National Audit of Percutaneous Coronary Interventions

Data import: Logical and Internal Validation rules

09 October 2014

There are a variety of issues that relate to the way data gets from a percutaneous coronary intervention (PCI) centre's database into the NICOR (National Institute for Cardiovascular Outcomes Research) servers.

The current NAPCI dataset can be downloaded as an excel spreadsheet from the NICOR website at:
http://www.ucl.ac.uk/nicor/audits/adultcardiacintervention/dataset

or

from the BCIS website at:
http://www.bcis.org.uk/pages/page_box_contents.asp?pageid=693&navcatid=25

The majority of units use a PCI database to collect the data, and then export it in the form of a csv file to NICOR. This document describes the import system for this csv file, the rules used to accept and reject data, the way each procedure is uniquely identified, and how data completeness are assessed.

Some Scottish centres use a previously established electronic data collection system, but based on a different dataset. The differences in datasets mean that a number of assumptions and translation rules have been set up and are documented below.

Best wishes

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Summary of changes

- If 2.02 Indication for intervention is 98. Unlisted or 99. Unknown, return fatal error (Change implemented on 22/04/2015).

Contents

English, Welsh, N. Ireland data import

Introduction

It is expected that the complete dataset from any unit will be uploaded on about a monthly basis to the NICOR servers. This csv file will therefore contain:

- Cases that have already been imported and have not been altered since last import
- Cases imported on the last occasion, but that have now been altered (either by having previously missing fields completed, or by having erroneous fields corrected.)
- Cases that are new, and have never uploaded before. (Some of these will be complete and some incomplete).

Pre-Import routines

- The csv file being imported is first backed up on the NICOR server. All csv submissions are backed up (as of Nov 2012).
- The importing computer's Regional Settings are checked (Control Panel) for US date format configuration of (mm/dd/yyyy). If the format is US, then a warning is generated and the import is aborted.
- There must be a local up-to-date NICOR Reference Values database on the user's PC (use Send/Receive Data – replication in the NICOR Portal).

Importing

Each record (consisting of 113 data fields for dataset versions 5.5.7 and **124** data fields for dataset version **5.6.2**) is then analysed and must satisfy certain criteria if it will be allowed to be imported into the NICOR database. These are the critical validation rules, and if the record fails, it is rejected and a report (the import log) listing reasons for failure is provided after import.

Before validation runs, all field values are checked against the dataset for illegal values inconsistent with the dataset, and any illegal values found are removed and logged in the import log.

Fatal errors (data rejected)

Mandatory data:

A **Fatal** error occurs (and the record is rejected) if:

- csv record does not have 113 fields per record
- No valid hospital code.
- No valid corresponding encryption key for hospital code.
- No Hospital Number (i.e. patient Case Record No.)
- No valid Procedure date / time & =>1980. (This must be date AND time as it uniquely identifies the procedure). 00:00 will be rejected as a time value as it is used as a default for some units when no time has been entered
- Clinical syndrome (2.01) data is missing (i.e. this field must contain the data 'stable' or 'ACS'. Unknown or blank fields will cause the record to be rejected.)
- If 2.02 Indication for intervention is 98. Unlisted or 99. Unknown, return fatal error
- Date of Birth field is missing or not a valid date format.

Appropriate Procedure:

Each record must either be a PCI procedure (defined as number of lesions or vessels attempted is >0), or be a diagnostic angiogram during which either an intravascular ultrasound study, an optical coherence tomography study or a fractional flow reserve study was performed. This is defined as below

A **Fatal** error occurs (and the record is rejected) if:

If all of the following are false (i.e. the record is accepted if any one of the following are true):

Diagnostic device (3.19) is 1
Diagnostic device (3.19) is 2
Diagnostic device (3.19) is 3
Diagnostic device (3.19) is 4
Diagnostic device (3.19) is 5
Diagnostic device (3.19) is 6
Number of lesion attempted (3.11) is =>1
Number of vessels attempted (3.10) is =>1

Inconsistent data:

A **Fatal** error also occurs (and the record is rejected) if:

If Clinical Syndrome (2.01) is '1. Stable',
Then Indication for Intervention (2.02) cannot be 3,4,5,6,7,8,11 or 12.

