**FULL STUDY TITLE**

The Urological Society of Australia and New Zealand (USANZ) Clinical Quality Registry

**SHORT TITLE OR ACRONYM**

The USANZ Renal Surgery Clinical Quality Registry

**LAY DESCRIPTION OF THE PROJECT (2-3 LINES ONLY)**

This project will assess the feasibility of a renal surgery registry in Australia and New Zealand. Patterns of care and outcome data will allow for surgeons and opportunities to improve quality of care.

**STUDY INVESTIGATOR(S)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **Email** | **Institution** | **Study Role**  |
| Jayde Archer | registrysupport@usanz.org.au | * Urological Society of Australia and New Zealand
 | Registry Coordinator and Database Support |
| Simon Wood | Simon.Wood@health.qld.gov.au | * Metro South HHS
* Greenslopes Private Hospital
 | Principal Investigator |
| Kiran Hazratwala | northernurology@gmail.com | * Mater Health Services North Queensland
 | Principal Investigator |
| Phillippe Wolanski  | philippewolanski@gmail.com | * Mater Health Services North Queensland
 | Principal Investigator |
| Rachel Esler | Rachel.esler@gmail.com | * Royal Brisbane Women’s hospital
 | Principal Investigator |
| David Winkle | Dwinkle@mc.mater.org.au | * Mater Hospital Services Brisbane
 | Principal Investigator |
| Troy Gianduzzo | troygianduzzo@gmail.com | * Wesley Hospital Brisbane
 | Principal Investigator |
| Henry Duncan | henry@duncanurology.com.au | * Royal Darwin Hospital
* Darwin Private Hospital
 | Principal Investigator |
| Nick Brook | nicholas.brook@adelaide.edu.au | * Royal Adelaide Hospital
 | Principal Investigator |
| Michael O’Callaghan | Michael.OCallaghan2@sa.gov.au | * Repatriation General Hospital
 | Principal Investigator |
| Alex Jay | apmjay78@gmail.com | * Flinders Medical Centre
 | Principal Investigator |
| Darren Foreman | dforeman@sturology.com.au | * St Andrews Hospital Adelaide
 | Principal Investigator |
| John Miller  | urology@internode.on.net | * Western Hospital Adelaide
 | Principal Investigator |
| Mark Frydenberg | frydenberg@optusnet.com.au | * Epworth Hospital
* Cabrini Hospital
 | Principal Investigator |
| Jeremy Grummet  | jpgrummet@hotmail.com | * Alfred Hospital
* Bairnsdale Hospital
* Masada Hospital East
 | Principal Investigator |
| Scott Donnellan | scottdonnellan@bigpond.com  | * Monash Medical Centre
 | Principal Investigator |
| Anu Jayathillake | anuradhahome@yahoo.co.nz | * Peninsula Health Victoria
 | Principal Investigator |
| Howard Lau | drhlau@gmail.com | * Westmead Private Hospital Sydney
 | Principal Investigator |
| Albert Tiu | alberttiu@yahoo.com | * John Hunter Hospital
* Belmond Hospital
* Newcastle Private
* Lingard Private Hospital
* Hurstville Private Hospital
* Lake Macquarie Private
 | Principal Investigator |
| Nader Awad | naderandpenny@ozemail.com.au | * Port Macquarie Hospital
* Armidale Private Hospital
 | Principal Investigator |
| Richard Pemberton | pembertonbinns@westnet.com.au | * St John of God Hospital
* Hollywood Private
 | Principal Investigator |

[1. INTRODUCTION 4](#_Toc500186321)

[2. BACKGROUND 4](#_Toc500186322)

[2.1 Primary Aim(s) 5](#_Toc500186324)

[2.2 Secondary Aim(s) 5](#_Toc500186325)

[3. OBJECTIVE(S) 5](#_Toc500186326)

[3.1 Primary Objective(s) 5](#_Toc500186327)

[3.2 Secondary Objective(s) 5](#_Toc500186328)

