

CENTRAL CARDIAC AUDIT DATABASE (CCAD) DATA VALIDATION REPORT

Data validation visit to Cardiac Surgical Unit, Barts and The London Hospitals

Visitors:

Lin Denne (CCAD Data Auditor)

Mr Brian Fabri (QAP assessor – Consultant Surgeon, Cardiothoracic Centre, Liverpool)

Mr Jonathan Hutter(QAP assessor – Consultant Surgeon, Bristol Royal Infirmary)

Date of visit: Thursday April 21st, 2005

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 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

Alan Wood	Consultant Cardiothoracic surgeon
Nick Silversides	Senior information analyst Medical Degree Microsoft certified systems Engineer for windows 2000 (since Feb 2001) Data Manager Lead
James Wood	Information analyst Physics Degree Permanent appointment since 4 Sept 2004
Debbie Timmings	Cardiac Audit officer BSc computer science

The above personnel provide audit services for the whole cardiothoracic directorate. It was estimated that about 0.5 – 0.8 WTE was utilised to provide the service to the cardiac surgery department.

AW felt that the current complement of staff was satisfactory and funded.

The team were pleased to note that Job descriptions were available for all team members and held in the HR department.

(b) Software system and network

Cardiac surgery is undertaken on 2 sites, St. Bartholomew's Hospital and The London Chest Hospital. Occasional emergency work is carried out at the Whitechapel Hospital. These multiple sites make provision of the service more difficult and labour intensive.

The main server for the PATS system is housed in the ICT department but the server and the PATS Cache database are managed by the cardiac audit team. The PATS system being available for data entry on approx 240 computers within the cardiothoracic directorate.

All individuals within the directorate require a user account to access the PATS system. Access to the various components can be specified for each user. Only the four personnel above have access to the analysis modules of the system.

There is an office within the department for the data personnel

(c) Overview of process

A PATS system, purchased in 1999 is used with a direct entry system. The core Data set plus some additional fields are entered at the time of operation by the operating surgeon or the assistant. Anaesthetic specific data is entered by the anaesthetist at the time of operation. The PATS system has reliable mortality data but other outcome data is only available in 23% of patients. Some other time related data are available on the PAS system.

3. Data collection processes and cross checks

The core data set plus additional fields to enable an operation note to be generated are completed after the operative procedure by either the operating surgeon or the first assistant. (291 data fields)

AW commented that some surgeons felt that to avoid any chance of gaming the data was completed by the assistant, whilst others felt that the information was so important that they should enter it themselves in order to ensure that it was correct. AW stated that data was entered as intended at the end of the operation in about 90% of cases, the main incentive to achieve this figure was the requirement to generate the operation note from the data.

Data entered was mainly preoperative and operative data and outcome data was only collected on the PATS system in 23% of cases.

This was recognised by AW as a current failing of the system but it was intended to try to include more outcome data in the future. However AW stated that some further outcome data relating to time of stay on ITU and total stay was available via the PAS system.

Mortality data was checked monthly by the audit team and where necessary the patient status updated.

The anaesthetist completes data relating only to the anaesthetic technique (100 data fields)

Cross checks

To ensure that all patients are entered into PATS system

Each day a check was made with the bed manager system on a SQL 2000 database with a web based entry screen and cross checked against the PATS entry to ensure that all patients having cardiac surgery were entered into the PATS system.

A check is made every 6 months from a photocopy of the theatre log books to ensure that data exists on all patients having cardiac surgery.

Checks are also made between the PAS and the PATS system to ensure that both systems are complete.

Every Monday the consultants receive an overview of their current surgical activity on the PATS in the form of a summary report which includes all mortality. This allows consultants to identify and complete missing fields. Information is also presented at the monthly audit meetings as histograms so that it is possible to identify any personnel not completing the missing fields. Once a missing field is completed it no longer appears on the next week's list of missing fields.

No checks are made using ITU log books or the perfusion records however the visiting team was well satisfied that the checks used were satisfactory to ensure that all patients having cardiac surgery were included in the database.

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

The PAS system was used to collect mortality data by checking the discharge date and destination ie mortality would be identified. The information was then entered into PATS. A weekly report of deaths is sent to each consultant for checking. No response from the consultant is accepted as confirmation of correct data. No formal signing off of the data occurs.

In the past an annual check of the bereavement office records was made and cross checked against the PATS data. This is not routinely done currently.

Checks were not made using the ONS office.

The visiting team were fairly confident that the systems in place would ensure that a complete record of mortality was achieved.

5. Feedback mechanisms in place to validate data

Weekly reports are automatically generated and sent to each clinician containing missing field and mortality data. AW felt that this was a major reason for the success of the system

The visiting team were very impressed by the feedback mechanisms and the way that the PATS is used to its maximum potential both for the generation of this feedback and the production of output documents such as the operation report and Discharge summary. The operation notes are routinely printed out by the CT secretaries.

