

Australian & New Zealand Collaborative Perfusion Registry (ANZCPR) Users Guide

This document is split into a user's guide – the basics that every user will need to know – and an administrator's guide, which covers details on how to configure and manage the database, as well as explanations on how the database is structured.

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Introduction

The ANZCPR is designed to meet the data collection requirements of the collaboration, that is, to provide a de-identified prospective data set on cardiac surgical procedures performed in centres throughout Australia and New Zealand. Patient identifying data is collected at the local site only. Once the data is exported from the database, the identifying information is removed and each record is assigned a unique identity for the master dataset.

Upon receiving the database, the first thing that you will need to do is to appoint a site administrator. The database administrator should refer to the administrator's guide (section 2.0) for instructions on how to install and configure the database. Once the database has been installed and configured, please refer to the user's guide.

The database is password protected, so you must log in to access the data entry forms.

Currently the database can be integrated with the Data Management System, JOCAP, and Connect software.

Procedure types: Currently the procedures in the dataset are grouped as isolated CABG, isolated AVR, isolated MVR or MV repair, combined AVR + CABG, or combined MVR + CABG or Other. For all cardiac surgical procedures however, the data should be entered into the database so that we can accurately track and define the case-mix for our surgical population.

1. User's Guide

1.1 The front page

The front page refers to the form that is opened after logging in to the database. This page has the options of either: creating a new record, searching for existing records, or accessing the 'data dictionary' to search for data field definitions or code values. The data dictionary is useful when analysing data.

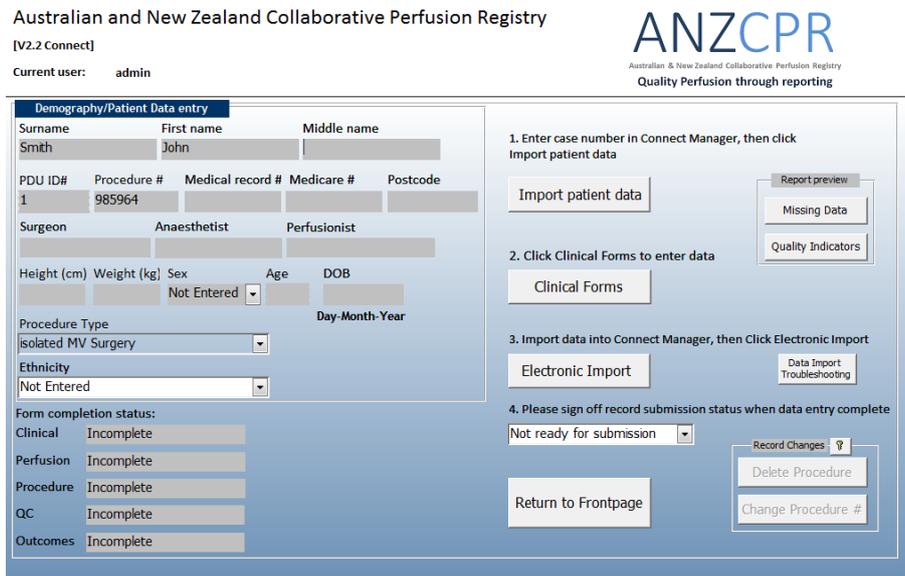
1.2 Creating a new record and entering demographic data

1. Click the 'Create New Record' button



Enter your hospital procedure or case number (**Procnum**), and the Procedure type. Press 'OK'.

2. Enter the demographic data: Click the 'Import patient data' button to transfer the demographic data (grey fields). Enter the ethnicity manually.



To enter clinical data, click the 'Clinical Forms' button.

1.3 Clinical data entry

The clinical data entry forms are divided into the following categories: **Clinical**, **Perfusion**, **Procedure**, and **Outcomes**. To enter the clinical forms section click **'Clinical Forms'** button. The following screen appears, and is the data entry form for Clinical Data.