[4. HYPOTHESI(E)S 5](#_Toc500186329)

[5. STUDY DESIGN 5](#_Toc500186330)

[6. STUDY SETTING/LOCATION(S) 5](#_Toc500186331)

[7. STUDY DURATION 6](#_Toc500186332)

[8. STUDY POPULATION 7](#_Toc500186333)

[8.1 Recruitment Process 7](#_Toc500186334)

[8.2 Inclusion criteria 7](#_Toc500186335)

[8.3 Exclusion criteria 7](#_Toc500186336)

[8.4 Potential for Risk, burdens and benefits 7](#_Toc500186337)

[9. STUDY OUTCOMES 7](#_Toc500186338)

[9.1 Primary Outcome 7](#_Toc500186339)

[9.2 Secondary Outcome(s) 7](#_Toc500186340)

[10. STUDY PROCEDURES 8](#_Toc500186341)

[10.1 Recruitment and consent of participants 8](#_Toc500186342)

[10.2 Withdrawal of participants from a study 8](#_Toc500186343)

[10.3 Randomisation 8](#_Toc500186344)

[10.4 Measurement tools used 8](#_Toc500186345)

[10.5 Study involvement by participants 8](#_Toc500186346)

[10.6 Data management and Storage 9](#_Toc500186347)

[10.7 Safety considerations/Patient safety 9](#_Toc500186348)

[10.8 Data monitoring 10](#_Toc500186349)

[11. SAMPLE SIZE AND DATA ANALYSIS 10](#_Toc500186350)

[11.1 Sample size and statistical power 10](#_Toc500186351)

[11.2 Data analysis plan 10](#_Toc500186352)

[12. ETHICAL CONSIDERATIONS 11](#_Toc500186353)

[13. DISSEMINATION OF RESULTS AND PUBLICATIONS 11](#_Toc500186354)

[14. OUTCOMES AND SIGNIFICANCE 12](#_Toc500186355)

[15. BUDGET 12](#_Toc500186356)

[16. GLOSSARY OF ABBREVIATIONS 12](#_Toc500186357)

[17. REFERENCES 12](#_Toc500186358)

## INTRODUCTION

This study aims to establish the feasibility of a surgical registry for patients undergoing renal surgery in participating centres. This information will allow for benchmarking within Australia and New Zealand in addition to comparison with international registries such as the British Association of Urological Surgeons Renal Registry. This data can be analysed to determine relationships between patient factors, surgical indications, surgical technique and renal surgery outcomes, providing opportunities for improved quality of care.

Unlike clinical trials or other research projects, which are hypothesis driven and in which patients are given the option of participating, Clinical Quality Registries (CQR) attempt to ensure quality through benchmarking, and so need to recruit all patients who undergo a given intervention to avoid the risk of bias.

This study will assess the feasibility of data collection, registry processes and barriers to recruitment and participation for patients and surgeons across Australia and New Zealand. No changes to current clinical practices are planned hence no additional risks are anticipated for participants.

Initially, a pilot program will collect data from a subset of public and private entities (listed in Section 7) within both metropolitan and regional areas to test the feasibility of data collection processes and allow for protocol refinement. If successful, the study will then be rolled out to additional sites.

## BACKGROUND

Clinical quality registries (CQRs) systematically collect an agreed minimum dataset of data across multiple sites on clinically relevant outcome measures. Data is analysed allowing for the comparison of procedures, providers and institutions.

Currently there is no standardised data collection on the patterns of care or surgical outcomes for renal surgery procedures and hence the USANZ Registry Steering Committee has established this registry with the aim of filling these knowledge gaps and improving outcomes for patients undergoing this surgery.

The number of CQRs in Australia is growing rapidly in response to community demands for better monitoring of health care outcomes and it is essential that the Australian and New Zealand Urologists can benchmark their performance and surgical outcomes. Feedback to practitioners has been shown to drive performance improvement, especially if the data are perceived to be high quality.

