

Central Cardiac Audit Database (CCAD) Data Validation Report

Data validation visit to Cardiac Surgical Unit, Leeds General Infirmary

Visitors:

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Contents:

1. Introduction

2. Structure of data collection systems

- Personnel
- Software system and network
- Overview of process

3. Data collection processes and cross checks

- Routine for regularly comparing PAS and database, checking both ways and correcting discrepancies
- Routine checking of independent theatre logs against database
- Routine for using PAS for ICU stays and ward stays in database

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

- System for cross checking mortality with hospital deaths office
- System for checking against mortuary records
- System for checking mortality against PAS
- Routine ONS check against local mortality data

5. Feedback mechanisms in place to validate data

6. Review of data

- Discrepancies between submitted and ONS tracked mortality
- Incidence of missing data
- Data on incidence of risk factors
- Logic checks on submitted data
- System security

7. Further issues

8. Summary and Recommendations

Appendix-Background and History of Cardiac Data Collection

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

The adult cardiac surgical audit system has been led and progressed under the direction of Mr Philip Kay, Clinical Audit lead. The Cardiac Surgical Database Manager and Co-ordinator is Mr James Peckover (JP), who is supported by Mr. Philip Hartley, Database administrator, and line managed by Mr Ralph Higginson, Systems Manager. Mr Higginson is currently fully occupied with implementation of the Cardiobase system, and Mr Hartley on long term sick leave is likely not to be re-recruited. JP is responsible, not only for Cardiac Surgery (SCTS), but also for Cardiology (BCIS and MINAP) and there are plans for him also to assume some responsibility for Paediatric Cardiac Audit. Additionally a support data clerk at St. James's Hospital has recently left and not been replaced. Another part-time database co-ordinator has left and not been replaced. It is clear that as JP's

responsibilities for Audit have increased with time, and as the complement of personnel has shrunk, so the time that he can give to validation has decreased.

(b) Software System Network

Mr Kay emphasised that in this new cardiac surgical facility, which was properly wired, that there was good integration of all terminals enabling an efficient and effective network function.

The physical structure of the Cardiac Surgical Audit is based upon the PATS (Patient Administration and Tracking system). This was introduced at Leeds General Infirmary in 1991. All Cardiac Surgeons and secretaries have access to the database in individual offices and computer terminals are present in two cardiac surgical wards, CICU and Cardiac Theatres. Direct linkage between PATS and PAS enables automatic import of the patient's hospital number and demographic data.

(c) Overview

Either the SHO or Registrar normally inputs pre-operative data on the wards. The operating surgeon enters the operative data, including a section for free text, in the theatre area, and at this stage has the opportunity to check all pre-operative data. Completeness of data entry can be seen on the screen and a calculated Parsonnet and EuroSCORE is given. Perfusionists similarly enter their own data (for off pump bypass graft procedures, "pump standby available" is entered). An operation note is generated along with a preliminary summary patient record, which is accessed by the secretary. Post-operative details of complications and discharge medication are finally entered by the Registrar to generate a final automatic discharge summary.

3. Data Collection Processes and Cross Checks

Each day the secretary will issue a theatre operating list and the following morning, (also taking account of night and weekend activity) checks the theatre list against actual operations undertaken by scrutiny of operation notes and reviewing operations postponed or cancelled.

Secondly the perfusionists run their own database (KCSS) which is a second independent record of operation activity.

A third cross check takes place at the monthly mortality/morbidity meeting when the Registrar leading the meeting checks the perfusion records versus the PATS system for actual operation numbers. This monthly half-day audit meeting allocates its first hour to activity, mortality and morbidity and then discusses topics.

HES data sent quarterly to the Cardiac Surgical unit by the Trust has shown up disparities and Mr. Kay reported that the Trust recognises that the PATS system is more accurate than HES data.

A further cross check exercise took place in response to the request for cardiac surgical outcome data from a national newspaper under the Freedom of Information Act.

Surgeons are encouraged to separately enter outside of hospital waiting list initiative and private patient surgical activity to fully represent operative workload.

Additional checks for activity include firstly a check of the theatre register against the PATS system and JP has evolved a manual and latterly a computer based system to undertake this cross check but is currently unable to do so, because of lack of time. Secondly, Michael Allen, Deputy Manager of Operations, described a further check of activity against contracts and accounting records but that this was currently recognised not to be robust.

No independent cross check takes place between PAS and separate ITU records.

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

Mortality data collection is primarily collected and collated using the PATS system and then cross checked against the "book of the dead", which is held in the Bereavement Office adjacent to the mortuary. The Trust distributes mortality information to all individual surgeons on a quarterly basis. This information is taken from the HES/PATS records and includes names, dates of birth, and hospital numbers. This information is checked by the individual surgeon against the patient's notes and returns and any amended data are returned to the Trust's Statistics Office where appropriate alterations are made.

No routine ONS (Office for National Statistics) check takes place against local mortality data.

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

Feedback to individual surgeons takes place by means of the monthly mortality and morbidity meetings. Secondly, quarterly Trust returns of mortality information from HES past records and thirdly annual feedback by Mr. Kay prior to the SCTS returns enable further ratification of operative numbers and deaths by individual surgeons.

Each individual surgeon has been encouraged to keep his own database of activity off site.