Select each form by clicking on the list on the left hand side of the main data entry form.

Hint: a quick way to enter the data is to tab from field to field, and type 'N' to enter no or 'Y' for yes.

Definitions for each field can be accessed by clicking on the '?' button next to the field.

Default values will be populated as per your preferences set in the admin console (by the administrator). Data entry shortcuts can be achieved by clicking the corresponding button where applicable.

For example by clicking **'No Valve'** on the **'other/combined'** Clinical Form will result in "no" being entered into all fields for that table.

Once data entry is complete for a particular form, the form completion status can be changed to **'Completed'**. This will initiate a data checking process to let the user know if there are any fields missing data. To continue, the user can opt to return to the form and enter the missing data, or, if the data cannot be obtained, the status will be displayed as **'Completed – missing data'**. The clinical form completion status field on the data entry master form will be updated automatically. Once all the clinical forms are completed the record can be signed off as completed.

1.4 The forms:

Clinical:

See above

Perfusion:

Remember: To use the scroll bar on the right hand side of the form to see all of the fields!

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Quality Perfusion through reporting

985964 Perfusion Please note shaded fields can be generated from Connect data. Place cursor in field and click ? button to display field definitions Current user: admin 985964

Date of Admission ? Date of Surgery ? Enter current date Theatre entry ? Enter current time

Perfusion circuit data

Oxygenator ? Coating ?

Arterial Filter ? Coating type - circuit ?

Reservoir type ? Coating type - oxygenator Coating ? Circuit static priming volume ?

Arterial Pump type ? Arterial pulsatility ? Circuit total priming volume ?

Perfusion monitoring data

Arterial Blood Gas ? rCRMO2 (Invos) ?

Venous Saturation ? BIS ?

Capnography ? Other cerebral monitor ?

Cannulation data

Aorta Ascending Transverse Descending No ?

Femoral artery ? Axillary artery ? Innominate artery ?

Atrial Multiple stage Bivacaval Single stage No ?

Other venous Femoral IVC+SVC direct IVC direct SVC direct ?

VAVD ? CO2 insufflation ?

Perfusion general data

Return to Demography/ Patient Data Entry

Procedure:

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985964 Procedure Place cursor in field and click ? button to display field definitions Current user: admin 985964

Procedure Type ?

CABG anastomosis data

CABG ?

Left internal mammary graft ? Radial artery graft ? Gastroeploic artery graft ?

Number Left internal mammary distal anastomoses ? Number radial artery distal anastomoses ? Number gastroeploic artery distal anastomoses ?

Right internal mammary graft ? Number of vein graft conduits ?

Number right internal mammary distal anastomoses ? Number of distal anastomoses (vein grafts) ?

Valve surgical/implant data

Aortic valve prosthesis ? Pulmonary valve prosthesis ?

Mitral valve prosthesis ? Tricuspid valve prosthesis ?

Mitral valve repair ? Tricuspid valve repair ?

Aortic occlusion/ Surgical access

Method of aortic occlusion ? Minimally invasive incision ?

Number of X clamp applications ?

Return to Demography/ Patient Data Entry

Outcomes:

985964 **Outcomes** Place cursor in field and click ? button to display field definitions **Current user: admin** 985964

ICU data

Calculated ventilation time

Enter theatre out./ICU in time (date/time): Enter current time

Enter Extubation time (date/time):

Ventilation time (hrs) ?

Difference Hours

Calculated ICU stay

Enter discharge from ICU (date/time):

ICU stay duration (hrs) ?

Readmission to ICU ?

Reason for readmission ?

Return to theatre ?

4hr blood loss (ml): ? Cryoprecipitate units: ?

RBC units: ? Platelet units: ? (# of units, not pooled bags)

FFP units: ? Factor7 dose (ug): ? Prothrombinex ?