In the United Kingdom the British Association of Urological Surgeons (BAUS) has collected national clinically rich audit data on Nephrectomy procedures since 2004. They now run [**several audits**](https://www.baus.org.uk/professionals/baus_business/data_audit.aspx) and publish surgeon-level outcomes. The BAUS society believe that the release of accurate data on outcomes will drive forward the standards of surgery, help patients make informed decisions about their care, and support surgeons' needs for professional revalidation.

Surgical outcomes assessment is not a new concept to most surgeons. It was recognised over 100 years ago and, whilst there has been no requirement for clinicians to publish outcomes data, a significant number of urologists have been involved in clinical audit and outcome assessment for many years.

The USANZ Clinical Quality Registry aims to collects information on each Nephrectomy procedure performed, the patient’s risk factors, surgical techniques and post-operative complications including mortality rates.

AIM(S) OF STUDY

### Primary Aim(s)

Our primary aim is to capture data on a national level to allow for accurate analysis of all clients undergoing full or partial Nephrectomies or Nephroureterectomy and improve surgical outcomes and training.

### Secondary Aim(s)

Our secondary aim is to analyse outcome measures such as;

* Determining whether relationships exist between outcome measures recorded (diagnosis by procedure/ technique by procedure/ risk factors) and patient complication rates/ transfusion rates/ mortality rate and length of stay in hospital to make suggestions on future best practise

## OBJECTIVE(S)

### Primary Objective(s)

Objective 1: To capture and record data on diagnosis by procedure type, technique by procedure type (e.g. laparoscopic/ robotic/ open), average patient risk factors, complication rate (risk adjusted), transfusion rate (risk adjusted), mortality rate, length of stay for all clients undergoing complete or partial Nephrectomy or Nephroureterectomy within Australia and New Zealand.

### Secondary Objective(s)

Objective 2: To examine whether diagnosis by procedure is associated with any complications (transfusions/ mortality) and length of stay in hospital for complete or partial Nephrectomy or Nephroureterectomy surgery.

Objective 3: To examine whether technique by procedure (e.g. laparoscopic/ robotic/ open) is associated with any complications (transfusions/ mortality) and length of stay in hospital for complete or partial Nephrectomy or Nephroureterectomy surgery.

Objective 4: To examine whether average patient risk factors are associated with any complications (transfusions/ mortality) and length of stay in hospital for complete or partial Nephrectomy or Nephroureterectomy surgery.

## HYPOTHESI(E)S

Renal surgeons in Australia and New Zealand will be able to participate in a clinical quality registry and it will be feasible to collect relevant data to provide participating clinicians with useful patterns of care and outcome data. This information may be used to enhance the quality of renal surgery in Australia and New Zealand.

## STUDY DESIGN

This observational study will gather information about participant’s risk factors, the type of surgery and various outcomes post-surgery and compile this into a registry for national and international benchmarking. There is no change to current practice within hospitals and no change to current patient care.

## STUDY SETTING/LOCATION(S)

This study will commence data collection in the pilot phase at the following clinical locations (led by the principal investigator/consultant urologists at each site):

|  |  |
| --- | --- |
| Princess Alexandra Hospital (PA) | Queensland |
| Mater Hospital Brisbane | Queensland |
| Greenslopes Private Hospital | Queensland |
| Mater Private Hospital Townsville | Queensland |
| Townsville Hospital | Queensland |
| Royal Brisbane and Women’s Hospital (RBWH) | Queensland |
| Wesley Hospital | Queensland |
| St Andrews Hospital | South Australia |
| Repatriation General Hospital  | South Australia |
| Flinders Medical Centre | South Australia |
| Royal Adelaide Hospital | South Australia |
| Noarlunga Health Service | South Australia |
| Armidale Private Hospital | New South Wales |
| Port Macquarie Public Hospital | New South Wales |
| Newcastle Private Hospital | New South Wales |
| John Hunter Hospital (Newcastle) | New South Wales |
| Westmead Private Hospital | New South Wales |
| Hurstville Private Hospital | New South Wales |
| Lingard Private hospital | New South Wales |
| Lake Macquarie Private Hospital | New South Wales |
| Belmont Hospital | New South Wales |
| Darwin Private Hospital | Northern Territory |
| Royal Darwin Hospital | Northern Territory |
| Epworth Hospital | Victoria |
| Cabrini Hospital | Victoria |
| Monash Medical Centre | Victoria |
| Peninsula Health | Victoria |
| Peter MacCallum Cancer Centre | Victoria |
| Masada Hospital East | Victoria |
| Bairnsdale Hospital | Victoria |
| Alfred Hospital | Victoria |
| St John of God Hospital Subiaco | Western Australia |
| St John of God Hospital Murdoch | Western Australia |
| Hollywood Private Hospital | Western Australia |
| Osborne Park Hospital | Western Australia |

