

CENTRAL CARDIAC AUDIT DATABASE (CCAD) DATA VALIDATION REPORT

Data validation visit to Cardiac Surgical Unit, Northern General Hospital, Sheffield

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

a) Personnel

Cardiothoracic data collection at the Northern General Hospital (NGH), Sheffield is under the direction of Mr D Hopkinson, Consultant Cardiothoracic Surgeon and Jo-Anne Daly (JD) Cardiothoracic Information Manager. JD has a degree in physiology, a background in audit, self-taught IT skills and has achieved a Masters Degree in Health Informatics from Sheffield University. She has overall responsibility for system development and management throughout the Cardiothoracic Directorate. Her salary is on the Northern General Hospital pay spine grade 10, JD is line managed through the unit managerial structure. She is supported by Louise Kirk, Cardiothoracic Information Assistant who has a clerical/IT/medical secretarial background. Louise also has responsibility for Infoflex data entry training.

The lead role in the development and implementation of the Infoflex software system throughout the Trust has been undertaken by Stephen Stewart who has a nursing

background and is Clinical Informatics Change Co-Ordinator. JD works closely with Stephen to ensure that the strategic direction of the Cardiothoracic system is complementary to that in other areas of the Trust.

Additional personnel involved in surgical data collection include all Consultant Surgeons (7), locum consultant (1), and their corresponding registrars, also secretaries to the Consultant Surgeons (6), and some members of the perfusion staff (3).

Under the management of JD this group has wide ranging responsibility for data collection and system development and management within the Department Management Team.

The Cardiothoracic Data department has a stand-alone functionality having little interaction with the Hospital Audit Department and is self-supported and self-governing within the Cardiothoracic Directorate.

b) Software System and Network

Five years ago there was a move from the PATS system to Infoflex (www.infoflex-cims.co.uk). Since its inception this has undergone upgrades and now provides requirements for cardiac surgery data management, including submission to CCAD, and other national bodies. This is in addition to local requirements e.g. Koerner forms, CICU, lung cancer, rapid access chest pain clinics, MINAP, interventional cardiology, Cardiology rehabilitation, out-patient departments, interventional reports etc. The functionality of the Infoflex system was clearly described to the visiting team in the document "CCAD Data Validation Report – Sheffield Teaching Hospitals 2005". This describes the one-way interface to the Sheffield Teaching Hospitals PAS systems along with the system structure, inter-relationships, backups and security system.

Throughout the directorate there are 78 machines with Infoflex installed.

c) Overview of Process

Following completion of building works at NGH it is planned that a dedicated pre-admission clinic will enable pre-op entry of clinical and risk stratification data. Currently however the system is as follows: -

Firstly, the secretarial staff produces theatre lists the day prior to the procedure. The information assistant registers patient demographic data on Infoflex. This also ensures that the latest demographic information is loaded from the NGH PAS. Secondly, clinical data including risk factors and procedure details are entered onto the system by the responsible consultant surgeon/first operator, following the procedure. The EURO-score is not automatically generated by Infoflex, but by completion of separate risk screens. This can be done in the theatre reception, theatre recovery or in the consultant's office. Currently Infoflex does not generate an operation note. Thirdly, the consultant's secretary enters post-operative outcome data including discharge information and medication when the discharge summary is created. The summaries are saved with the patient's operative date details in Infoflex.

For emergency/non-scheduled patients the process is identical although no pre-registration takes place.

When data is submitted the Information Manager uses CCAD import logs to identify missing data and incomplete records. Dependent on the nature and quantity of missing data this is either entered by the Information Manager or notes are pulled and given to the responsible consultant to complete the record.

A wide-ranging enthusiasm for data entry exists. It is largely consultant led, and with the evolution and development of Inflex it has gained the confidence of users. Mr Hopkinson and JD felt that the preparations for this visit were a valuable part of the continued improvement of the audit process.

Data submission is via flat file extract to CCAD. JD produced a list of problems associated with import logs/CCAD validation of SCTS data from the NGH perspective as follows: -

- 1) No apparent logic to subject on logs – number of errors go up and down.
- 2) Valve explant required even when procedure is repair.
- 3) Valve pathology required on all valves not just those having procedure.
- 4) Procedure date and discharge date – if patient dies on table error displayed and says procedure date should be before discharge date.
- 5) Only get updated information the next day.
- 6) Non-user friendly summary screen.