Morbidity/Mortality

Stroke	<input type="text" value="Not Entered"/> ?	Insertion of IABP	<input type="text" value="Not Entered"/> ?	Septicaemia	<input type="text" value="Not Entered"/> ?
Seizures	<input type="text" value="Not Entered"/> ?	ECMO	<input type="text" value="Not Entered"/> ?	Deep sternal infection	<input type="text" value="Not Entered"/> ?
New Coma	<input type="text" value="Not Entered"/> ?	VAD	<input type="text" value="Not Entered"/> ?	Pneumonia	<input type="text" value="Not Entered"/> ?

Perfusion/QC: This form is completed automatically via electronic data transfer. The data should be checked however and may be edited where appropriate. This is relevant when artefacts may be present, for example nasopharyngeal probe removal during CPB may affect the minimum temperature recorded.

985964 **Perfusion/QC** Please note shaded fields are generated from DMS data. Blank fields are = 0 All data is displayed as cumulative data unless otherwise indicated. **Current user: admin** 985964

Perfusion quality indicator data

influencing factors for benchmark quality indicators: ?

pCO2 <35 or >45 mmHg

pO2 <100 mmHg

Hb <6 g/dl

Hb <7 g/dl

CI <1.6 l/min/m2 > 5 minutes

MAP <40 mmHg > 5 minutes

Ven sat < 60% > 5 minutes

Art temp >37

Surgeon low flow request

Blood glucose <4 or >10mmol

CPB blood gases performed CPB ACT's performed

CPB intermittent blood gas data

Min pH

Max pH

Min pCO2

Max pCO2

Min pO2

Max pO2

Min Lactate

Max Lactate

Min Hb

Max Hb

Min Glucose

Max Glucose

CPB continuous blood gas data

Time pCO2 < 35 mmHg

Please describe other factors that led to noncompliance with any of the quality indicators: ?

Check this box if this procedure should be alerted for safety or quality improvement review

Form completion status

Quality Indicator Report

1.4 Miscellaneous functionality

Changing a procedure number can be performed using the 'Change Procedure #' button.

Deleting a procedure requires the administrator to login to the database to access the 'Delete Procedure' button.

Australian and New Zealand Collaborative Perfusion Registry
[V2.2 Connect]
Current user: admin

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Demography/Patient Data entry

Surname: Smith, First name: John, Middle name: []

PDU ID#: 1, Procedure #: 985964, Medical record #: [], Medicare #: [], Postcode: []

Surgeon: [], Anaesthetist: [], Perfusionist: []

Height (cm): [], Weight (kg): [], Sex: Not Entered, Age: [], DOB: []

Procedure Type: isolated MV Surgery

Ethnicity: Not Entered

Form completion status:
Clinical: Incomplete
Perfusion: Incomplete
Procedure: Incomplete
QC: Incomplete
Outcomes: Incomplete

1. Enter case number in Connect Manager, then click Import patient data
2. Click Clinical Forms to enter data
3. Import data into Connect Manager, then Click Electronic Import
4. Please sign off record submission status when data entry complete

Buttons: Import patient data, Clinical Forms, Electronic Import, Return to Frontpage, Report preview, Missing Data, Quality Indicators, Data Import Troubleshooting, Record Changes (circled), Delete Procedure, Change Procedure #

Ventilation time and ICU stay are calculated automatically on the **Outcomes** form, and the exit from theatre time can be entered automatically by clicking the button next to this field when the patient is leaving theatre. The ventilation time and ICU stay are calculated when the extubation time or ICU discharge time is entered.