If Clinical Syndrome (2.01) is '1. Stable', and an Indication for Intervention (2.02) of 1, 2,9,10,98 or 99,
Then Procedure Urgency (2.03) must be '1. Elective.

If Clinical Syndrome is '2. Acute Coronary Syndrome',
Then Indication for Intervention (2.02) cannot be 1 or 2

If Clinical Syndrome is '2. Acute Coronary Syndrome', and Indication is 3-99, Then Procedure Urgency (2.03) cannot be '1. Elective.'

If Indication for Intervention (2.02) is 4,5,6,7, 8 or 12
Then Procedure Urgency (2.03) must be 3 emergency or 4 Salvage
If Clinical Syndrome is 2. ACS then 2.09 Admission Route must be 1. Direct to centre or 2. Inter-hospital transfer or 3 Already in hospital

Timing errors:

A **Fatal** error also occurs (and the record is rejected) if:

If Clinical Syndrome(2.01) is 2
Then reject record if 3.01 date/time of operation < date/time of arrival

Discharge date (4.04) cannot precede Date / Time of operation (3.01)

Records passing all these requirements are imported.

Unique record identification
A unique record is defined by:

1.01 Hospital Site Identifier
1.02 Local Patient Case Record Number
3.01 Date and time of PCI procedure

If during the importing of a record, an existing record has identical values for these 3 fields, it will be assumed to be the same record, and any updated or modified fields will be overwritten in the existing record.

If no record is found with identical values in these 3 fields, then it will be assumed to be a new record, and will be imported as such.

Therefore, when updating an existing record to fill in missing fields or correct errors, BE CAREFUL if you modify data in these 3 key fields. If you do, then after uploading the new csv file, you will need to delete the first (and now duplicated) record from NICOR.

Data Quality

Records passing the above tests will be imported, but further checks on quality are performed, and warnings generated as follows:

Serious Errors (but record saved)

Right most semi- colon is removed if present in a multi-value field item (PFL database). No warning logged. For all other poorly formatted multi-values, report as a warning, then fix formatting to "v1;v2;v3...n"

- Valid NHS Number (1.03)
- Date/time arrival at PCI hospital (5.26) cannot be before date/time arrival at first hospital (2.08)
- 3.11 Number of lesions attempted cannot be less than 3.12 number of chronic occlusions attempted
- 3.11 Number of lesions attempted cannot be less than 3.13 number of restenoses attempted
- 3.11 Number of lesions attempted cannot be less than number of 3.14 instent stenoses attempted
- 3.13 Number of restenoses attempted cannot be less than number of 3.14 instent stenoses attempted
- 3.15 Number of stents used cannot be less than 3.16 number of drug eluting stents used.
- 3.17 Drug(s) eluted by stents(s) cannot just be '0. None' (single value) when 3.16 the number of drug eluting stents used is greater than zero [it can contain a 0 among other values]

  (EXCEPTION: 3.16 can be 0 if 3.17 = 34 Mguard – which does not elute a drug)

- The Number of Lesions Successful (3.32) cannot be more than Number of Lesions Attempted (3.11)

- If Number of lesion attempted (3.11) is =>1 and Number of vessels attempted (3.10) is = 0 or blank
  "Inconsistent data entry: You state you have performed a PCI treating 1 or more lesions but that ZERO vessels have been treated – please enter the correct number of vessels treated"

- If Number of lesion attempted (3.11) is = 0 or blank and Number of vessels attempted (3.10) is >=1
  "Inconsistent data entry: You state you have performed a PCI treating 1 or more vessels but that ZERO lesions have been treated – please enter the correct number of lesions treated"

