used by the Congenital Audit at present). DB highlighted that this approach had promoted a culture of responsibility within centers and individuals. There was general agreement that this model could work within the congenital audit.

7.2. There was support for transparency and CMC felt it was important to be open and transparent about the data including its strengths and limitations. How the CHD audit markets itself and the data is key to how it will be perceived by the press and other interested parties. CMc reported that John Deanfield (NICOR) suggested the press be invited to attend the Stakeholders meeting. DB agreed that public presentation of the CHD work needs to be considered and the good news on overall outcomes highlighted. The audit also needs a clear vision of its direction over the next five years.

8. PRAiS and SMRs: current vs alternative methodologies and presentations

8.1. Based on discussions between CORU and David Spiegelhalter, MU provided examples of VLAD plots and options for presenting single and multiple-centre data as a summary of outcomes over a period. There are a number of general principles for presenting outcomes e.g. presenting key information in the graphs and accompanying all analyses with appropriate caveats. The motivation for recalibrating PRAiS on 2009/12 was explained. Essentially it is considered that given recent scrutiny of data and activity in increasing completeness of comorbidity data, the relationship between "recorded comorbidity" and mortality risk may have changed markedly.

8.2. Standardized survival RATIOS may be better than SMR. Where mortality rates are low, survival ratios are less subject to the variability introduced by small samples sizes than mortality ratios (the information is of course the same but mortality ratios can look more sensational, particularly if target audience cannot reasonably be expected to understand and account for the width of control limits). "Standardisation" in this context is the process of accounting for every units outcomes over the period of interest adjust expectations. CORU and DS recommend against this process for two reasons – 1) it removes useful contextual information re national changes/trends in outcomes over

time and 2) it introduces an element of surprise for individual centres. Centres should be in a position to know what centralised analysis will "say" about them from the information they have locally.

8.3. The choice of confidence interval methodology and limits: when accounting for variable risk, the control limit on a funnel plot depends on case mix as well as case volume. For this reason, each unit has its own funnel. Also, this funnel is an approximation. For these reasons, it is suggested that multiple funnels are presented and in a way that reinforces the point that this is by no means an exact science. Important decisions remain about the level at which control limits are set.

8.4. Subsequent discussion focused on ways of presenting data in others ways, for example ACS presents survival data and some believed this was a more positive approach than publishing mortality outcomes. There was a general feeling that centers need be actively involved in how data is presented.

9. Open forum for discussion with Panel

9.1. The final group discussion highlighted the following recommendations:

- The CHD audit needs to highlight positive achievements made by the audit
- Governance arrangements within NICOR and the CHD Audit need to be reviewed and clearly documented.
- Working groups within the CHD audit (Research and Steering Groups) need to be transparent. Processes and meeting documentation, including nomination of new members, needs to be available. Stakeholders need to be consulted on a more regular basis especially views on analyses and publications.
- The audit needs to develop policies on validating data ahead of publication. All reporting, including the portal, will be based on the signed off data. There will need to be an internal SOP for signing off data. LD has already started this process.
- The audit needs to review its outlier policy. This should be aligned to other audits (e.g. adult cardiac surgery).
- Annual reporting needs to be quicker and unified so that information on the website is in line with data in other reports.
- All congenital centers should have congenital dedicated database managers at Band 7 equivalent.
- Feedback loops need to be clear. The SCTS Blue book is timely with contemporary outcomes. The CHD audit needs a way of sharing annual data.
- The CHD audit clinical lead also needs to be paid for his work in that time is made available for NICOR responsibilities, whilst other parts of his overall Job Plan are backfilled with new resources.
- The congenital audit now has a dedicated project manager (Tracy Whittaker) and analyst (Owen Nicholas).