National Congenital Heart Disease Audit

Contributors' Meeting: 10 March 2014

In attendance

Forname	Surname	Role	Organisation
Vicky	Banks	Data manager	GOSH
David	Barron	Consultant surgeon, Chair SCTS Congenital Subcommittee	Birmingham
Carolyne	Boyles	Data manager	Southampton
Kate	Brown	NCHDA research & outcomes lead	GOSH
Rita	Butler	Data manager	Belfast
Rebecca	Cosgriff (mins)	Audit project manager	NICOR
Sara	Cullen	Data manager	Dublin
Kate	English	BCCA ACHD rep for NCHDA	LGI
Rodney	Franklin (chair)	NICOR NCHD lead	RBH
Oliver	Ghez	Consultant surgeon	Brompton
Andreas	Hoschtitzky	Consultant Surgeon + SCTS rep for NCHDA Res Comm	AHCH
Sheila	Jamieson	Data manager	Freeman
Philip	Kimberley	Data manager	Brompton
Attilio	Lotto	Consultant surgeon	Glenfield
Robin	Martin	BCCA president	BRHC
Chuck	McLean	SCTS congenital database subcommittee chair	RHSCGlasgow
Lars	Nolke	Consultant CT Surgeon	Dublin
Andrew	Parry	Consultant Surgeon	Bristol
Macy	Rind	Cardiac admin	Dublin
Ray	Samson	Data manager	Glasgow
Maria	Serrato	Quality and Safety Lead for CHD	Brompton
John	Stickley	Information manager	Birmingham
Serban	Stoica	Consultant Surgeon & SCTS rep for NCHDA Res Comm	UHBristol
Prem	Venugopal	Consultant surgeon	Alderhay
Thomas	Witter	Congenital database managers' lead	EVH

1. Welcome and Introductions — **Action**

RF welcomed attendees to the meeting and introduced the agenda.

2. NICOR update

2.1 Governance

RF described NICOR's mission and aims to attendees before going on to give an account of the recent internal and UCL external reviews of NICOR following the Leeds data release in March 2013.

Following internal review and subsequent governance changes, all NICOR staff and audit steering groups were invited to complete a questionnaire by an external UCL review panel. The subsequent report, which was made available

in December 2013, highlighted 13 key areas for development:

1. *External communications*
   Including recruitment of a dedicated Communications Manager, use of social media, and revision of the NICOR website.

2. *Internal communications*
   The effectiveness of new meeting structure in improving this will be assessed
3. *Consistency between audits where appropriate*
4. *Relationship with specialist societies to be formalised with MoUs*
5. *Managing outliers process to be consistent, simple and efficient*
   This process must also apply to data quality outliers
6. *NICOR's roles and purpose need to be defined and developed*
7. *Institute of Cardiovascular Science and UCL context*
8. *Governance arrangements to be included at staff inductions*
9. *Data provision*
   Including development of a diagram outlining who is responsible for the quality of data at any given point, to be published on the NICOR website.
10. *Data points*
11. *Analytics/statistics; more staff to be recruited*
12. *Responsibility of hospitals to be formalised with MoUs*
13. *IT Systems to be redeveloped under the Informatics and IT working group*

RF explained that the Congenital audit will henceforth be known as the 'National Congenital Heart Disease Audit (NCHDA)'.

A slide showing NICOR's new committee structure was also shown. It was noted that an additional BCCA representative is required for the congenital audit research committee. **RM**
Action: RM to nominate an additional BCCA rep for the NCHDA Research Group.

A query was raised regarding how NHS England fits into the governance structure of NICOR, and who assesses the appropriateness of requests received from them?

RF responded that NHS England funds NICOR via HQIP, the latter of which may be represented on the NICOR Advisory Board. The NCHDA Research Group assesses any requests for access to the audit's data; including those received from NHS England. Indeed, some requests have been rejected such as one for access to surgeon specific outcomes.

This sparked a discussion around consultant outcomes publication, including the legitimacy of publishing these data when they were not submitted with this purpose in mind.

Concerns were raised about insufficient surgeon representation on the audit's steering committee, where decisions relating to surgeon outcomes are made. Some also felt that too many NICOR representatives are on the steering committee.

RF explained that there are three surgeon representatives on the committee

(two SCTS reps and the BCCA President who may be a surgeon or cardiologist), and that the group must remain at a manageable size. Whilst NICOR representatives are required to provide information about the day-to-day running of the audit, the steering group remains clinically led.