- If 'Vessels attempted' (3.09) contains at least one valid code (1 to 6) then If Number of lesion attempted (3.11) must be >=1 and Number of vessels attempted (3.10) must be >= 1
  "Inconsistent data entry: You state you have performed a PCI treating 1 or more vessels but you have entered ZERO for either number of lesions or number of vessels attempted. Please enter the correct values in these fields"

- If 'Vessels attempted' (3.09) is BLANK then Number of lesion attempted (3.11) must be 0 and Number of vessels attempted (3.10) must be 0 and Diagnostic device (3.19) must contain 1 (IVUS) 2 (Pressure wire) or 6 (OCT)
  "Inconsistent data entry: You have not stated which vessel you attempted. The vessels attempted field can only be blank in an interventional diagnostic only study."

- If 'Out of hospital arrest' (6.03) = 1. Yes"
  And 'Arterial blood gas on arrival in cath lab: pH' (6.06) is blank,
  "**Missing: 6.06 Arterial blood gas on arrival in cath lab (pH)** when '6.03 Out of hospital arrest' is 1. Yes. Please supply if available.

- If 'Out of hospital arrest' (6.03) = 1. Yes"
  and 'Arterial blood gas on arrival in cath lab: Lactate' (6.07) is blank
  "**Missing: 6.07 Arterial blood gas on arrival in cath lab: Lactate,** when '6.03 Out of hospital arrest' is 1. Yes. Please supply if available.

- If 'Out of hospital arrest' (6.03) = 1. Yes"
  and 'Arterial blood gas on arrival in cath lab: Base excess' (6.08) is blank
  "**Missing 6.08 Arterial blood gas on arrival in cath lab: Base excess** when '6.03 Out of hospital arrest' is 1. Yes. Please supply if available.

- PCI Hospital Outcome (4.01) cannot be '6. (death)' if the Status at discharge (4.03) is '0. alive', and vice versa (ie 'dead' must appear in either both or neither field)

- 5.19 Arterial complications cannot be 'none' if 4.01 PCI hospital outcome is '5. arterial complication'

- 4.01 PCI hospital outcome cannot be 'none' if 5.21 patient status during transfer to theatre is '1. external massage', '2. haemodynamically unstable' or '3. haemodynamically stable'

- 4.01 PCI Hospital Outcome must be 1 or 2 if Clinical syndrome = 1 and 4.02 Enzyme postop =2 (elevated >= 5x)

- If 5.25 (Left Main Stem Protected) = 1 (yes) then 2.14 previous CABG must be 1 (Yes), and 3.09 (Vessels attempted) must contain the value 2 (Lmain)

- Height must be saved in cm and must fall between 100cm and 244cm. Values outside this range are removed and logged (there is an auto-conversion to cm from numbers entered as metres which is logged with a warning)

- Weight must fall between 30kg and 190kg. Values outside this range are removed and logged

- Errors are also noted and logged if the following date/time fields have a value but are not in a valid date and time format or are before 01/01/1980:
  onset of symptoms (2.07)
  arrival first at hospital (2.08)
  arrival at PCI hospital (5.26)
  procedure date time (3.01)
  first balloon date time (3.26)
  discharge date (4.04) [date only field]

If a patient with an acute coronary syndrome is admitted directly to a PCI centre then the arrival time can be entered into either field 2.08 (arrival at first hospital) or field 5.26 (or arrival at PCI hospital). To be valid there should either be an entry in only one of these fields, or an entry in both - but if it is in both then it must be identical in both fields . Thus:

- In patients with both:
  2.01 Clinical Syndrome = option 2. Acute coronary syndrome
  AND
  2.09 admission route = option 1. Direct
  If data are present in both field 2.08 AND field 5.26 (arrival at first hospital, or arrival at PCI hospital) and are not identical this will generate a serious warning.

Minor errors (missing values)

Any value recorded as unknown or left blank is considered missing.

