

CENTRAL CARDIAC AUDIT DATABASE (CCAD) VALIDATION REPORT

Data validation visit to The John Radcliffe Infirmary , Oxford

Visitors:

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1. Introduction

National data collection in adult cardiac surgery is well established and has evolved to include risk models and more recently public reporting of outcome data. Implicit in this initiative is the need for accurate data and a proposal for data validation has been made in the Society of Cardiothoracic Surgeons (SCTS) Fifth National Adult Cardiac Surgical Database Report 2003. There is a need for ensuring that data submitted for the Central Cardiac Audit Database (CCAD) project is robust because of a number of perceived shortcomings

- Lack of accurate recording of the number of operations at some centres
- A high level of missing data for the items which are required for adequate risk adjustment in some centres
- Lack of independent validation of submitted mortality data

In an ideal world it may be desirable to impose an independent system where all data collected on all patients undergoing cardiac surgery is validated and corrected by independent personnel. This is not achievable within current available resource. The proposal for SCTS data validation is that each organisation should be subjected to a data validation visit. This would involve an independent review of the data that the hospital had submitted to CCAD, and a review of the processes that should be in place to ensure that the data is robust. The planned visits are to be organised by personnel from CCAD and undertaken by a combined team from CCAD and the SCTS.

The CCAD software has been rewritten over recent months and included in the development is functionality to allow the hospital that is submitting data and the validation team to view aspects of missing data, discrepancies of mortality between submitted and ONS traced data, and potential 'gaming' of risk factors. The access rights to this part of the soft ware is only available to the submitting hospital and visiting team, and not to general CCAD users.

The CCAD software development is now in a live format and we have used this as the basis for this validation report.

2. Structure of Data Collection Systems

a) Personnel

The Adult Cardiac Surgical Audit System is under the direction of the Clinical Audit Lead, Mr Chandi Ratnatunga, Consultant Cardiothoracic Surgeon. The Cardiac Information Manager is Mr Colin Evans (CE). Mr Evans joined the Cardiac Services Department as a dedicated IT Manager. He is graded as A&C 7 and has extensive experience of information technology within the Health Service most recently in developing PAS systems. CE is supported by Travis Denton who similarly has an IT background with experience of the currently used software and hardware. A third member of the Department, Grant Gerrard is specifically responsible for the maintenance of MINAP and data on cardiac rehabilitation. A fourth post is vacant and awaiting appointment and it is envisaged that this individual will have specific responsibility for submitting data to the CCAD, for data quality, training and systems of feedback.

Mr Evans and his staff are housed within a dedicated office which appeared to be a spacious and comfortable working environment.

b) Software system and network

The current software system is Datacam, which has replaced a paper based system in 2001 and is now fully integrated and supported by the hospital information system. It interfaces with the hospital PAS system, for example, allowing import of patient demographic data, admission and discharge dates and mortality within PAS. Datacam exists on all 90 PCs within the Cardiac Services Department. A recently introduced logic check allows specification of patient admission date, operation date, discharge date etc rather than using a default. The system allows for generation of an operation note and also the facility for discharge summaries, which is evolving.

c) Overview of process

Over the last 12 months (with the temporary cessation of the pre-operative clinic) there has been some variability in the first data entry. With re-establishment of the pre-operative clinic most pre-op data is entered by the specialist nurses and SHOs who are also responsible for entering risk data.

The second level of data entry is in the theatre, with entry of operative data. It was commented that there has been a differential take-up in enthusiasm for this, with data being entered variably by the surgical registrar, the anaesthetist or the surgical assistant. This was an opportunity for checking the completeness and accuracy of the pre-operative patient data. An operation note is generated and printed accordingly.

Following patient discharge from the ward the notes are forwarded to the surgeon's PA. At present there is a variable and sometimes excessive lag time for these to be made available for dictation of a discharge summary. There is then a final check on completion and accuracy of data entry including post-operative complications – this is at present being reviewed, notes are then sent for coding.