CM suggested that congenital surgeons should sit within the overarching NICOR committee structure; especially the Professional Liaison Group. RF responded that the PLG membership included the SCTS President and if the SCTS wished there to be a congenital rep as well then the SCTS President should communicate with the PLG Chair direct (Prof Iain Simpson).

It was queried who can have access to NCHDA data and RF stated that access can be gained via submission of a research application, directly by going to the Congenital Portal, or a FOI, depending upon the nature of the information requested. In future ongoing research applications will be published on the Portal to further transparency and avoid duplication of research projects.

Concerns were raised about media requests for data such as consultant identifiers. Steering committee members explained that requests can be rejected on methodological grounds and patient identity concerns given the small numbers of a given procedure; and that this has been done in the past.

CM stated that the only way to avoid media and commercial publication of data is to ensure that that audit's own publications are the most robustly analysed, risk adjusted, and patient centred possible. If this is not done then justification can be made for publishing unadjusted data from HES.

2.2 Outlier policy

RF presented a slide illustrating the current NCHDA outlier policy. The process is that, after due checking of data accuracy, 'green line' breaches trigger a letter from the NCHDA Lead and Presidents of the SCTS and BCCA prompting local audit anmd submission of a report within 25 working days to the Societies and NICOR. Red line beaches were similar but the letter also would be sent to the Trusts MD and Governance Lead.

A slide was then shown illustrating the draft proposed NICOR outlier process, and explained that it is a work in progress and is being shown to allow for discussion and comment. This is based on NAGCAE guidance, and doesn't include green/red differentiation at this stage. There is an on-going process driven by NHS England that calls for a more standardised approach to dealing with outliers across the whole NHS. RF stated that it may not always be appropriate to react in the same way across different specialties; societies must engage to ensure that they are comfortable with the final product.

DB gave a presentation on lessons learnt from the National Adult Cardiac Surgery Audit (NACSA) 'Maintaining Patients' Trust' Outlier document. NACSA has a three tiered data validation process, which is carried out prior to outlier identification. This is at individual surgeon level. Outliers are identified as yellow, amber or red and the level of action taken is dependent upon both outlier severity and recurrence.

Immediate parallels cannot be drawn with congenital, as congenital combines surgery and cardiology, and reports at unit level only. It covers a huge range of different procedures making comparisons between individual consultants more complex, as it is difficult to compare 'like with like'. Risk adjustment is also difficult and it is acknowledged that, although the PRAiS model is the best there is at present, it is not possible to fully risk adjust for all patients .

There was a perception that the Euroscore model over adjusts for risk, but DB clarified that the model used for governance purposes is recalibrated to the contemporary cohort to ensure accurate adjustment.

NCHDA will aim for data to be submitted no more than three months in arrears, follow a clear outlier process, propagate a culture of responsibility, with a contributors meeting taking place at least annually and correspond with future SCTS annual meetings. The possibility of a second meeting, possibly by teleconference was discussed but not resolved.

A congenital equivalent to the Maintaining Patients' Trust document will be written, with support from Prof. Ben Bridgewater.

There was some discussion about how whole centre performance alerts should be managed locally after the annual PRAiS mediated analysis; currently there appears to be a default for suspension of activity whilst this is investigated, as occurred in Leeds in March 2013. This still remains to be clarified and will need to be included in the Maintaining Patients' Trust document. Guidance for Medical Directors is also being written by HQIP relating to this.

3. Dataset and data validation

3.1 Dataset changes

Implementation of the new dataset has been delayed, and will become mandatory in April 2015. The final version will be distributed to contributors as soon as possible, most likely by October, so that new fields can be incorporated into database software well ahead of this date.

There has been external pressure to begin reporting on devices, including closure, pacemaker and valve implantation devices. These new fields will also be to the CRM dataset to avoid duplication and facilitate future linkage. This will include device serial numbers. These changes were backed by the group.

Attendees discussed the issue about only surgeon and interventional cardiologist identifiers (GMC number) being collected by the audit, and that the audit should consider including non-interventional clinicians, such as the patient's cardiologist, intensivist and anaesthetist, given the team approach to care, especially for congenital heart surgery.

Validation would also be very complex.

RF explained that surgeon GMC code collection has been mandated by HQIP, and the occurrence of a named intensivist varies across Trusts. If the society wishes for other physicians to be included in the collection of GMC codes then a written request must be submitted to the audit for consideration. DB stated that overall responsibility needs to be taken by the surgeon for the operation and the outcome of the patient.

It was also suggested that data items not used currently for analysis should not be collected for information governance reasons. RF stated that not all desired analyses has been carried out due to other priorities and a lack of analytical support. However there are strategic plans in place to utilise additional dataset items for more systematic analysis in the future. Many dataset items are collected to stimulate research even where they are not utilised for standard audit outputs.