The number of data fields that can be counted as legitimately “blank” depends on:

- Whether or not a patient had emCABG
- Which of four data subsets they fall into:
  1. Stable Patients
  2. Unstable Patients no STEMI
  3. STEMI Patients
  4. Non interventional procedures (imaging or pressure assessment only)

Thus:

Items excluded from all data completeness calculations

- 2.20 LVEF

- 3.05 Operator2
- 3.06 Operator2Status
- 3.07 Operator3
- 3.08 Operator3Status
- 3.35 ProcedureComment
- 5.14 Research Id
- 5.33 Second Operator GMC Number
- 5.34 Third Operator GMC Number

Also

- Exclude 5.20 time to by-pass in data completeness calc if 5.21 patient status during transfer to theatre is 0
- Exclude 5.28 Referring hospital in data completeness if 2.09 Admission route (ACS only) is 1. Direct to cardiac centre or 3 Already in hospital.
- Exclude fields 6.04 to 6.11, if field 6.03 (out of hospital cardiac arrest) is 0.No

A non interventional procedure defined as 3.10 number of vessels attempted = 0 and 3.11 number of lesions attempted = 0 and 3.19 while diagnostic device field contains at least 1,2,3,4 or 6. Under these circumstances

- Exclude 3.09 Vessel treated (it can be blank)

If stable, exclude

- 2.04 Shock
- 2.07 SymptomOnset
- 2.08 Date/Time arrival at First hospital (ACS only)
- 2.09 AdmRoute
- 2.10 PresentingECG
- 2.11 RecentLysis
- 2.12 EnzymesRaised
- 2.28 IRAFlowPreOp
- 3.26 IRAOpen
- 3.34 IRAFlowPostOp
- 5.26 Date/Time arrival at PCI hospital (ACS only)
- 5.27 Date/time call for help
- 5.29 Date/time of ECG triggering PPCI pathway
- 5.30 Patient location at time of STEMI

If Unstable patient NO STEMI, exclude

- 2.05 AnginaClass
- 2.06 NYHAScore
- 2.28 IRAFlowPreOp
- 3.26 IRAOpen
- 3.34 IRAFlowPostOp
- 4.02 PostOpEnzymes
- 5.27 Date/time call for help
- 5.29 Date/time of ECG triggering PPCI pathway
- 5.30 Patient location at time of STEMI

If Unstable patient WITH STEMI exclude

- 2.05 AnginaClass
- 2.06 NYHAScore

- 4.02 PostOpEnzymes

Data Completeness of Key Fields- Minimum Data Standard

While the calculation above looks at the overall completeness of the record against the entire dataset, there are several key fields for which data completeness is extremely important. These are the fields involved with risk stratified outcome assessment and operator reported outcomes. It is a priority that units have more then 90% data completeness for these fields which are:

All PCI Procedures

- 1.03 NHS number
- 1.06 Date of Birth
- 1.07 Sex
- 2.03 Procedure urgency
- 2.04 Pre-procedure shock
- 2.16 Diabetes
- 3.09 Vessels treated
- 4.01 PCI hospital outcome
- 4.03 Discharge status
- 4.04 Discharge date
- 5.05 Medical History
- 5.06 Renal disease
- 5.35 Creatinine
- 2.18 Weight

PCI for all Types of Acute Coronary Syndrome

- 2.07 Date/Time symptom onset
- 5.27 Date/Time call for help
- 2.08 Date/Time arrival at first hospital
- 5.26 Date/Time Arrival at PCI Hospital

Primary PCI

- 5.30 Location of patient at STEMI onset
- 3.26 Date/time of first balloon inflation

Scottish data upload from Minerva

Some Scottish PCI records submitted to NICOR are sourced from the Scottish Cardiac Register and are submitted by the Co-ordinator, on behalf of the individual hospitals, in one file. A number of assumptions have been made which are critical in understanding the derivation of the data, and for the appropriate analysis of these data.