It was recognised that the entry of timely and accurate outcome data could be more robust. At present outcome data is entered at the time of the discharge summary rather than when the patient is discharged from the hospital and the current process was seen as fallible with multiple points of entry. A recent initiative has seen the adoption of specific outcome screens on the Datacam menu, which are completed by the ITU nurses at the time of patient discharge.

One concern volunteered by CE is that of a poor audit trail. Datacam was established with shared identification codes which are now becoming individualised in order to facilitate proper attribution within the audit trail. Newly appointed junior hospital doctors are regularly inducted by CE, and this is recognised as an opportunity for emphasising the importance of data collection in cardiac surgery. Mr Evans commented that with the increasing achievement of the potential of the Datacam system and with the regular monthly report feedback (see later) that "consultants have bought into the ownership of their data".

Currently a monthly report is generated and circulated by e-mail to consultants. If there is no response then the record is taken as complete and accurate. A review of

Datacam entry takes place at a monthly Tuesday morning Audit Meeting which considers patient data 2 months in arrears.

3. Data collection processes and cross checks

The main cross check of Datacam is against the theatre logbook. CE sends out a weekly report to the operating theatre representative, currently one of the surgical assistants and a manual check is made between Datacam and the theatre logbook. Secondly a weekly CRU movement report enables a further manual check of patient activity against Datacam.

This system of cross check at two separate levels has the confidence of CE – “using these systems we are not going to miss a patient”.

At present little use is made of either perfusion records or HES data for activity cross checks. There is however an increasing level of cross check between Datacam and the Contracts Department as a further record of activity. The tissue bank at the John Radcliffe Hospital also sends a monthly report of all valve activity allowing a further cross check with Datacam. The confidence in the Cardiac HES data is low.

4. Processes in place to ensure mortality data collection is complete

The interface that exists between PAS and Datacam ensures that any patient mortality reported to the hospital Bereavement Office will be automatically documented on the Datacam system. A date of death is available through PAS. For Datacam the date of death is either entered by the clinician or manually entered by the cardiac Data Office on receipt of the monthly list of mortality.

There is a monthly report of all hospital in-patient mortality from the Central Information department and this is crosschecked against Datacam and CE reports that this shows no discrepancies. An additional cross check is through the mortality report which is generated by the central information team from PAS which itself is updated regularly from the ONS.

5. Feedback mechanisms in place to validate data

As we saw from the the System protocol (later), there is a weekly surgical data validation report and monthly surgical risk factor report. These are circulated to consultants, their secretaries and Liz Williams and Pritam Clark (in theatre) who validate against the theatre logbook. There is also validation against CRU movements. These 2 checks are used to validate for completeness and accuracy. It is requested that omissions are corrected by those originally entering the data. This process is currently requiring significant input from CE, but has established the principle of “data responsibility and ownership”.

The monthly SCTS validation report and monthly risk factor report are circulated to consultants and their secretaries, and these reports are circulated to ensure completeness and accuracy of data. This is the opportunity for each consultant to review activity, data entry and mortality. CE reported that this final data check is

emphasised to consultants who are fully aware of this before onward submission to CCAD.

Departmental Audit Meetings were initially paper based and then were centred on the monthly reports circulated by CE – this has proved problematic and now registrars construct slides to present the data. The Audit Meeting takes place the first Tuesday of every month and is attended by surgeons, cardiologists and anaesthetists and consists of audit data presented two months in arrears by unit and by consultant. Mortality and morbidity are also discussed.

A list of empty data fields is shown on the monthly report. CE emphasised that the monthly presentation of empty data fields served to emphasise omissions, and since completion of this data at a later date was time consuming for the registrar concerned this served to encourage completeness at the first opportunity. CE reported that the feedback of monthly reports was showing benefits and further encourage medical staff to “buy into” the system.

Additionally for the first time Mr Ratnatunga has organised a review of five sets of case notes by one of the Specialist ITU Nurses to act as an internal validation of data entry and this will be presented at the monthly Audit Meeting. It is possible that this may roll out into a regular three monthly sample case note internal validation.