6. Review of Data

Analysis of Data Submitted to CCAD- 2004

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
1,574	35	0

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

Variable	Leeds	'National'
Age	100	100
Sex	99.9	99.9
NHS number	84.8	83.9
Post Code	99.6	99.9
Procedure	93.7	98.4
Surgeon Identifier	92.2	90.4
Post operative morbidity	73.8	61.4
Discharge status	100	97.5

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

Risk factor	Completeness Leeds 2004	Completeness national 2004
Age	100	100
Sex	100	100
PVD	97	80
Previous surgery	4	77
Renal failure	93	96
Active endocarditis	100	100
Iv Nitrates	93	87
LV dysfunction	100	96
Most recent infarct	97	96
Shock pre-op	83	88
Ventilated pre-op	93	91
IABP	5	61
IV inotropes	100	87
PA systolic	100	68
Urgency	94	98
Non coronary surgery	100	100
Surgery on aorta	100	100
Acute VSD	100	100
Data quality index	87	89

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

Risk factor	Leeds incidence	National incidence
Mean age	63	64.5
Male	73.6	69.8
Mean EuroSCORE	4.0	4.3
Fair LV	28.1	23.1
Poor LV	6.2	5.4

Data for the purpose of this visit was reviewed on 21.2.05 following upload of LGI data to the CCAD beta test site and mortality cross check against ONS undertaken the previous week. CCAD reports that 1,574 operations took place 2003-4, whereas the PATS system reports 1,311 cases.

(a) Discrepancies between submitted and ONS tracked mortality

35 patients were reported alive on data base, dead on ONS – this may be due to the reporting of ONS tracked deaths not respecting the CTCS definition of mortality i.e. death within the base hospital during that admission. No patients were reported dead on database but alive on ONS.

(b) Incidence of missing data.

The data completeness for core variables is shown in table 2 comparing the Leeds data set with the national aggregate. This shows very close concordance between the Leeds and the national aggregate. Completeness on post-operative morbidity at 73.8% compared with a national aggregate of 61.4% is good compared with the national data. Table 3 shows the percentage completeness of EuroSCORE fields compared to national data. Overall this shows a percentage completeness of EuroSCORE fields of 87% compared to 89% for national data. Two fields stand out namely previous surgery 4% completeness compared with 77% national data and intra-aortic balloon pump 5% completeness compared with 61% for national completeness. On the Leeds PATS system each of these defaults to an answer of “no” unless otherwise stated – this may therefore amount to a transcription error of data submission and will be further investigated.

(b) Data on incidence of risk factors

Table 4 shows the incidence of risk factors at LGI compared to pooled national data and demonstrates that the incidence is similar to national data and there is no evidence of gaming from this analysis.

(c) Incidence of logic checks on submitted data

Logic checks for the Leeds data are as follows

Current definitions are as below

1. Fatal Errors = 0 (expected - records rejected at import)
2. Serious Errors = 1357/13421 [10%] (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. There are no fatal errors. There is a 10% rate of serious error as shown in the text and these require further investigation for feedback and improvement in data quality.

(d) System security

There is no system security for lock out so surgeon's data can be accessed by any individual and altered.

7. Further Issues

- (a) PATS has no mandatory fields and correction of this may benefit the completion of EuroSCORE fields and the Society data set fields.
Problem of double entry: if for example, pre-op data is input and then the operation is cancelled; a second operation date may lead to a double entry. Similarly when JP took over system there was failure of concordance between PAS and PATS leading to double entries. Furthermore patients can be entered with different identification numbers. e.g. NHS number, UR number, local referring hospital number and again these can lead to double entries.
- (b) Consideration has been given to internal validation of sets of notes either between Consultants in Leeds or between Trusts e.g. Hull, South Tees but not yet undertaken.
- (c) PATS does not lend itself to simple logic checks e.g. excessive cross clamp times, inconsistent heights and weights etc. In addition JP volunteered that it is a difficult system to interrogate.
- (d) CCAD Help Desk - JP commented that CCAD has been busier over recent months, slow to respond, and he often has to contact Nadeem Fazaal directly

8. Summary and Recommendations

- (a) Visit worked well – undertaken by two QAP assessors and Healthcare Commission representative. There was full and complete opportunity for understanding the LGI Cardiac Surgery Data system.
- (b) The LGI system appears basically robust but is inadequately resourced. Audit culture is strongly embraced by Clinicians but not by Management and consequently the perception of audit is that of number crunching rather than progressive quality improvement.
- (c) JP is quite over committed, very busy making regular monthly hospital, regional and national data reports, in addition to maintaining the SCTS, MINAP, and BCIS returns, and departure would leave the system in the lurch.

We have some recommendations

- (a) Urgent consideration should be give to recruiting support personnel
- (b) Consideration is given to utilising independent record sources e.g. to X check theatre register v PATS which is currently precluded by lack of time. Full use made of X check between perfusion and PATS records.
- (c) Establish X check between HES data and PATS records – in future this will feed into the star ratings
- (d) The validation and verification of data submitted to CCAD would be improved by a monthly download, which would yield smaller numbers to verify yet this is difficult due to resource implications e.g. disparity between PATS and CCAD for activity, incidence of redo surgery, IABP numbers.
- (e) Consideration be given to reasons for Logic check failures
- (f) In time, all audit staff and surgeons should have access to CCAD, and ONS can be utilised as a mortality X Check
- (g) We would encourage the development of the feedback systems to further improve data quality

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 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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