

CENTRAL CARDIAC AUDIT DATABASE (CCAD) DATA VALIDATION REPORT

Data validation visit to Cardiac Surgical Unit, James Cook University Hospital,
Middlesborough

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 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

Personnel

Cardiac Surgery at the James Cook University Hospital Middlesborough is part of the Cardiac Services Directorate and the visiting team was introduced to the Surgical Audit Group which was made up as follows:-

Mr Andrew Owens, Clinical Audit Lead & Clinical Director- Consultant Cardiac Surgeon,

Anne Lister, Clinical Governance Lead for Cardiac Services - 20 year background in audit and clinical governance. Also responsible for Cardiology Services, Anaesthetic Services and Research Activity.

Tracey Smailes, Surgical Team Database Manager - clinical background.

Pam Chapman, Clinical governance Nurse -0.5 Clinical Audit/0.5 ITU Nurse – interface between clinical and audit activity.

Carol McClure, IT Projects Manager – works for the Trust Information Director. Currently permanently seconded to Cardio Services.

Audit Clerks – Cardiac Services employ a number of audit clerks, (at the time of the visit one was absent on Maternity Leave) who support data entry and routine activity. The responsibilities and administrative duties of Audit staff including the Audit Nurse and the Audit Lead are described in the document “Roles within the Cardiothoracic Surgical Audit Team”.

In total the Cardiothoracic Division Clinical Governance Team includes 8 w.t.e. audit staff, and 5 w.t.e. IT staff managed by 1 w.t.e. Clinical Governance Lead. The department is located in a portacabin area geographically close to core cardiac surgical, cardiological and anaesthetic activity.

Software System and Network

The data collection system is supported by a bespoke Access 97 software system. Users are able to log on to any machine in the division and access the networked package. Currently consideration is being given to purchase of a dedicated commercial cardiac surgery audit package. In time it is anticipated that the data entry system will be web-based.

Overview of Process

At the beginning of our visit, we were given a lever arch file which contained comprehensive details of the structure and make up of the cardiac services audit programme. Files documented the members of the audit team, their roles, and the system of data validation, systems of cross check, and governance. Also included were examples of Cardiothoracic Surgical Reports, Audit projects and Validation projects. These are referred to in the text.

The system and mechanisms for data entry are clearly described in the document “Patient Journey Through Cardiac Surgery”. On the day of admission patient demographics are entered by the secretary pre-operatively. This is facilitated by an automatic link to CaMis which is the in-hospital patient administration system.

Following completion of an operation, patient clinical details including all of those fields required for the SCTS Minimum Data Set are entered, generally by the operating surgeon. During progression from one screen to the next any incomplete entry is highlighted by a pop-up “still fields to complete”. In addition there are internal validation mechanisms e.g. for ejection fraction and defaults for routine/elective surgery - elective patients cannot be receiving IV nitrates or have IABP inserted. As the patient leaves the operating theatre an operation note is generated which accompanies the patient to the ITU. There is a further summary field at the end of the operation note which again highlights incomplete record entries. EuroSCORE and Parsonnet scores are automatically generated.

At the time of discharge a computer generated summary is completed by the SpR/Nurse Practitioner on the ward. This includes a drug prescription list which

contains its own logic /validation systems e.g. correct drug doses, appropriate anticoagulant doses etc.

Since the summary is read by a number of clinical staff, it provides useful validation of complete data entry, omissions, inaccuracies, etc. The efficiency of this document review and the numerous other checks during the data collection process is reflected in the very high standard of the data collected. A description of the evolution of this process since the inception of the SCTS database pilot in January 03 is summarised in the document "SCTS Data Validation and Reporting Time Scales".

Patient death is documented on the discharge summary and validated by clinical staff, by CaMis, by clinical review, by surgeons and by subsequent reports – see later.

It was recognised that the current operation notes and discharge summaries are not "user friendly" – they read as lists rather than fluent text documents but this is ongoing development work which is being evolved within the Trust and in line with Trust directives.

A robust audit trail exists for each stage of data entry including identity of entrant, nature of entry, time of entry and any change that has taken place.

3. Data Collection processes and Cross-Checks

This activity is summarised under the documents "SCTS Data Validation – Weekly, Monthly and Annual". The validation process includes the following:-

Weekly

1. Check of all patients on the database versus the theatre list.
2. Check CICU logbook for deaths & update CCAD database.
3. Check Cardiac Surgery wards records for deaths & update CCAD database.
4. Check the divisional mortality database & update CCAD database.