6. Review of data

Review of data is as shown.

This review is based on an enquiry of CCAD Lotus Notes. There are a total of 3,962 patient records submitted. For the years 2004 that this data review is based upon there were 921 patient records (note the data completeness frame shows 920 patient records).

The Oxford data for patients operated upon in the fiscal year 2004 is as shown below.

Table 1. Discrepancies between submitted and ONS tracked data, 2003-4

Number of patients	Reported alive on database: dead on ONS	Reported dead on database: alive on ONS
921	None	4

Overall deaths	53 (all deaths at last ONS X check)
No. hospital recorded deaths	40
No. ONS recorded deaths	27

Table 2. % Data completeness for core variables: Oxford compared to pooled ‘national’ data

Variable	Oxford	‘National’
Age	100	100
Sex	100	99.9
NHS number	99.0	90.3
Post code	100	100

Procedure	100	99.0
Surgeon identifier	100	90.0
Post-operative morbidity	33.2	67.1
Discharge status	87.3	99.1

Table 3: % completeness of EuroSCORE fields compared to national data

Risk factor	Completeness Oxford 2003-4	Completeness national 2003-4
Age	100	100
Sex	100	100
PVD	90	89
Previous surgery	91	87
Renal failure	90	97
Active endocarditis	100	100
Iv Nitrates	92	93
LV dysfunction	89	97
Most recent infarct	100	97
Shock pre-op	89	89
Ventilated pre-op	89	93
IABP	0	72
Iv inotropes	92	93
PA systolic	36	78
Urgency	95	98
Non coronary surgery	100	100
Surgery on aorta	100	100
Acute VSD	100	100
Data quality index	84%	92%

Table 4: incidence of risk factors compared to pooled national data

Risk factor	Oxford incidence	National incidence
Mean age	Mean 65.9	Mean 65.2
Male	72.4%	71.1%
Mean EuroSCORE	4.7	4.5
Fair LV	30.0	24.8
Poor LV	9.0	6.0

Oxford data – Logic Checks

Fatal errors will prevent that record from being uploaded - **None**

Serious errors will be flagged up and will require attention from the unit – **3,962**

Minor errors will flag up flaws in data which may prompt further action from the unit - **2**

Fatal errors

The only errors which will prevent the record from being uploaded is the absence of a patient identifier or an operation type.

Serious errors

The following problems will flag up a serious error

1. Lack of NHS number
2. Dates should be available for admission, operation and discharge
3. Lack of date order logic ? i.e. the following should be in chronological order: admission, operation date, discharge date
4. There should be a surgeon identifier which should fit with a recognised list of GMC codes for the submitting unit
5. Discrepancies between submitted and ONS derived mortality (if the ONS derived mortality falls within the hospital stay)
6. Operation type should pass logic checks ?
 - a. if the operation is a CABG, there should be some data that vessel or vessels have been grafted
 - b. If the operation type is a valve there should be data about which valve has undergone surgery
 - c. If the operation type is a valve and grafts there should be data on both vessel(s) grafted and valve undergoing surgery

Minor errors

Absence of data in any field which is required to produce a EuroSCORE for a particular record will flag up a minor error.

Mr Evans commented that he was only just becoming confident with the completeness and accuracy of data which is entered onto DataCam. He found it slow to submit data to CCAD and slow to interrogate the Lotus notes, and the interface was not easy to use. Following the installation of a local version of Lotus notes to the local PC network, management of the CCAD interface had become quicker and easier. Currently the submission of 2003/2004 data is being completed and there has not yet been a start on data submission for 2004/2005. At present, following review, data is being batched and submitted to CCAD.

Mr Evans explained that the normal DataCam process is for records to be flagged as requiring submission whenever they are created or updated (this ensures every change to a record results in a new record feed to CCAD). The CCAD download process picks up all records flagged for submission, creates a file of them for transmission to CCAD, and sets the record flag to "sent". It is possible to override this process and thereby create a file for submission of any records deemed appropriate.

