

Draft CCAD Data validation visit to Freeman Hospital, Newcastle

Visitors:

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Date of visit: Friday March 18th 2005

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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 Central Cardiac Audit Database (CCAD) project is robust because of a number of perceived shortcomings

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

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

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

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

2. Structure of Data Collection Systems

a) Personnel

The adult cardiac surgical database at the Freeman Hospital has been established and evolved by Mr Leslie Hamilton, Consultant Cardiac Surgeon, Mr Sion Barnard, Consultant Thoracic Surgeon and Mrs Sheila Jameson (SJ), Cardiothoracic Services Information Manager.

SJ is supervisor and manager of Cardiothoracic Services and ordinarily has a complement of 2 ½ whole time equivalent data clerks in her department. Currently one data clerk is on maternity leave. There is one vacant post and consequently the only support at present is Craig who visits from the Royal Victoria Infirmary two days a week. SJ has responsibility not only for maintenance of input to the SCTS database but also for MINAP, BCIS, PICANET and also the paediatric database for which a validation visit took place the day previously. SJ has her own dedicated office and separate to this there is space for 2 data clerks within their own office. Since a Head was appointed to the IT department at the Freeman Hospital the service has evolved and strengthened.

b) Software system and network

This is based upon the PATS database (Patient Administration and Tracking System) which was purchased in 1996. It is a paper based system and all data entry and enquiries are channelled through the office of SJ. Any request for data has to be signed by one of two signatories (Mr Barnard or Mr Hamilton) and SJ.

c) Overview of process

The PATS database form incorporates a structured clerking sheet to include the SCTS minimum dataset and elements of EuroSCORE are highlighted in red to ensure completion. Prior to surgery the pre-operative part of the form is completed by either Nurse Practitioner or SHO. Included within this is a calculated EuroSCORE which is derived from the anaesthetic sheet at the time of the patient operation.

At the time of operation the operative component is completed by the Registrar or Consultant and finally at the time of patient discharge the post-operative course is completed by the doctor dictating a discharge letter. Boxes exist for operation findings and also post-operative course in relation to either an automated operation note or automated discharge letters. The data form is an integral part of the patient record and is inserted into the notes and does not exist as a separate document. We formed the impression that completion of this form is strongly embedded within the Audit culture and members of the medical team were fully aware of their responsibilities.

The anaesthetic form has a stick-on label which enables for the patient EuroSCORE to be calculated by the Anaesthetist and this is used as the source of the EuroSCORE entered into the PATS record.

The PATS data is entered onto the form in the same format as it is entered onto the database – facilitating this entry and encourages entry of valid data. If the form is incomplete then missing data can easily be identified and returned to the Registrar for completion. At the completion of the patient admission, the form is signed by the responsible SpR. It is also signed by the Consultant, as an agreement that data is

correct and appropriate for further analysis and presentation. This also acts as a cross check for data input and validation. Once the patient has been discharged the notes are then sent to coding, then returned to the secretaries for discharge summary and then the complete form duly signed and sent to SJ for data entry. We understood that this process takes at the shortest 2 to 3 weeks but may take longer than this.

3. Data collection processes and cross checks

Separate to the PATS database form and data entry the following **activity** cross checks exist. The perfusion log is taken as the gold standard of activity with off-pump operations being entered as pump standby.

Firstly every month the Freeman and RVI perfusion register is photocopied and the list of patients is entered into PATS. This creates 3 separate categories of patient entries (a) patients entered (b) a missing patient list and (c) patients needing to be entered. This is undertaken as a manual process with patient entries ticked off accordingly.

Secondly, a six monthly cross check takes place between the operating theatre log and the PATS system again as a manual tick exercise.

Thirdly, every three months using the hospital HES data all revascularisation procedures, on an Excel spreadsheet are cross validated against the PATS entries using Access. This allows a further comparison check and we understood that this was improving incrementally the quality of HES data.

Fourthly and finally, using the BCIS database, there is a further cross check of interventional patients who go directly to theatre who are also cross checked against the PATS system. Intensive Care Unit records are not much used for checking activity nor is any ITU record used to record complications which are obtained from the patient notes. SJ does regularly use daily operation notes as a record of intent and compares these with the theatre book which is a record of cases completed.

Regarding **data quality** and risk profile regular cross checks are made between the EuroSCORE as calculated on the anaesthetic form and that generated by entry of the data on the PATS form, and any systematic discrepancy is fed back.

There is a system for internal validation. Every 3 months, 25 sets of notes are reviewed firstly to check the patient's notes versus the data entry form, secondly to cross check the patient's notes versus PATS and thirdly to cross check the form again PATS. This is the current system for checking data correctness. Discrepancies are fed back to individuals.

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

This is undertaken by a number of means. Firstly, every month there is a list of mortality from the Hospital Information Services (this is fed in from the Bereavement Office). This enables a first cross check of mortality. Secondly, SJ ensures that she always receives the notes at some stage. This appears to be strongly embedded within the Audit culture so that even if the patient is transferred to another part of the hospital and subsequently succumbs then the patient notes are still always destined

to return to the cardiac data office. Currently no routine check takes place for ONS tracked mortality.

5. Feedback mechanisms in place to validate data

The following processes are in place for feedback. There is a monthly half-day Audit Meeting which documents all mortality (not surgeon specific) all morbidity and then consists of topic presentations.

Every six months individual surgeons have VLAD curves calculated and presented for feedback. This is separate from routine audit.

Every year there is a departmental Grand Round where each surgeon is in receipt of individual records of activity, mortality and morbidity which is checked accordingly prior to discussion.

The recent Guardian public disclosure of surgeon specific outcomes was used as a further opportunity for individual cross checking of surgeons' activity and mortality.