The Help Desk was described as slow in recognising problems e.g. incorrect EURO-scores, turn around times for corrections take up to 4 weeks. Also difficulty in verification of the number of records submitted, e.g. how are double entered records deleted – are they deleted locally or are they deleted at CCAD or both? How does cross check take place?

3. Data Collection processes and Cross-Checks

Processes in Place to Validate Submitted Data Against Independent Records of Activity

A number of checks are carried out to ensure all operations are captured including

- 1) On a daily basis perfusion staff enter data on Koerner (Koerner form is primarily a record of theatre admission/activity) forms onto Inflex. This information links to the operative procedure and so acts as a crosscheck.
- 2) On a weekly basis all activity (cardiac, thoracic and minor procedures including cancelled operations) is checked. The information assistant crosschecks weekly activity on Inflex against weekly theatre schedule. Perfusion staff crosscheck weekly activity on Inflex against theatre logs and perfusion database.

There is a strong departmental culture of complete and accurate data. Any deficiencies were picked up by Louise and prompted discussion with secretaries/perfusionists/surgeons in order to correct and complete data. Perfusionists were fully involved in this process.

- 3) On a monthly basis consultants are given a list of all cases on Infoflex to check against personal logbooks. This includes information on individual consultant activity, number of cases done, procedure including date, status on discharge, urgency, plus outcomes. These monthly reports were generally very accurate because a weekly check irons out any differences.
- 4) On a quarterly basis surgeons receive a breakdown of the previous quarters activity by surgeon again to check against own records and to discuss at Audit/Consultants Meeting. These quarterly reports consist of the above data plus operative data in more detail and EURO-score.

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

There are a number of ways in which mortality data is captured including: -

- i. Part of the demographic information on the PAS interface includes death indicator and date of death. The "status at discharge" data item in the surgical record is cross checked against the death indicator/date of death items in the demographic record by the Information Manager and any discrepancies investigated.
- ii. Status at discharge is entered by the Consultant's secretary when generating discharge summary and is cross checked against the medical record and dictated information.
- iii. If a patient dies on the operating table the Consultant Surgeon usually completes the status at discharge item.
- iv. As part of the weekly activity check the outcome data from the Koerner forms is crosschecked against theatre logs.
- v. As part of the monthly activity check the consultant cross checks mortality with their own logbooks.

Within the Trust there are a number of ways in which mortality information on PAS is kept up to date of which the four primary ones are

- i. In hospital deaths, ward notifies Admissions Office who update PAS.
- ii. Out of hospital deaths notified by GPs, relatives etc direct to Trust.
- iii. Out of hospital deaths notified by Sheffield Informatics Service.
- iv. Out of hospital deaths notified by National Strategic Tracing Service as part of weekly trace of new/recent patients' NHS numbers.

Recent work has been undertaken to realign patient deaths across the Trust PAS systems. These were all verified first with the NSTS before notification was entered.

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

In addition to the validation that takes place as described above as part of activity checking, internal cross validation takes place.

A list of all procedures is obtained from Infoflex and a 10% sample of each surgeon's procedures is selected by the Information Manager. This is not a random sample - a spread of procedures reflecting each surgeon's activity is chosen. The records for each surgeon are then divided amongst colleagues and no one validates their own records. The validator completes a paper data collection sheet, which mirrors the data items on Infoflex. Additionally the validator also awards points in each of the

EURO-score categories. The data items completed by the validator are then compared to the items held on the original record on Inflex by the Information Assistant. Any discrepancies in the original and validated records are fed back via the lead consultant to be discussed and reconciled at the Audit/Consultant Meeting. The visiting team were shown documentary evidence of the above validation system. This is a process, which is undertaken seriously and with effect. One issue raised by this is the consequence of the revalidation on CCAD data submission. The example shown to the visiting team indicated that approximately half of the patient records examined were up-scored and half were down-scored, although this did not result in a net change in the EURO-score risk.

Audit Meetings are undertaken on the last Friday of each month and consist of 2 hours in the morning to cover mortality and morbidity, and an overview of the month's activity and also presentation of audit projects. The second two hour period is used as a Surgeons Meeting for discussion of business issues, presentation of CUSUM/VLAD curves and discussion of in-house clinical governance.