The CCAD helpdesk has generally been slow, he commented that Nadeem Fazal has been very helpful.

There was some discussion regarding the review of data. At present there is a discrepancy between numbers entered on DataCam and numbers at CCAD. This is being rechecked and it's now 17 in total, but checking on a quarterly basis the discrepancies in each quarter range between -26 to +64. This is being investigated – there may be an issue around admission, operation, discharge dates.

There followed some considerable discussion regarding the issue of data completeness and the use of default options. Clearly a default option allows a 100% data completeness for variables and this issue needs to be discussed at the next tripartite meeting. Some fields shouldn't be measured on completeness because it encourages defaults, which may be inappropriate. Multiple defaults may lead to worse data.

In Table 3 the 0% completeness for intra-aortic balloon pump is presumed to be due to a data submission error. The perfusionists do cross check IABP use manually every month.

7. Further issues

The current data entry system and validation procedure has been documented in a protocol - Cardiothoracic Adult Data Entry and Validation Procedures (Colin Evans, Cardiac Information Manager, 1/4/2005)

8. Summary and Recommendations

In summary there was a full and complete opportunity for understanding the Oxford Cardiac Surgery data system. Mr Evans and Mr Ratnatunga recognised that over the years there had been difficulties with the accuracy of cardiac surgery data which had led to some detailed review.

The current system as described and presented has clearly evolved significantly over the last 12 months and is gaining the confidence of the Cardiac Services IT Department and consultant surgeons. We were impressed by the enthusiasm and commitment to the audit process by CE and his team.

We have some recommendations

1. Consideration should be given to establishing an audit trail – this we understand is recognised and being addressed. Included within this is a lack of input identifier which we also understood is being addressed.
2. It appeared that there could be more consistency and rigour in the timing and responsibility for data entry. Accuracy and completeness in data entry is an evolving process and needs to be embraced by all those involved in the process. This is clearly being emphasised by CE himself, and through the feedback systems that he has put in place.
3. The shortcomings of post-op morbidity data entry (which are part of the minimum data set) are recognised and are being addressed.
4. The monthly e-mail reports of completed data should perhaps require a formal sign off rather than the current default option?
5. Datacam to be made available to all consultants
6. Consideration should be given to running a course for units to use Lotus notes.

Appendix

Background and History of data collection and validation in Cardiac Surgery

National data collection in Adult Cardiac Surgery began in 1977 with the voluntary reporting of basic activity and outcome data on adult cardiac operations. Data were received from 100% of UK NHS and all the Republic of Ireland units and the aggregated national data was fed back to each unit to allow comparison of local results with national average. Since 1997 this included individual surgeons' results for coronary artery surgery.

The National Adult Cardiac Surgical Database was established in 1994 and the current data set includes demographic, procedural and outcome data for each patient. The reasons for collecting more comprehensive data were firstly a growing public and political interest in cardiac surgical outcomes, secondly ignorance of changing patterns of patient populations with a professional and public misconception about that coronary artery surgery carried little or no risk. Thirdly in North America the release of crude mortality data on Medicare patients in the late 1980s with no risk adjustment for patients' specific risk factors or co-morbidity caused considerable concern within the cardio-thoracic surgical community.

In the early 1990s the development of the internal market focussed attention on the purchaser/provider split in healthcare provision. It became clear that the success of the new healthcare market depended on an accurate understanding of the nature of the patient population and the availability of comprehensive data collection for understanding severity of the illness, resource allocation and outcome analysis.