6. Review of data

Recently data on 3,138 patients has been submitted to CCAD, this analysis is based upon the 1,666 patients operated on in 2004. Discrepancies between submitted and ONS tracked mortality is unavailable.

Table 1. Discrepancies between submitted and ONS tracked data

Number of patients	Reported alive on database: dead on ONS	Reported dead on database: alive on ONS

Data not available at the time of the visit.

Table 2. % Data completeness for core variables: Hospital BAL compared to pooled 'national' Data

Variable	Hospital BAL	'National'
Age	100	99.9
Sex	99.9	99.9
NHS number	99.9	89.1
Post Code	100	100
Procedure	100	98.6
Surgeon Identifier	97	90.5
Post operative morbidity	23	63.2
Discharge status	100	98.6

Excellent data completeness with the exception of post operative morbidity. Excellent completeness of NHS number was noted.

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

Risk factor	Completeness Hospital BAL 2004	Completeness national 2004
Age	100	100
Sex	0	100
PVD	100	84
Previous surgery	100	79
Renal failure	100	95
Active endocarditis	100	100
Iv Nitrates	100	95
LV dysfunction	100	95
Most recent infarct	100	95
Shock pre-op	100	82

Ventilated pre-op	100	87
IABP	100	60
Iv inotropes	100	83
PA systolic	100	63
Urgency	100	99
Non coronary surgery	100	100
Surgery on aorta	100	100
Acute VSD	100	100
Data quality index	90	87

Excellent data completeness was noted. The value for the patient sex is clearly a mistake on CCAD data and is the reason for the data quality index of only 90%.

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

Risk factor	BAL incidence	National incidence
Mean age	66.2yrs	64.7
Male	73.7	69.9
Mean EuroSCORE	4.7	4.4
Fair LV	30.1	24.5
Poor LV	7.4	6.2

The correlation between the data and the CCAD national incidence suggests that the data entry is correct and does not suggest any evidence of gaming of the data.

Concern was expressed by AW about the apparent discrepancy between the Data returned from CCAD and the information provided to CCAD. For example the sex is recorded as provided 100% in table 2 but 0% in table 3. This accounts for the Data quality index being given as 90%. These were accepted as errors by the visiting team but AW pointed out that returning incorrect data was likely to reduce confidence in the system. The visitors pointed out that these were trial assessments and all efforts would be made to ensure that correct data is returned. The CCAD data however did demonstrate that there was excellent completion of data fields.

Discrepancies between submitted and ONS tracked mortality

Data was not available at the time of the visit.

Checks to ensure correctness of data.

No checks are made to ensure that the data fields are completed correctly. A regular review of case notes has been considered by AW but has not been implemented. However the cross checks on the CCAD data does not suggest any discrepancies to suggest either that the data is incorrect or that there is any evidence of gaming of the data.

Security of the system.

The PATS system does not have the facility to lock the data to avoid later changes being made to the data, but AW did not feel that there was any evidence that late and inappropriate changes to the data occurred.

The visiting team agreed that a locking system on the PATS system would be a useful improvement and would pass this back to Dendrite to ask if it is possible to include this in further updates of the system. It was noted however that it is possible to track the date of all data entries and the user making the changes.

7. Further issues

The data team expressed disappointment that the front end of the PATS system is not very user friendly and that the promised update to a Web based system has not yet been implemented by Dendrite. Consideration will be given by CCAD to encouraging Dendrite to implement this improvement to the PATS system.

The team were pleased to see that all systems were fully documented and all relevant bespoke source code (eg web reports, bed manager web application) is contained using Microsoft Visual Sourcesafe.

8. Summary and Recommendations

(a) The visiting were impressed with the small number of personnel required to run the system effectively. This is achieved by the very high calibre staff having devised a direct entry system with multiple automatically generated feedback mechanisms so that the system largely runs itself.

(b) The team were impressed that the PATS is used to its maximum potential. It was recognised that the outcome data was limited and fairly urgent consideration should be given to increasing the outcome data.

(c) The routine cross checking of mortality records with the bereavement office records is recommended.

(d) Consideration should be given to incorporating a formal 'signing off' of the data by the consultant staff, this is currently only implied by a nil response when the data is circulated.

(e) Very good systems exist to ensure completeness of data collection but consideration should be given to developing a system to check correctness of the data. This might for example include an independent review of the case notes of approximately 20 notes on three monthly basis .

(f) Overall the visitors were very impressed by the system in use and are fully satisfied that it fulfils all the current criteria.

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

1. Fine L, Keogh B, Cretin S, Orlando M, Gould M. How to evaluate and improve the quality and credibility of an outcomes database: validation and feedback study on the UK Cardiac Surgery Experience. *BMJ* 2003;326:25-28.
2. Ben Bridgewater on behalf of the adult cardiac surgeons of northwest England. Mortality data in adult cardiac surgery for named surgeons: retrospective examination of prospectively collected data on coronary artery surgery and aortic valve replacement. *BMJ*, Mar 2005; 330:506-510.
3. The Guardian, Health. 15 March 2005