## STUDY DURATION

The pilot phase is intended to run for a period of 24 months and will collect data from patients via a convenient sampling method in the above mentioned clinical locations until all processes are refined.

## STUDY POPULATION

### Recruitment Process

Renal surgeons contributing to the registry will be responsible for identifying patients at the time they are accepted for renal surgery specifically complete or partial Nephrectomy or Nephroureterectomy. They will be provided with a patient information and consent form (PICF) which will include a contact phone number and email should they wish to decline to participate in the registry.

Patients undergoing renal surgery may be entered into the registry at a later time point by their treating surgeon provided they are given the patient information and consent form and given sufficient time to decline to participate or withdraw from the registry if they wish.

Confirmation that the participant has received the PICF will be entered into the registry record for each participant.

### Inclusion criteria

All patients over the age of 18 scheduled to undergo a complete or partial Nephrectomy or Nephroureterectomy surgery.

### Exclusion criteria

Nil

### Potential for Risk, burdens and benefits

This clinical registry involves the collection and analysis of health information. Involvement in the registry does not involve any risk to health care providers or patient participants other than those risks associated with the storage and analysis of health care data.

No information regarding service providers or identifiable patient populations will be published. Data is stored against a system generated unique identifier and any reports will contain aggregated de-identified data only.

 It is anticipated that the registry will provide patterns of care and outcome data to participating clinicians that will provide opportunities to enhance quality of care.

## STUDY OUTCOMES

### Primary Outcome

Centralised registry data for measuring

* Diagnosis by Procedure Type
* Technique by Procedure Type (E.g. Laparoscopic, Robotic, Open etc.)
* Patient risk factors

### Secondary Outcome(s)

* Complication rate (risk adjusted)
* Transfusion rate (risk adjusted)
* Mortality rate
* Length of stay (median and range)

## STUDY PROCEDURES

### Recruitment and consent of participants

As detailed in section 8.1 Recruitment Process participants will be identified based on the acceptance of surgery. Potential participants will be provided with the PICF outlining the proposed collection of health related data into the registry. The aims of the registry and the possible outcomes and uses of the data are described. The information sheet will also clearly provide a contact number and email should the participant wish to opt out of the registry or withdraw at a later time. Confirmation that the participant has received the PICF will be entered into the registry record for each participant.

In the event a participant wishes to opt out, the Registry Database Manager will manage this process and remove all of the participant’s data from the registry.

Posters and documentation relating to the registry may also be displayed in outpatient and ward areas.

### Withdrawal of participants from a study

#### 11.2.1 Participant withdrawal from study

As outlined above, the PICF provides a contact number and email should the participant wish to opt out of the registry or withdraw at a later time. Confirmation that the participant has received the PICF will be entered into the registry record for each participant.

In the event a participant wishes to opt out, the Registry Database Manager will manage this process and remove all of the participant’s data from the registry.

Withdrawal from the registry will not affect clinical care or management protocols.

### Randomisation

Not applicable to this study.

### Measurement tools used

Data will be collected by the surgical team and based on a standardised data set. Data can be entered directly into the secure online registry or collected on a paper based form and entered online at a later time by the surgeon in charge. Data will be collected from pre to post-operative and will be led by the consultant urologist responsible for the patient’s surgery. There may be other staff involved in the collection of data and these staff will be provided with training and education on the registry and data set. The accuracy and quality of the data will be managed by the Database Manager – see section 10.8 Data Monitoring.