They are as follows:

Fields currently included in the Scottish return

1.01	Hospital Identifier
1.02	Local Patient Identifier (REP_MinervaID)
1.06	Birth Date
1.07	Sex
1.08	Patient Ethnic Group
2.01	Clinical Syndrome (PCI)
2.02	Indication for Intervention
2.03	Procedure Urgency
2.04	Cardiogenic shock (Pre-procedure)
2.05	CCS Angina Status (Pre-procedure; Stable only)
2.06	NYHA Dyspnoea Status (Pre-procedure; Stable only)
2.11	Recent Lysis (ACS only)
2.13	Previous MI
2.14	Previous CABG
2.15	Previous PCI
2.16	Diabetes
2.17	Height
2.18	Weight
2.19	LV Ejection Fraction Category
2.21	Number grafts present (Pre-operation)
2.22	Number grafts patent (Pre-operation)
3.01	Date and time of operation
3.09	Vessels attempted (**CCAD territories)**
3.10	Number of vessels attempted
3.11	Number of lesions attempted
3.12	Number of Chronic Occlusions attempted
3.13	Number Restenoses attempted
3.14	Number Instent stenoses attempted
3.15	Number Stents used
3.16	Number Drug-eluting stents used
3.17	Drug(s) eluted by stent(s)
3.18	GP IIb/IIIa drug(s) used during procedure
3.24	Circulatory support
3.25	Arterial management
3.32	Number Lesions Successful
4.01	PCI Hospital Outcome
4.03	Status at discharge
4.04	Discharge Date
5.01	Local Procedure Identifier
5.02	Cholesterol
5.03	Smoking status

5.04	Family history of CAD
5.05	Medical history
5.06	History of renal disease
5.07	Ventilated PreOp
5.09	ECG ischaemia
5.11	Follow on (Adhoc) procedure
5.15	Arterial access

Fields excluded from the Scottish return

1.03	NHS Number (under review regarding Data Protection compliance)
1.04	Patient Name (Surname)
1.05	Patient Name (Forename)
1.09	Administrative Category
1.10	Postcode Of Usual Address
2.07	Date/time of symptom onset (PCI; ACS only)
2.08	Date/Time arrival at hospital (ACS only)
2.09	Admission route (ACS only)
2.10	Presenting ECG (ACS only)
2.12	Cardiac Enzymes/Markers Raised
2.20	LV Ejection Fraction
2.23	Left Main Stem Stenosis (Pre-PCI)
2.24	LAD Proximal (Pre-PCI
2.25	LAD Other Stenosis (Pre-PCI)
2.26	RCA Stenosis (Pre-PCI)
2.27	Cx Stenosis (Pre-PCI)
2.28	Flow in IRA PreOp (ACS only)
3.02	Consultant Responsible for Procedure (under review regarding Data Protection compliance)
3.03	Primary Operator
3.04	Primary Operator status
3.05	Second Operator
3.06	Second Operator status
3.07	Third Operator
3.08	Third Operator status
3.19	Diagnostic device(s) used during procedure
3.20	Procedural device(s) used
3.21	Athero-thrombus removal device(s) used
3.22	Brachytherapy device(s) used
3.23	Emboli protection device(s) used
3.26	Date/Time of first balloon inflation (PCI)
3.27	Left Main Stem Stenosis (Post PCI)
3.28	LAD Proximal Stenosis (Post PCI)
3.29	LAD Other Stenosis (Post PCI)
3.30	RCA Stenosis (PCI)
3.31	Cx Stenosis (PCI)
3.33	Number coronary grafts patent PostOp
3.34	Flow in IRA PostOp (ACS)
3.35	Operation report/comment
3.36	Device failure
4.02	Enzymes PostOp
5.08	Q Wave on ECG