6. Review of Data

This review of data is based upon the 1,042 patients operated upon at the Northern General Hospital Sheffield in the fiscal year 2004. The national comparison is data submitted on 21,048 patients operated upon in the same time frame.

Review of data shows no discrepancies between submitted and ONS tracked mortality. There are no patients reported alive on the database and dead on the ONS and no patients are 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.

Table 3 other than PA systolic pressure shows 100% data completeness yielding a data quality index of 96%.

Table 4 shows the incidence of risk factors compared to pooled national data and the Sheffield mean EURO-score of 4.9 versus national EURO-score of 4.6 implies that there is no systematic gaming of operative risk.

At the time of review of the 1042 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: dead on ONS	Reported dead on database: alive on ONS
1042	0	0

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

Variable	Sheffield	'National'
Age	100	100
Sex	100	99.9
NHS number	98.8	90.8
Post Code	100	99.9
Procedure	100	99.2
Surgeon Identifier	100	94.6
Post operative morbidity	91.9	66.1
Discharge status	99.4	99.3

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

Risk factor	Completeness Sheffield 2004	Completeness national 2004
Age	100	100
Sex	100	100
PVD	100	95
Previous surgery	100	91
Renal failure	100	96
Active endocarditis	100	100
Iv Nitrates	100	92
LV dysfunction	100	98
Most recent infarct	100	96
Shock pre-op	100	89
Ventilated pre-op	100	92
IABP	100	83
IV inotropes	100	92
PA systolic	0	74
Urgency	100	99
Non coronary surgery	100	100
Surgery on aorta	100	100
Acute VSD	100	100
Data quality index	96	93

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

Risk factor	Sheffield incidence	National incidence
Mean age	65.2	65.4
Male	70.7	69.5
Mean EuroSCORE	4.9	4.6
Fair LV	26.8	25.1
Poor LV	9.2	6.1

Logic checks for the Sheffield 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. 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

Currently an individual user account is set to allow users to view, create and enter data, and delete records. Only system managers have the ability to delete records. Data sets are not automatically locked once completed, but locking of events is a feature of the system which has been employed.

Any consultant data can be changed but a secure audit trail does exist. The latest updated version of Infoflex does create groups for specific actions e.g. create, change, delete.

7. Further Issues

Mr Hopkinson raised a number of issues. He sought clarification of EURO-score risk for left ventricular function, what qualifies as surgery on the thoracic aorta (eg replacement of the ascending aorta, aortic pleating procedures, aortic root enlargement procedure etc), PA systolic pressure, urgency and carotid bruits. He further emphasised that the EURO-score is a pre-operative score, not a post-operative or peri-operative score. He felt that there was a general mis-conception about when this data was entered and validated and that this had implications for publication of unit and surgeon specific data. Mr Hopkinson also questioned the future directions of the CCAD project. Once we have 100% accuracy and 100% completeness where do we go next? How will CCAD be used?"

There is an Inflex user manual, which describes procedures and protocols.

There is little time for system development or development of system for thoracic surgery. There is an increasing stream of ad hoc requirements for information.

Inflex is a cross-city system and new functionality allows greater validation and auto-completion of data.

Issue of default options needs resolving – this needs to be addressed responsibly- conflict between complete and accurate data. Some fields lend themselves to a default option.

Mr Faichney raised the question of the award of a certificate for good quality data systems.

9. Summary and Recommendations

There was a full and complete opportunity for examination of the NGH Cardiac Surgery Data Systems. The visiting team was impressed with the production of an explanatory document summarising all details of the data validation system and cross checks and also an example of the internal validation exercise. The system at NGH is run by an enthusiastic, hard working, forward looking team. It seems likely that other areas in the NGH would benefit from this department's expertise.

Recommendations

- 1) Urgent need for another person the same level as Louise as an additional member of the team who should be graded 6/7 on the NGH pay spine.
- 2) Consider using Inflex to generate EURO-score.
- 3) Issues raised by Mr Hopkinson need to be addressed (a) for internal clarification and (b) for general consumption.
- 4) As in previous site visit reports we suggest that consideration is given to written protocols and procedures, were a key person to become unavailable for a period of time.

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 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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