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985964
Outcomes
Place cursor in field and click ? button to display field definitions
Current user: admin
985964

Clinical Data entry Forms
Perfusion
Clinical
Procedure
Outcomes
Perfusion/QC
Local Interface
Incident Report

ICU data

Calculated ventilation time
Enter theatre out /ICU in time (date/time): 28/01/2016 12:33
Enter Extubation time (date/time): 29/01/2016 08:45
Difference: 20.2 Hours
Ventilation time (hrs): 20

Calculated ICU stay
Enter discharge from ICU (date/time): 01/02/2016 15:30
Difference: 98.9 Hours
ICU stay duration (hrs): 99
Readmission to ICU: No
Reason for readmission: []
Return to theatre: No

1.5 Importing data from the Connect software

Once the record has been imported into Connect Manager, the data can be imported into the ANZCPR. This should be performed on the same computer that the Connect Manager software is installed. If the ANZCPR is installed on the touchscreen PC, exit the clinical forms before running the transfer, to avoid a conflict that may occur if data is being entered for a patient at the same time that data is being transferred from Connect.

Click the electronic import button. Don't interrupt it while it is running. At the completion of the import, a message box will appear with the message 'finished transfer'. The data should then be visible on the perfusion data entry form in the shaded fields.

1.6 Searching for existing records

Click the 'view existing records' button on the front page to display the patient/procedure list, sorted in descending order of procedure number. This is intended to let you see the most recent patients. You may also choose to sort according to completion status, to track records that require additional data entry.

View Patient List Exit to Frontpage

To search for a patient, type the Surname or Procedure number below
To select a patient, double click on the corresponding line

Procnum Surname: Sort by completion

Procnum	Surname	DOB	Surg date	Procedure	Complete
1234			14/01/2009	Isolated CABG	No

1.7 Data Dictionary

Click the 'Open Data Dictionary' button to search for data field definitions or code values. It also references the related ANZSCTS database data fields. To search for the data for a field, place the cursor in that field and click the binoculars icon. For example the cursor is on Variable Field, click binoculars then type in the name of the variable you wish to search for.

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Current user: admin

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Data Dictionary

[Return to Frontpage](#)

Variable #: 2026

Variable: Recent MI

Variable name: Mirecent

Table Name: Clinical

Validation rule:

Definition: Myocardial infarction within 90 days. Specify if < 21 days or between 21-90 days.

ASCTS Definition: Time period between the last documented myocardial infarction and surgery.

PDU Data Code: 1;"Yes <90 days";2;"Yes <21 days";0;"No";-99;"Not Entered"

ASCTS codes: 1 = <=6hrs, 2 = >6hrs +<24hrs, 3 = 1-7 days, 4 = 8-21 days, 5 = >21 days

2. Administrator's guide

2.1 Introduction/Overview

The ANZCPR database consists of three separate .mdb database files:

- PDUServer.mdb – the front-end, which contains the forms, reports and the queries used by forms; the tables in PDUTables.mdb are linked to this database file.
- PDUTables.mdb – contains all tables containing clinical data.
- PDUTransfer.mdb – contains all tables, queries and modules needed for importing patients and transferring electronic data – although this database does contain tables, they all store data temporarily only – it also contains linked in tables from PDUTables.mdb

2.2 Installation and configuration

When you receive the database files, follow these steps to get the database up and running. Each site needs to have a 2-3 letter abbreviation code and a numeric code. If this has not been determined, please contact Richard Newland.