### Study involvement by participants

This study requires no additional actions by the participants other than what is originally required for surgery.

### Data management and Storage

Dendrite is an international company with a nearly 20-year track record as a specialist provider of clinical quality databases and analysis software and was therefore selected by the society as the preferred vendor for the USANZ Registry.

The secure web based registry will be hosted on a server within the Urological Society of Australia and New Zealand environment which will allow users and registered members to access the registry through a specified secure URL.

The USANZ hosting environment is located in the Rackspace primary Sydney data center located in Erskine Park. This datacenter meets the certifications as outlined here: <https://www.rackspace.com/en-au/certifications>

The physical server infrastructure is entirely dedicated to USANZ with the following overall configuration:

* A physical server plus a hypervisor running a VMWare virtualized environment running 2x Virtual machines. These utilize local SAS HDD’s on the hypervisor for storage. This entire environment is sitting behind a physical Firewall, dedicated to USANZ.

All backups are held within the same data center, but on an EMC Isilon backup storage completely separate to the main environment. Incremental backups are run every 24 hours, and full system backups are run once a week.

The national registry has been designed to receive data from unlimited users across a number of facilities across Australia and New Zealand while ensuring security and confidentiality of information.

In keeping with the ACSQHC framework for Australian Clinical Quality Registries the Dendrite software can be easily interfaced with other applications to enhance their value through linkage to other disease and procedure registers or other databases.

For more information on Dendrite see [www.e-dendrite.com](http://www.e-dendrite.com) or



Data is stored against a system generated unique identifier and any reports published will contain deidentified data only.

Only society members will have access to the registry for data input and this will be managed by the USANZ Registry Steering Committee. User Administration and Access Control within the Dendrite System (including setting up user profiles, passwords and level of access) will be managed by the Registry Support Database Manager.

### Safety considerations/Patient safety

We do not anticipate any patient safety issues.

### Data monitoring

Data submitted to the registry will be subject to regular audits on the quality and completeness of the data. Any incomplete or inaccurate data identified will be sent back to the data provider and remedied as soon as possible. These audits will be managed by the Registry Support Database Manager.

Where data validation will also be performed and cross checked against national or state published procedure counts to ensure all cases have been captured or a baseline is established.

During the pilot phase of the project outliers will not be assessed as it is not feasible or appropriate to do so. The primary goal of the pilot is to test the feasibility of data collection processes and allow for protocol refinement.

No individual surgeon data or identifiable health service data will be published however surgeons can extract data at any time for cases they have contributed to the registry via the ‘Export My Data’ system functionality.

The governance and data custodianship of the USANZ Registry will be made transparent to all members. All reporting policies, data access, steering committee terms of reference and quality frameworks will be made publically available and the custodianship will be managed by the Registry Custodian and the USANZ Registry Steering Committee.

For more information see the USANZ Registry Steering Committee Terms of Reference.

SAMPLE SIZE AND DATA ANALYSIS

### Sample size and statistical power

As outlined in section 1 Clinical Quality Registries (CQR) attempt to ensure quality through benchmarking, and so need to recruit all patients who undergo a given intervention to avoid the risk of bias.

This study therefore aims to recruit and complete data collection of all patients undergoing a complete or partial Nephrectomy or Nephroureterectomy surgery within Australia and New Zealand however during the pilot phase a sample of patients across multiple centres over a 24 month period whom have accepted Nephrectomy/Nephroureterectomy surgery.