The comment from Mr Hamilton was that "the consultants do now believe the data".

6. Review of data

The Freeman data for patients operated upon in the fiscal year 2003-2004 is as shown below .

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

Number of patients	Reported alive on database: dead on ONS	Reported dead on database: alive on ONS
1,161	None	5

Overall deaths check)	80 (all deaths at last ONS X
No. hospital recorded deaths	44
No. ONS recorded deaths	40

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

Variable	Freeman	'National'
Age	100	100
Sex	99.9	99.9
NHS number	99.6	82.6
Post code	100	99.8
Procedure	100	98.3
Surgeon identifier	100	83.8
Post-operative morbidity	100	60.4
Discharge status	100	97.3

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

Risk factor	Completeness Freeman 2003-4	Completeness national 2003-4
Age	100	100
Sex	100	100
PVD	100	84
Previous surgery	100	79
Renal failure	100	95
Active endocarditis	100	100
Iv Nitrates	100	80
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	100%	87%

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

Risk factor	Freeman incidence	National incidence
Mean age	Mean 65.7	Mean 64.7
Male	73.7	69.9
Mean EuroSCORE	4.5	4.4
Fair LV	18.9	24.5
Poor LV	4.8	6.2

Freeman data – Logic Checks

1. Fatal Errors = 0 (expected - records rejected at import)
2. Serious Errors = 9775/9817 (these values need checking but the records is imported)
3. Minor Errors = 9775

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

Minor errors

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

This review is based upon enquiry of CCAD Lotus notes. Of the 1,161 patients operated upon then no patients are reported alive on the database but dead on the ONS. The 5 patients reported dead on the database but alive on ONS were thought by SJ to be patients for whom no NHS number existed. The discrepancy between overall deaths and the number of hospital recorded deaths reflects the fact that the cross check will also record deaths following discharge from hospital.

Table 2 shows an excellent record of data completeness for core variables and the completeness of the EuroSCORE fields is 100% giving a 100% data quality index. This may reflect the paper based system and additional checks that take place prior to entry of data onto the database.

Table 4 shows the incidence of risk factors compared to pooled national data and shows that there is little evidence of gaming of Freeman entry as compared with the national incidence.

Regarding the logic checks these are shown but at present are not thought to be meaningful or contributing to the value of this review. Indeed, of the serious errors that have been validated by SJ 99% have no errors at all, and appear to arise through disparities in recorded CABG and valve entries.

Regarding system security this is only through SJ . Any access to data is through a form which is signed by SJ and either Mr Barnard or Mr Hamilton. Once the data is entered then it does not appear that it is possible for this to be altered retrospectively.

7. Further issues

A cross link between PAS and PATS requires a hospital number and there is a slow educational process taking place to emphasise the importance of the NHS number. Software does exist based on the postcode, date of birth, name, all of which can generate an NHS number.

The use of a paper based form does seem to enable a closer record of where mistakes of data entry are taking place and who is making them and allows you to pick up discrepancies in the form as you go along.

It was emphasised that the data clerk doesn't accept a PATS form unless it is signed by the surgeon and by the SpR responsible.

Regarding interaction with CCAD, SJ documented that she was aware that it was just starting to accept SCTS data entry. She commented that there was a good e-mail response but that Lotus notes was very slow. This specifically applies to exports which have to be done overnight. She commented that Andy Raine on the Help Desk was of great help.

8. Summary and Recommendations

In summary

- (a) The visit worked well. There was full and complete opportunity for understanding the Freeman Cardiac Surgery data system.
- (b) The culture of Audit and the systems in place seem robust but are currently under-manpower resourced and very much dependent on one individual. All three of us were impressed with the very positive atmosphere within the organisation. The Cardiac Surgical Database Report April 2003 to March 2004 is testament to the rigour of audit at the Freeman.
- (c) It was impressive to see just how much work was being undertaken by one individual in maintaining and progressing the cardiac surgical database. We would suggest that the current audit process and cycle is documented by protocol.
- (d) Although this system is paper based it does have the appeal of completeness and thoroughness, although all recognise that completeness of data returns doesn't equate to accuracy.

We have some recommendations

- (a) Consideration must be given to returning the Cardiac Audit Department to its full complement of personnel.
- (b) All the check and balance systems in place at Freeman seem to translate into a very robust system of ensuring that data is complete, and we would suggest that the current audit process is documented by protocol. The recruitment of personnel will enable these systems to be strengthened.
- (c) Consideration in time might be given to converting from a paper to electronic record although we have some reservation in making this recommendation when the system clearly works for the Freeman Hospital.
- (d) Consideration could be given to ONS cross checks for mortality as a further certainty regarding mortality.
- (e) Consideration should be given to giving all surgeons access to CCAD for feedback.
- (f) Although the system works well we wonder whether there may be something to be said for entering the data onto PATS earlier in the patient journey, namely at the time of operation rather than leaving the record to be entered after the discharge summary.

Appendix

Background and History of data collection and validation in Cardiac Surgery

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

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

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

Further important developments in this “data collection journey” have been firstly the introduction of an agreed data set for the national database, secondly the public disclosure of surgeon’s specific outcome data in New York, and thirdly the report of the public enquiry into children’s heart surgery at Bristol Royal Infirmary. All directed attention towards clinical governance, and, in December 1997 there was an extraordinary general meeting held at the Royal College of Surgeons.

This concluded that there was “ a need for quality assurance driven by the change in public perception of doctors and their accountability and the public’s wish for more detailed information about doctors’ activity”

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

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

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

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

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

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

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

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

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

- processes for collection and collation of data
- data analysis and feedback
- data submission to CCAD
- quality assurance of the above systems

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

References

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