Monthly

1. Theatre logbooks are checked for emergency patients i.e. not on the theatre list.
2. The clinical review database (which forms the basis of a joint monthly clinical review meeting) is checked for the previous month's surgical deaths & CCAD database updated.
3. Clinical activity is cross-checked with the surgical and thoracic database.

Annually

1. Check of activity against HES activity data for each procedure and each consultant.
2. Check of deaths against HES data for each procedure and each consultant.

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

This is partly covered by the database validation exercise described in section 3. In addition it is described in more detail in the document "Mortality Validation for the Cardiothoracic Surgical Database". This describes several mechanisms, which are used to provide a comprehensive and accurate picture of mortality within cardiac surgery. This includes the following:-

1. The Cardiothoracic Surgery database links into the hospital's PAS system and updates the surgical database from PAS. Dates of death are automatically linked to the patient.
2. There is a strong culture of reporting of death amongst hospital administration staff including ward clerks, secretaries and local PCTs which heightens the accuracy and completeness of mortality data.
3. The Cardiothoracic Audit Team contacts each department within the Cardiothoracic Division twice a week to further document mortality including theatres and CICU.
4. Scrutiny of CICU logbooks, examined quarterly.
5. Reports are run from the mortality database by Audit staff quarterly with consequent update of the Cardiothoracic Surgical database accordingly.
6. Quarterly reports are distributed to each Consultant Cardiothoracic Surgeon for individual validation.
7. Monthly clinical review meetings discuss all deaths reported within the Division.
8. Audit staff who work in clinical areas e.g. Pam Chapman, are able to provide timely updates to the surgical database.
9. A clinical entry by SpR or Nurse Practitioner at the time of discharge death is a further feed to post-operative complications and discharge status.

The above process is further described in the document "Tracking and Reporting of Surgical Deaths in the Division of Cardiothoracic Services".

The daily/weekly, monthly, quarterly and annual tasks are also summarised in a similar document.

Currently ONS is not used as a routine hospital cross check for mortality but the CCAD ONS cross check does act as further independent validation.

5. What feedback mechanisms are in place to enable surgeons to validate their own data?

Documents describe the systems for validation of data and associated feedback mechanisms; "Instructions for Validating the SCTS Database", "Cardiothoracic Surgical Database User Guide" and "EuroSCORE – Comparison and Validation" – this both describes the mechanism for undertaking a EuroSCORE validation and the result of an in-house validation exercise. This latter exercise compared the IT calculation of EuroSCORE against manual calculation by audit staff to ensure accurate input of clinical data. It involved the random selection of 30 sets of post-op cardiac surgical patient notes and a manual calculation of EuroSCORE by Cardiothoracic Audit Nurses compared with that calculated by the surgical database following routine data entry. The results demonstrated that overall in 83% of patients there was no difference between the database calculation and the manual calculation and the inaccuracies in 17% (5 patients) were each described with conclusions and an on-going action plan. There is also documentation of the validation of discharge

summary information with a clear description of the method and results and an action plan.

Importantly there is also the description of a comparison of HES data versus the surgical database. That this process is taking place is important since concordance between CCAD data and HES data is likely to be sought in the future by the Health Commission and may feed into performance status.

The structure of the joint monthly clinical review meeting was described. This is attended by all members of the Cardio Services Directorate and includes a formal review of the previous month's clinical activity, discussion of near misses and morbidity and usually the presentation of a topic. Additionally and separately to this the Friday morning clinical meeting is an opportunity for presentation of clinical activity and outcome by the review team. The day is also used for surgeons meetings, MDTs, registrar teaching, surgery wet lab training, and an opportunity for topic presentation e.g. HES validation exercise, incidence of stroke, incidence of re-opening etc. The format of review of clinical data is documented in an annual Cardiothoracic Surgical report which is produced both quarterly and annually.

There is also documentation of the forward plan for Cardiothoracic Services Audit and the programme and feedback of an annual clinical audit day was also available for perusal.

6. Review of Data

This review of data is based upon the 1,173 patients operated upon at the James Cook University Hospital in the fiscal year 2004. The national comparison is data submitted on 23,082 patients operated upon in the same time frame.

Review of data shows that there are no patients reported alive on the database and dead on the ONS. There are six patients reported dead on the database and alive on ONS.

Table 2 shows very good data completeness for core variables hospital compared with pooled national data, especially with respect to post-operative morbidity.

