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## 1.0 Purpose

This document outlines the standard procedures that ANZDATA undertakes to ensure the quality of data that is collected, published and provided to external parties. It serves to orientate new staff to expected practices within the organization and documents the standard quality assurance practices performed by the registry in line with the data governance principles outlined in document 2.2.

Components of this quality assurance process include measures to ensure:

- Completeness of survey population
- Completeness and timeliness of survey return by contributors
- Accuracy of data collected from renal units
- Completeness, timeliness and accuracy of data received from donate life
- Completeness, timeliness and accuracy of data received for the Living Donor Registry
- Completeness, timeliness and accuracy of data received from NOMS, NZBS and Baxter Healthcare.
- Timeliness and accuracy of reports
- Timeliness and accuracy of data supplied to other registries
- Timeliness and accuracy of data supplied to external parties through data requests process

## 2. Policy Details

### 2.1. Completeness of survey population

- ANZDATA asks all Australian and New Zealand renal units to report all new dialysis and transplant patients to the registry
- The Registry Manager regularly contacts and attends renal units to provide ongoing education and reminders about ANZDATA data collection
- Tissue Typing Centres provide a list of patients on the waiting list for a kidney transplant and all new transplants to ANZDATA on a monthly basis. This list is cross checked against existing ANZDATA records and units are contacted to clarify the status of patients not already known to the Registry.

## 2.2. Completeness and timeliness and of survey return by contributors

- Units are requested to complete data entry by a specific date for each survey period
- Reminder emails are sent to designated ANZDATA contacts at each renal unit to enquire about the status of survey completion if data is not returned by the requested date
- Follow up phone calls and or unit visits are undertaken in the case of prolonged delays in data collection
- A manual log of data collection completeness is kept and reviewed weekly at the ANZDATA staff meeting
- An automated completeness report is run when required

## 2.3. Accuracy of data collected from renal units

- Upon receipt of the forms from each unit, the Registry checks the new information against the form returned from last survey for each patient.
- Registry administrative staff conduct manual review of data completeness and accuracy during data entry for paper based data
- Business rules coded within the data entry interface (used by both contributors and registry staff) generate yellow and red flags when atypical values or contradictory information is entered
- Following completion of data entry for a unit, automated validation checks are conducted to detect invalid or missing data
- The validation report is reviewed by registry management and queries are sent to the reporting units
- Transplant operation details are cross checked with data from the Australia and New Zealand Organ Donation Registry and from Tissue Typing Centres in Australia and New Zealand.
- Patients who have transferred are followed by contacting the new caring unit and recording new events during that survey period.
- Each living patient from the end of the previous survey is accounted for in the new survey period. Patients lost to follow up are coded as such

## 2.4. Completeness, timeliness and accuracy of data received from donate life

- The Donor Electronic Record (EDR) file is transferred from Donate Life to the Registry after each deceased donor transplant
- Manual review of the EDR is conducted by 2 ANZOD staff members and any missing, atypical or contradictory data is noted
- Queries are sent to Donate Life staff via email. Minor errors are corrected manually, in the case of substantial errors, the corrected EDR is resent to ANZOD and undergoes repeat manual review

- At the end of each month, ANZOD is supplied with a summary of all donor activity by jurisdiction from the Australian Organ and Tissue Authority (AOTA). Any discrepancy in donor numbers being ANZOD records and the AOTA report is rectified prior to the production of monthly reports.

## 2.5. Completeness, timeliness and accuracy of data received for the Living Donor Registry

- All renal transplantation units in Australia and New Zealand are requested to report all new living donor transplants on a monthly basis
- Units not reporting for the month are sent reminder emails followed by phone calls to designated living donor contacts
- Registry administrative staff conduct manual review of data completeness and accuracy during data entry for paper based data
- Business rules coded within the data entry interface (used by both contributors and registry staff) generate yellow and red flags when atypical values or contradictory information is entered
- Following completion of data entry for a unit, automated validation checks are conducted to detect invalid or missing data

2.1..1. The validation report is reviewed by registry management and queries are sent to the reporting units

## 2.6. Completeness, timeliness and accuracy of data received from NOMS, NZBS and Baxter Healthcare

- NOMS, NZBS and Baxter Healthcare supply ANZDATA with regular data files on a monthly or annual basis according to standing memoranda of understanding
- NOMS data is linked to ANZDATA records using the probabilistic data linkage using the Link Plus ® software
- NZBS data is linked to ANZDATA records using deterministic data linkage based on the New Zealand National Health Index Number (NHI)
- Baxter Healthcare data is linked to ANZDATA records using Link Plus ® software
- Independent manual validation of the linkage is conducted by two ANZDATA staff members and discrepancies are discussed and resolved by consensus
- Renal units are contacted to follow up the status of patients listed in NOMS/NZBS but not listed in ANZDATA

## 2.7. Data quality review prior to annual data lock

- Following completion of data collection for a survey period a locked data set is produced for analysis to ensure reproducibility of future analyses
- A validation script is run prior to data lock to detect discrepancies, atypical results, and missing data and excludes dates outside of the survey period

- Manual review of these errors is conducted by registry staff and where appropriate, units are contacted to clarify data
- Prior to data lock, certain variables collected from units are cross checked with NOMS/NZBS data (eg Blood group and HLA typing) and discrepancies rectified
- An error log is kept of data inaccuracies noted in previous locked data sets and these are corrected prior to each new data lock

#### 2.8. Timeliness and accuracy of reports

- Weekly review of the reports schedule is undertaken in the ANZDATA staff meeting and any issues with achieving reporting deadlines are discussed and addressed
- Regular reports are produced by ANZDATA staff using standard code which is corrected when any errors are detected
- Version control and code integrity is ensured using BitBucket® and SourceTree® software
- Manual review of all reports is conducted by the registry manager or other responsible ANZDATA staff prior to public release
- The ANZDATA, ANZOD and Living Kidney Annual reports undergo an editorial process, including content review by relevant working groups, the Organ and Tissue Authority and other relevant bodies prior to publication.

#### 2.9. Timeliness and accuracy of data supplied to other registries

- Regular data supply to other organ transplantation outcome registries is conducted each month when the ANZOD monthly report is released, in line with established data sharing agreements

#### 2.10. Timeliness and accuracy of data supplied to external parties through data requests process

- Refer to procedure 2.3 for details of requests approval and data extraction which includes quality assurance measures

#### 2.11. Auditing

- Contributing units are requested to review individual centre reports and inform ANZDATA of any discrepancies between local records and the ANZDATA report
- Internal ad hoc audits are undertaken by the registry manager to assess data quality

## 2.0 Exhibits / Appendices / Forms

Nil



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### 3.0 Document History

<b>Revision</b>	<b>Date</b>	<b>Description</b>
2017.1	21/09/2017	Creation
2019.1	14/02/2019	Updated the 'completeness, timeliness and accuracy of data received from NOMS/NZBS' section to capture the linkage of Baxter Healthcare data.