### Data analysis plan

As this registry aims to record and monitor the general pattern of actual practice and patterns of care analysing the data does not usually require complex statistical tests. Data will instead be analysed using descriptive statistics. This is where the data are described numerically and the results will be calculated based on:

* The frequency of certain events/values occurring (i.e. rates and percentages);
* Estimates of the central point of your data, such as the mean or the median;

As the dataset is based on the BAUS model the questions included have already been considered for risk adjustment. These include;

* the **Charlson co-morbidity index**
* the **Body Mass Index (BMI)**
* size and stage of the tumour
* other medical conditions affecting the patient
* whether the procedure was performed as part of a more major operation and other risk factors for surgery in general

## ETHICAL CONSIDERATIONS

Ethical considerations primarily relate to the collection and analysis of health information. We believe it is appropriate to apply an opt out consent process for this type of clinical registry as outlined in the NHMRC ‘Qualifying Conditions for Consent’

<https://www.nhmrc.gov.au/book/national-statement-ethical-conduct-human-research-2007-updated-december-2013/chapter-2-3-qualif>

Participants will be provided with an information and consent document at the same time they receive information about their surgical procedure. This document clearly outlines the nature and intent of the data collection process and the aims of the registry. It also contains clear instructions for those patients who do not wish to participate or decide to withdraw at any point.

Another consideration relates to confidentiality, storage and analysis of health care data. As outlined previously data will be stored against a system generated unique identifier and any reports will contain aggregated de-identified data only.

Additional ethical considerations relate to potential identification of individual surgeon or health service outcome data. There is no intention to publish any report that would allow the identification of any individual health service or provider. Decisions regarding publication of any high level reports will be made by the USANZ Registry steering committee.

The governance and data custodianship of the USANZ Registry will be made transparent to all members. All reporting policies, data access, steering committee terms of reference and quality frameworks will be made publically available and the custodianship will be managed by the Registry Custodian and the USANZ Registry Steering Committee.

## DISSEMINATION OF RESULTS AND PUBLICATIONS

Registry reports may be published from time to time by the Registry Steering Committee. These reports will be similar to the British Association of Urological Surgeons (BAUS) reporting templates that include high level patterns of care and aggregated surgical outcomes.

As previously outlined the USANZ Registry Steering Committee has no plans to publish or make public any information that would identify individual services results.

All public data will be de-identified and reports will be high level to ensure urology units are not able to view or identify other facility data.

Participating surgeons will be able to extract their patient de-identified data at any time for cases they have contributed to the registry via the ‘Export My Data’ system functionality. This will allow participating clinicians to benchmark performance and identify opportunities for service improvement.

The surgeons (the authors) keep the right to disseminate any relevant results of this study to colleagues, patients and key internal and external stakeholders in the form as they see relevant, subject to their legal, privacy, contractual and employment obligations.

## OUTCOMES AND SIGNIFICANCE

This pilot project will assess the feasibility of data collection into a renal registry in Australia and New Zealand. It will allow refinement of registry protocols and reporting mechanisms. It will assess the feasibility, accuracy and usefulness of outcome reporting. It will allow the USANZ Renal Registry Steering Committee to assess the risks and benefits of wider participation in the registry. Individual service providers contributing data to the registry will benefit from the ability to audit their own clinical service and benchmark against national and international data sets. Service quality improvements may flow from this information.

## BUDGET

Funding for the Registry data storage and analytics system and funding for registry oversight and management is being provided by USANZ. Any costs associated with contribution of data to the registry by participating clinical services will be the responsibility of that service.

## GLOSSARY OF ABBREVIATIONS

ACSQHC  Australian Commission on Safety and Quality in Health Care

BAUS The British Association of Urological Surgeons

BMI Body Mass Index

CQR Clinical Quality Registry

HHS Hospital and Health Services

PA Princess Alexandra Hospital

RBWH Royal Brisbane and Women’s Hospital

USANZ Urological Society of Australia and New Zealand

PICF Patient Information Consent Form

## REFERENCES

<https://www.baus.org.uk/professionals/baus_business/data_audit.aspx>

<http://www.e-dendrite.com/about-us>

<https://www.nhmrc.gov.au/book/national-statement-ethical-conduct-human-research-2007-updated-december-2013/chapter-2-3-qualif>

<https://www.rackspace.com/en-au/certifications>