5.10	Drug therapy PreOp
5.12	Training procedure
5.13	Research procedure
5.14	Research title
5.16	Largest balloon/stent used
5.17	Longest stented / treated segment
5.18	Procedural Complication
5.19	Arterial Complications
5.20	Time to bypass
5.21	Patient status during transfer to theatre
5.22	Why no IIb/IIIA during procedure
5.23	Indication for stent
5.24	Surgical cover
5.25	Left Main Stem Protected

This means that several of the validation checks for the English data will not apply to the Scottish upload, specifically here are the rules and the problem in purple below each:

A **Fatal** error therefore also occurs (and the record is rejected) if all of the following are false (i.e. the record is accepted if any one of the following are true):

Diagnostic device (3.19) is 1 (IVUS)
Diagnostic device (3.19) is 2 (Pressure wire)
Number of lesion attempted (3.11) is =>1
Number of vessels attempted (3.10) is =>1

The Scottish Register does not currently return values to field 3.19

2. If Clinical Syndrome(2.01) is 2
Then reject record if 3.01 date/time of operation < date/time of arrival

The Scottish Register does not currently return values to field 2.08

3. Rejection also occurs if the following date/time fields have a value but are not in a valid date and time format and is not after 01/01/1980:

onset of symptoms (2.07)
arrival first at hospital (2.08)
procedure date time (3.01)
first balloon date time (3.26)
discharge date (4.04) [date only field]

The Scottish Register does not currently return values to fields 2.07, 2.08 or 3.26

4. Warnings (record saved)
Arterial complications cannot be 'none' if PCI hospital outcome is '5. arterial complication'

The Scottish Register does not currently return values to field 5.19

In addition any measurements of data completeness will need to be defined differently.

Agreed data correlations

Indication for intervention – 2.02

Values not collected.

2. Stable – coronary /LV anatomy

10. Hybrid procedure
11. Acute or subacute PCI thrombosis

Procedure Urgency – 2.03

Values not collected.
4. Salvage

Recent Lysis (ACS only) – 2.11

“Required but contraindicated” coded to CCAD “0. No”

Patent Grafts – 2.22

Grafts will be considered 'patent' if not recording 'occluded' or 'sub-total occlusion'

PCI Hospital Outcome - 4.01

Complications directly collected (“Register text”)	
1. Q wave MI	12. Re-infarction (ACS only)
2. Non-Q wave MI	13. Blood transfusion (“Major bleed”)
3 Elective CABG	14. Renal faiure/dialysis
4 Emergency CABG	15. GI bleed
5. Arterial complication (“Peripheral vessel”)	16. Tamponade
6. Death	17. Platelet transfusion
9. TIA/RIND	
10. Re-intervention PCI	“Unknown” is returned as Null
11. Re-cath (No PCI)	
Complication texts returned as “99.Unlisted”	
"CVA"	"Complete heart block"
"Abrupt closure"	"bradycardia"
"Re-Intervention PTCA - Different Lesion"	"Minor bleed"
"dissection"	"Anaphylactic"
"perforation"	"contrast allergy"
"Arrest -"	"Equipment lost in body"
"arrhythmia"	"Other - See comments"
Complications not specified	
7.CVA Embolic	8.CVA Bleed

History of renal disease – 5.06

Can not specify acute or chronic.
“4.Chronic renal failure” includes CAPD, Filtration and Haemodialysis

Medical history – 5.05

Values not collected
6. Valvular heart disease
7. Non coronary cardiac surgery

ECG ischaemia – 5.09

1. On resting ECG
"Yes - ECG - Changes at rest"
"Yes - ECG - Post MI"
2. On stress ECG

"Yes - ECG - Changes on Holter"
"Yes - ETT - Positive ECG"
"Yes - ETT - Positive symptoms"
"Yes - ETT - Positive symptoms and ECG change"
"Yes - Other"

3. On perfusion scan

"Yes - Echo - Positive stress echo"
"Yes - Nuclear - Positive perfusion scan"
"Yes - Nuclear - Positive wall motion study"