Further important developments in this "data collection journey" have been firstly the introduction of an agreed data set for the national database, secondly the public disclosure of surgeon's specific outcome data in New York, and thirdly the report of the public enquiry into children's heart surgery at Bristol Royal Infirmary. All directed attention towards clinical governance, and, in December 1997 there was an extraordinary general meeting held at the Royal College of Surgeons. This concluded that there was " a need for quality assurance driven by the change in public perception of doctors and their accountability and the public's wish for more detailed information about doctors' activity"

The collection and collation of data from the National Adult Surgical Database has recently resulted in a 5th report (2003) which documents the nature of contemporary cardiac surgery practice in the UK and Ireland. This is a considerable task which has been largely undertaken by one individual, Professor Sir Bruce Keogh, and the success and future of this project is now seen to rest with direct submission of data from individual cardiac surgical units to the central cardiac audit database (CCAD).

As important as the burgeoning momentum for outcomes of cardiac surgical procedures, there has been a growing concern regarding the nature and quality of data, which is used for outcome analysis. It is this, which in 2001 led to the introduction of the Society of Cardiothoracic Surgeons Quality Accreditation Programme whose mission statement was to "recognise and reward good quality monitoring schemes in adult cardiac surgical units". This meant that an adult cardiac surgical unit and its individual consultants had systems in place for knowing its

activity, case mix and outcomes, and had mechanisms in place for validating and verifying the data.

The importance of data quality and risk adjustment has been emphasised by both The Secretary of State for Health and the Chief Medical Officer are on record in requiring that outcome data should be “robust, validated and risk adjusted”. The recent Nuffield Rand paper (1) asserts that “at a minimum all information released for publication should be subjected to an independent check before release”, and this, in conjunction with the known shortcomings associated with HES data, and “gaming “ of data has further focussed attention on data validation and quality. This, through discussions at the Society of Cardiothoracic Surgeons and with clinical audit leads has led to the formation of a tri-partite oversight group (Society of Cardiothoracic Surgeons, Department of Health, Central Cardiac Audit Database) to govern further data submission directly to CCAD.

The rigour of this new process of data submission directly to CCAD from individual units and the validation of the same data is underpinned by three separate arms. Firstly, a Governance Document (James Roxborough) has been produced and makes recommendations as follows: -

- a) To safeguard confidentiality and security of patient, professional and institutional data and analysis using the data.
- b) To make CCAD the authoritative source of data on cardiac surgery.
- c) To provide HCC (Health Care Commission) with information and analysis to give patients and the public clear, accurate, accessible, understandable information on cardiac surgical outcomes.
- d) To foster greater understanding of the complexity, underlying outcomes among public patients, media and opinion formers.
- e) To consider proposals for modifications to or extensions to the audit dataset.

Secondly, a report on Validation for Adult Cardiac Surgery has been produced by the SCTS (final report 24.2.04). Thirdly, the SCTS has visited the CCAD to seek assurances regarding its daily working, relationship to other organisations, data confidentiality, intellectual property, and a vision for dealing with poor performance.

The spotlight has been further directed toward cardiac surgical outcomes with the Freedom of Information Act and the recent disclosure of surgeon specific outcomes (2,3).

Mr Mark Jones and Mr Ben Bridgewater made a mock validation visit to Manchester Royal Infirmary on 13.12.04. This informed a clinical audit lead meeting held at the Royal College of Surgeons on Monday January 17th2005 and a mandate was given by the Society, Department of Health, and the Healthcare Commission for a pilot of six visits to be undertaken to cardiac surgical units in England and Wales. The visits would be undertaken by the current assessors of the accreditation programme QAP, namely Mr Mark Jones, Mr Alan Faichney, Mr Brian Fabri, Mr Jonathan Hutter and also Mr Ben Bridgewater. The visits are undertaken by two Consultant Cardiothoracic Surgeons and a representative of the Central Cardiac Audit database and after six pilot visits have been undertaken; the process will be reviewed and scrutinised by the tri-partite group.

The main aims of the data validation visits are to look at and validate

- processes for collection and collation of data
- data analysis and feedback
- data submission to CCAD

- quality assurance of the above systems

A draft report is sent to the unit to check for factual accuracy, and then a final report of the visit will be circulated to representatives of the Unit, the SCTS, CCAD, and the Health Commission.

References

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