1. Create a new folder called ANZCPR, on the C drive (this can be any drive you wish to use but C will be used in this example).
(To create a new folder, open windows explorer, go into 'My Computer', click on the C drive to select it, then go into File>New>Folder.)
Copy the three database files – PDUServer, PDUtransfer and PDUtables – into this folder.
2. Create a folder in the ANZCPR folder for storing the data export files (to be used for data harvesting). Name this new folder ANZCPR Transfer.
3. Refer to separate documentation; Step 1 – To configure data sources (ODBC) connection
4. Refer to separate documentation; Step 2 – To set permissions using SQL server management studio.
5. Open the database PDUServer. If you are prompted by a security warning message click open. Click OK to browse for the file PDUtables. Locate the file PDUtables.mdb in the PDUDB folder, select the file and click 'open'. This will link in the tables from PDUtables. A message will appear telling you all tables were re-connected successfully.
6. Click f11 to open the navigation pane, and go to tables. Open the table Hosp_ID and enter the abbreviation for your hospital (2 or 3 letter abbreviation).
7. Close the table and open the table Config. Enter the hospital numeric code in the Hosp field. Close the server database.
8. Open the database PDUTransfer. If you are prompted by a security warning message click open.
9. Select Database utilities / linked table manager and select all Connect tables (with the globe icon). Select 'always prompt for new location', Click Ok and select data source/ Connect.
10. Click on forms and open the form called 'RelinkTables' and press the button. Locate the file PDUtables.mdb in the ANZCPR folder, select the file and click 'open'. Again, this will create a link to the tables database. A message will appear telling you all tables were re-connected successfully.
11. Create an icon on the desktop by right clicking on the desktop and select new/shortcut. Click browse and select the file PDUServer.mdb.
12. Double click the icon to log in as an administrator onto the database PDUServer. Username and password are both 'admin'
13. You are now on the front page of the database.

Welcome to the Australian and New Zealand Collaborative Perfusion Registry.

The mission of the collaboration is to promote the reporting and understanding of the effect of cardiopulmonary bypass on patient outcomes through encouraging evidence based practices, quality assurance, quality improvement and research.

The strength of the collaborative data set will be in its availability to all members that will allow them to utilise the data for appropriate research initiatives, however the mechanism for the creation of the data set relies on your participation in the collection of this data. Thankyou for your support.

The screenshot shows the main interface of the ANZCPR system. It is divided into two main sections: 'Registry Options' on the left and 'Admin functions' on the right. The 'Registry Options' section has a blue header and contains three rows of text with corresponding buttons: 'Enter a new patient into the registry' with a 'Create New Record' button, 'View or enter data in existing records' with a 'View Existing Records' button, and 'View data definitions form' with an 'Open Data Dictionary' button. There is also a separate 'Exit database' button. The 'Admin functions' section has a dark blue header and a list of ten buttons: 'Admin Console', 'Report Console', 'QC data output', 'Export Database', 'Update database version', 'Completion/Audit Report', 'ANZSCTS data import', 'Institutional reports', and 'Reset transfer database'.

On the RHS is the admin console

A close-up view of the 'Admin functions' menu. It features a dark blue header with the text 'Admin functions'. Below the header is a vertical stack of ten light blue buttons with dark blue text: 'Admin Console', 'Report Console', 'QC data output', 'Export Database', 'Update database version', 'Completion/Audit Report', 'ANZSCTS data import', 'Institutional reports', and 'Reset transfer database'.

Under **Admin functions**, go into the **Admin Console**

Administrative Console

The screenshot displays the Administrative Console interface with three main sections:

- Item locations:** A list of four items with their full paths:
 - Item: Data export location
M:\Cardiac Services\Cardiac Surgery\Data Management\Development
 - Item: TablesDb
M:\Cardiac Services\Cardiac Surgery\Data Management\Development
 - Item: TransferDb
M:\Cardiac Services\Cardiac Surgery\Data Management\Development
 - Item: USBDrive
- Users:** A section with an "Add New User" button and a list of users. The "admin" user is listed with "Reset password" and "Delete User" buttons.
- Default values configuration:** A list of configuration options with dropdown menus:
 - Data collection interval: 20 seconds
 - Myocardial protection: Antegrade cardioplegia
 - Cardioplegia type: Hyperkalaemic blood
 - Induction temperature: Tepid: 32-35 degrees celcius
 - Maintenance temperature: Tepid: 32-35 degrees celcius
 - Hot Shot: No
 - pH strategy alph/ph/other: alpha stat
 - Arterial Filter: 38-40um
 - Reservoir open / closed: open
 - Arterial Pump roller/centrifugal: roller
 - Coating (total partial none): partial
 - Coating type - circuit: Smart
 - Coating type - oxygenator: X Coating
 - ABG continuous/ intermittent: continuous
 - Hemofilter: None
 - Anticoagulant: Heparin
 - Anticoagulant administration: Bolus

A "Close Admin Console" button is located in the top right corner of the interface.