It was queried whether when a patient returns from theatre should be recorded, and RF stated that this information will be collected by linking to PICANET to avoid duplication and increase accuracy.

The definition of a hybrid procedure needs to be made explicit.

3.2 Coding changes

Not discussed for lack of time but will be linked to dataset changes which will be distributed in the Autumn.

3.3 Data quality

Not discussed for lack of time

3.4 Timetable of validation visits 2013/14

LD presented a slide illustrating the proposed timetable for validation visits pertaining to 2013/14 data. RF explained that the validation process needs to be complete to meet HQIP's deadline for publication 6 months after data entry deadlines. In the short term reporting may have to be 8-9 months after data entry deadlines. This means that validation visits must commence in May, so that they are complete by end of October 2014. It also means that units must have their data ready for validation visits much earlier than previously, and will have less choice of visitation dates.

Action: LD to disseminate the validation visit timetable to all stakeholders **LD**

An attendee queried whether the experience of validation visits, and attendance at them, could be improved. RF confirmed that a validation subcommittee has been established for this purpose; attendance could be dictated by a rota in future but will remain on a voluntary basis for the time-being.

3.5 Review of validation process including Minimum Data Standard

Not discussed for lack of time.

4. Congenital portal update

RF gave a presentation on behalf of DC relating to some recently detected issues with ONS mortality data, which is linked to the congenital audit.

Previously ONS has been used by the Congenital Audit as a 'gold standard', which has superseded hospital entered mortality data where discrepancies have occurred. In line with other NICOR audits, this policy has now been reversed. RF outlined the reasons for this to the steering group.

In November 2013 it was detected that an issue with new ONS software caused an error in mortality data that led to over 100 mortalities from October

2011 going undetected.

There is no implication for data prior to October 2011. The recalibration of the PRAiS model in summer 2013 may have been slightly affected, but this will be remedied when the recalibration is repeated over the next month.

It is important that units are given sufficient notice prior to analysis being published, and that any outlier process has been acted upon.

In addition to this, it came to light that ONS does not record mortality until any ensuing inquest has been concluded. Inquests occur in around 15% of congenital mortality cases and can take up over a year to resolve. This has led to deceased patients being recorded as alive in ONS.

It was raised that patients are lost to follow up when they go abroad, and that NHS numbers change after children are adopted. CM explained that such patients would go into a pre-existing 'unknown' category relating to long term outcomes.

TW requested that a new field stating that a patient has left the UK be added to the dataset.
Action: This proposed new dataset field is to be added to the agenda for discussion at the next steering group. **TWh**

5. PRAiS

5a Standardised survival ratios (SSR) and VLAD plots

RF presented both the old and new style funnel plots, explaining that it is statistically incorrect to show one control limit for multiple data points; each unit must be displayed against its own control limits.

It was queried why in-hospital and/or 1 year mortality is not shown. RF explained that the PRAiS model was not validated against these time frames. KB added that the motivation for 30 day mortality was with a view to producing VLAD charts, which need a defined end point not long post-operation to allow for active monitoring.

6. Research projects

6.1 Requests received

KB presented past and ongoing research applications, and explained the approvals process. It would be good for more surgeon led projects to be submitted.

KB also presented grant proposals, including some that look at quality measures other than mortality, and some diagnosis rather than procedure based analysis.

RF stated that ideally the audit would be diagnosis rather than procedure based, but that this is not achievable in the short term and must be worked towards incrementally.

6.2 Time trends – a good news story

KB discussed a project that looked at changed over time in 30 day mortality

rates for paediatric cardiac surgery. The purpose of the project is to explore changes in casemix. Comorbidity was removed due to poor data quality for these fields that could introduce a bias. The results showed that there is an increase in paediatric cardiac surgical activity with more high risk patients coming to surgery, yet mortality is decreasing over time. The analysis compares well internationally and acts as evidence against risk averse behaviour.

DB stated that the group should be very proud of these outcomes and the improvement that they demonstrate.

6.3 Aortic valve and reoperations project
Not discussed for lack of time.

6.4 Long term outcome of Fallot and switch
Not discussed for lack of time.

6.5 NHS England research projects
Not discussed for lack of time.

7. Open forum
Throughout

8. Next meeting
The group agreed that a meeting should be held annually at the SCTS conference, and that a second meeting could possibly take place in the Autumn at the Royal College of Surgeons or be via a teleconference.

LD requested that adult only centres are invited to attend in future and the group agreed.