Table 3 shows a data quality index of 100%.

Table 4 shows the incidence of risk factors compared to pooled national data and the Middlesbrough mean EURO-score of 4.3 versus national EURO-score of 4.6 does not suggest any systematic gaming of operative risk.

At the time of review of the 1,173 patients for the year 2004 through CCAD Lotus notes logic checks were not available.

Analysis of Data Submitted to CCAD- 2004

Table 1. Discrepancies between submitted and ONS tracked data

Number of patients	Reported alive on database:	Reported dead on database:
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1,173	dead on ONS 0	6
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Table 2.% Data completeness for core variables: Hospital compared to pooled 'national' data

Variable	Middlesborough	'National'
Age	100	100
Sex	99.8	100
NHS number	99.4	88.6
Post Code	99.9	99.8
Procedure	99.6	99.3
Surgeon Identifier	89.6	90.7
Post operative morbidity	98.8	68.3
Discharge status	98.9	99.4

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

Risk factor	Completeness Middlesborough 2004	Completeness national 2004
Age	100	100
Sex	100	100
PVD	100	95
Previous surgery	97	92
Renal failure	100	96
Active endocarditis	100	100
Iv Nitrates	99	93
LV dysfunction	99	98
Most recent infarct	100	96
Shock pre-op	99	90
Ventilated pre-op	99	93
IABP	99	84
IV inotropes	99	92
PA systolic	99	75
Urgency	100	99
Non coronary surgery	100	100
Surgery on aorta	100	100
Acute VSD	100	100
Data quality index	100	93

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

Risk factor	Middlesborough incidence	National incidence
Mean age	64.8	65.3
Male	73.6	70

Mean EuroSCORE	4.3	4.6
Fair LV	16.3	25.1
Poor LV	3.8	6.0

Logic checks for the Middlesborough data are as follows

Current definitions are as below

1. Fatal Errors = 0 (expected - records rejected at import)
2. Serious Errors = (these values need checking but the record is imported)
3. Minor Errors = 0

Fatal errors will prevent that record from being uploaded

Serious errors will be flagged up a will require attention from the unit

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

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

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

Logic check failures are as shown above.

7. Further Issues

At the end of the formal presentation and discussion Mr. Tony Roberts, Honorary Research Fellow, presented the use of cumulative funnel plots in portraying surgical mortality and the stratification of patients into low risk (EuroSCORE less than or equal to 5) and high risk (EuroSCORE greater than 5). He emphasised the importance of ease of interpretation of the plots and the use of a "rolling window" to review successive timeframes. During the course of this presentation it was clear that there was a strong culture of transparency and openness in reviewing surgical activity and post-operative outcome.

Documentation was also available to understand the systems in place for clinical governance, the trigger for and escalation of response.

Collaboration between the clinicians, Mr Roberts, the audit team & the IT service has produced a very elegant directorate web site which presents outcomes data as well as describing the department, staff, hospital etc. Patient information documents on all aspects of cardiac care are available on the web site. Other units embarking on such a project could learn from the Middlesborough experience and indeed they would be happy to offer help & advice if requested.

The ethos of the department is very much around data collection / audit and there is a recognition of the need for accuracy & validation. This approach is supported by the Trust in the number of audit & IT personnel made available to the directorate. Those staff involved feel that the accurate data they are able to provide is just as valuable to management as it is to staff members, patients, and for clinical governance.

The pride that members of the Cardiac Surgical Audit Team have in their department and the pride that the Trust has in its Cardio Services Directorate was reflected in an end of meeting discussion. This meeting was attended by the Chairman of the Trust Board, Chief Executive, Medical Director, Director of Nursing and the Divisional Manager and allowed further discussion of audit activity.

8. Summary and Recommendations

It was our unanimous view that this is an absolutely outstanding Cardiac Surgical Audit Programme which reflects the energy, enthusiasm and innovation of a synergistic and forward-looking team. The visitors were particularly impressed by the importance placed on the accuracy and validation of data. Our visit and review of audit processes emphasises that a quality system requires manpower and physical resource. We would fully support the ambition of the Cardiac Surgical Audit department in forming direct links with Trust governance structures but at the same time maintaining its own identity, in particular having its own dedicated IT support and maintaining audit departmental cohesion and continuity.

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, 1984 to 1995. All directed attention towards clinical governance, and, in December 1997 there was an extraordinary general meeting held at the Royal College of Surgeons, which 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 who are on record in demanding 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 CCAD, Health Commission) 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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