14. Set the item locations:

- Data export location is the full path of the directory you created in step 2 – include a backslash at the end (e.g., C:\ANZCPR)
- TransferDb is the full path the PDUTransfer.mdb file (e.g., D:\ \ANZCPR\PDUTransfer.mdb)
- TablesDb is the full path of the PDUTables.mdb file (eg, D:\ \ANZCPR \PDUTables.mdb)
- USBdrive is the drive name of the USB device (often E:\ or F:\ or similar)

It is very important to follow the above instructions correctly and ensure that all folder paths end with a backslash (except TransferDb and TablesDb which include the name of the file)

15. Add usernames for all the users who will need access to this database. New users will be prompted to set a password upon their first login.

16. It is advisable to change the default password for user 'admin'. Click reset password, confirm that you want to reset it. You will set a new password next time you log in as 'admin', so it is important that as soon as you have reset the password, you exit the database and log back on.

17. Enter all usernames, and when each user enters the database for the first time they will be able to set their personal password.

18. Enter the default values for the perfusion form fields if applicable.

19. Exit the database. It is now ready for use.

2.3 Deleting records

A record can be deleted by clicking the delete procedure button in the admin functions box. A message box is displayed in order to confirm the deletion of a record. This option is only available when logged in as user 'admin'.

2.4 Exporting the database (data harvesting)

The database can be exported in the form of text files by clicking the export database button. They will be saved to the folder specified in the item locations table (see 2.2, steps 2 and 7). If existing exported files are there, you must confirm that you want to overwrite them.

Data harvests will occur twice yearly; April (data included will be up until the end of February) & October (data included will be up until the end of August).

To export the data:

- Log in to the database as the administrator.
- Check that the data export location is defined in the admin console.
- Check that the data export location directory is empty.
- Click 'Export Database' on the front page.

To upload the files to the ANZCPR website, the process to upload the data is as follows;

- Each site has specific login details, so let Richard Newland know if you have forgotten or not been provided your login username/password.
- Go to the website <http://www.pducollaboration.com/default.aspx>
- Go to Managers/Your hospital
- Go to Data
- Click upload and select the text files
- Keep adding until you have uploaded all the PDU table files that have been exported.

2.5 Editing the database

This is not something you should need to do. If changes are necessary, a new database will be sent out to you. Queries can be created in the PDU server database, however whenever a new version of the database is sent out, it will be necessary to import the created queries into the new version. Alternatively, a separate query database can be developed for the purpose of storing site specific queries.

2.6 Backing up the database

Backing up the database is easily done by copying the database file PDUTables.mdb. This should be performed daily, and ideally there should be two backups in alternate locations, i.e., backup the database into one location one day, then the alternate location the following day. Copies of the server and transfer databases should be created initially, but do not require routine backups.

2.7 Electronic perfusion data entry requirements

In order to make calculations on the data from electronic perfusion software, and to transfer certain data fields, some conventions are required.

Comments:

- The word 'Rewarm' must be included as a comment during the procedure. It can also be entered as 'Rewarm – 37', etc., as long as 'rewarm' is included in the comment.
- The comment 'bypass start and bypass stop' must be used.
- The comment '1st ACT post hep' must be used to define the 1st ACT measurement after the anticoagulant is administered.
- The comment 'Heparin' and quantity must be entered to define heparin given during CPB.
- The comment 'Surgeon low flow' can be used to detect a low flow request for QC purposes.
- The comment 'Partial bypass' can be used to remove the period of partial bypass from evaluation of cardiac index for QC purposes.

Blood gas data:

- Blood gas, haemoglobin and glucose values transferred from an external blood machine (intermittent sampling) are used for quality indicator and preoperative results.
- Continuous data is also used for quantification of DO₂ if the Spectrum M4 is utilised. This requires collection of arterial flow data from the M4.

ACT data:

- ACT values should be entered in the coagulation table.

Making corrections to comments:

- Comments cannot be deleted in Connect, however they can be ignored by the ANZCPR transfer process by editing the comment, and entering the letter E (for error) in the edit field for the comment. For example, if the bypass timer button on the heart lung machine was accidentally started too early, the comment 'Bypass start' could be edited to have an 'E' as a comment to this entry. In the record, there would be 2 bypass start comments, but the first one would be ignored in the data transfer into ANZCPR.

2.8 Quality indicator data output

Perfusion quality indicator data can be exported in excel format. The aim of this feature is so that the data may be used as part of a continuous quality improvement program.

2.9 Relinking the Connect tables in the PDU Transfer database

When an update to the PDU Transfer database is made, it will be necessary to relink the tables in the Transfer database to both the PDU Tables and to the Connect tables. To relink the PDU tables, simply click the button once the PDU transfer database is opened. To relink the Connect tables;

- click F11 to access the database window and click on the tables section.
- at the top of the window select tools, and then database utilities / linked table manager.
- tick all of the Connect tables (the ones with a globe icon) and tick Always prompt for new location.
- click OK
- select machine data source and select the link to the Connect database.
- click OK

3.0 ANZSCTS data import

Sites that are contributing data to the ANZSCTS database can import clinical and outcomes data that has been submitted to ANZSCTS via the ANZSCTS data interface accessed through the admin console. A request to obtain the data in MS Access format must be made to the ANZSCTS site manager at your institution. To transfer the data, the ANZSCTStransfer database (supplied by PDUC) is also required. This database must be linked to the PDUtables database in the same manner as the PDUtransfer database.

Data may then be transferred according to the instruction on the ANZSCTS data interface form as shown below;

ANZSCTS Outcome Data Import

Step 1: Check outcome data completion status and note date of surgery range for data to be transferred

Step 2: Submit request to ANZSCTS site manager at your institution to download ASCTS data for date of surgery range

Step 3: Enter downloaded database location and filename

Step 4: Enter ANZSCTS transfer database location and filename

Step 4: Transfer downloaded outcomes data

3.1 Institutional data reporting

Data output for institutional reporting can be done via the Institutional reports interface form accessed via the admin console. (Note: This requires MS Office 2007 version.)

Enter the location and filenames of the files 'UnitAuditData.xls' and UnitAudit.ppt into the field on the form as shown in the example below (using your local locations).

Once the data has been exported to the excel file, the powerpoint links initially need to be created manually in the powerpoint file. Once this process is complete the links will then be updated automatically (when prompted) when the file is opened.

Institutional Data Reporting

1. Enter date range:

Date from:

Date to:

2. Enter output excel file location:

3. Click to export data to excel file:

4. Enter powerpoint presentation file location:

5. Open powerpoint presentation to update linked data:

3.2 Data completeness and accuracy

It is the responsibility of all users of the database to ensure the data collected is as complete and accurate as possible, however it is the responsibility of the Data Manager to identify and correct, where possible, missing or incorrect data. As part of the ongoing plan to improve data completeness and accuracy, the database contains various inbuilt functionality to assist with this process.

Currently, this should be achieved by;

- Identifying incomplete records by sorting the patient list by completion status
- Generating data completion reports - missing data and cases with outliers can be identified using the report generators in excel format (located in the admin console – completion reports)
- Auditing: Self audit can be performed by clicking the 'Generate audit data' button on the completion reports page. This will generate a spreadsheet containing 10 records selected at random in order to compare a number of database fields against the source data records.

Reporting of data will occur at least annually, and will comprise reports summarising the total data in the registry, the annual data collected and the individual site data, and will report outcome and quality indicator data.

Unexpected findings (outliers, unexplained variance) will be reported to sites as soon as identified in the report generation process.

3.3 Contact Details

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